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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2022
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to
Commission file number: 001-38492

Kiniksa Pharmaceuticals, Ltd.

(Exact Name of Registrant as Specified in Its Charter)

Bermuda	**98-1327726**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

Kiniksa Pharmaceuticals, Ltd.
Clarendon House
2 Church Street
Hamilton HM11, Bermuda
(808) 451-3453
(Address, zip code and telephone number, including area code of principal executive offices)

Kiniksa Pharmaceuticals Corp.
100 Hayden Avenue
Lexington, MA, 02421
(781) 431-9100
(Address, zip code and telephone number, including area code of agent for service)
N/A
(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A Common Shares	KNSA	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☐	Accelerated Filer	☐
Non-accelerated Filer	☒	Smaller Reporting Company	☒
		Emerging Growth Company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of April 30, 2022, there were 69,275,724 common shares outstanding in aggregate, comprised of:
34,275,046 Class A common shares, par value $0.000273235 per share
1,813,457 Class B common shares, par value $0.000273235 per share
17,129,603 Class A1 common shares, par value $0.000273235 per share
16,057,618 Class B1 common shares, par value $0.000273235 per share

Kiniksa Pharmaceuticals, Ltd.

FORM 10-Q

FOR THE THREE MONTHS ENDED MARCH 31, 2022

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or Quarterly Report, contains forward-looking statements. All statements other than statements of historical facts contained in this Quarterly Report including statements regarding our products' commercial sales, future results of anticipated products, future results of operations and financial position, expected timeline for our cash, cash equivalents and short-term investments, business strategy, product development, prospective products and product candidates, their expected properties, performance, market opportunity and competition, supply of drug products at acceptable cost and quality, collaborators, license and other strategic arrangements, the expected timeline for achievement of our clinical milestones, the timing of, and potential results from, clinical and other trials, potential marketing authorization from the FDA or regulatory authorities in other jurisdictions, potential coverage and reimbursement for our products and product candidates, if approved, commercial strategy and pre-commercial activities, research and development costs, timing of regulatory filings and feedback, timing and likelihood of success and plans and objectives of management for future operations and funding requirements, are forward-looking statements.

These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "goal," "design," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these identifying words. The forward-looking statements in this Quarterly Report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of risks, uncertainties and assumptions described under the sections in this Quarterly Report entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Quarterly Report. These forward-looking statements are subject to numerous risks and uncertainties, including, without limitation, the following:

- the impact of the coronavirus disease 2019, or COVID-19, pandemic on our business, including our commercial operations and clinical trials;
- our continued ability to commercialize ARCALYST (rilonacept) and to develop and commercialize our current and future product candidates, if approved;
- our status as an early-commercial stage biopharmaceutical company and our expectation to incur losses in the future;
- our future capital needs and our need to raise additional funds;
- our ability to manufacture sufficient commercial stock of our products to meet patient demand;
- the market acceptance of our products and product candidates;
- competitive and potentially competitive products and technologies;
- prescriber awareness and adoption of our products and product candidates, if approved;
- the size of the market for our products and product candidates, if approved;
- our ability to meet the quality expectations of prescribers or patients;

- the decision of third-party payors not to cover or to establish burdensome requirements prior to covering ARCALYST or any of our current or future product candidates, if approved, or to require extensive or independently performed clinical trials prior to covering or maintaining coverage of our product candidates, if approved;
- the lengthy and expensive clinical development process with its uncertain outcomes and potential for clinical failure or delay, including due to the COVID-19 pandemic and the ongoing war in Ukraine;
- the decision by any applicable regulatory authority whether to clear our current or future product candidates for clinical development and, ultimately, whether to approve them for marketing and sale;
- our ability to anticipate and prevent adverse events caused by our products and product candidates;
- our ability to improve our product candidates;
- our ability to identify, in-license, acquire, discover or develop additional product candidates;
- our ability to undertake and execute on business combinations, collaborations or other strategic transactions;
- our ability to have our products and product candidates manufactured in accordance with regulatory requirements and at acceptable cost and quality specifications;
- our ability to successfully manage our growth;
- our ability to avoid product liability claims and maintain adequate product liability insurance;
- our ability to obtain regulatory exclusivity;
- federal, state and foreign regulatory requirements applicable to our products and product candidates;
- our ability to obtain, maintain, protect and enforce our intellectual property rights related to our products and product candidates;
- ownership concentration of our executive officers, directors, certain members of senior management and affiliated shareholders may prevent our shareholders from influencing significant corporate decisions; and
- our ability to attract and retain skilled personnel.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report will prove to be accurate. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

You should read this Quarterly Report and the documents that we reference in this Quarterly Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those described in Part II, Item 1A. “Risk Factors” in this Quarterly Report. You should carefully consider these risks and uncertainties when investing in our Class A common shares. The principal risks and uncertainties affecting our business include the following:

- we have only recently begun generating product revenue, have incurred significant operating losses since our inception, and expect to incur significant operating losses for the foreseeable future and may never achieve or maintain corporate profitability;
- we will require significant additional funding to develop our portfolio, commercialize our products and product candidates, if approved, and to identify, discover, develop or acquire additional product candidates, and if we are unable to secure financing on acceptable terms when needed, or at all, we could be forced to delay, reduce or cease one or more of our product development plans, research and development programs or other operations or commercialization efforts;
- we depend heavily on the commercial success of ARCALYST, and have limited experience commercializing a therapeutic, supporting sales, marketing, and distribution activities and maintaining applicable infrastructure for these activities either directly and/or through agreements with third parties; as a result, we may not be able to sustain the commercialization of ARCALYST, or successfully commercialize any future approved product candidates;
- we depend heavily on the success of one or more of our product candidates, which are in various stages of product development; such success is dependent upon us advancing our product candidates in clinical development, obtaining regulatory approval and ultimately commercializing one or more of our product candidates on a timely basis, if at all;
- ARCALYST in recurrent pericarditis, as well as our current or future product candidates, if approved, may not gain sustained market acceptance by prescribers, patients, or third-party payors, in which case our ability to generate product revenues will be impaired;
- successful commercialization of our products and product candidates, if approved, will depend in part on the extent to which third-party payors provide funding, establish favorable coverage and pricing policies and set adequate reimbursement levels for our products and product candidates, if approved, and failure to obtain or maintain coverage and adequate reimbursement for our products and product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue;
- the incidence and prevalence for target patient populations of our products and product candidates have not been established with precision, and if the market opportunities for our products and product candidates, if approved, are smaller than we estimate, or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability may be materially adversely affected;
- clinical development of our product candidates is a lengthy and expensive process with uncertain timelines, costs and outcomes;
- we may encounter substantial delays in our current or planned preclinical and/or clinical trials, including as a result of delays in obtaining regulatory approvals for indications, site activation, enrollment, and conduct of the trials, which could delay or prevent our product development activities;
- we rely on third parties, including contract research organizations, or CROs, to activate our sites, conduct or otherwise support our research activities, preclinical studies and clinical trials for our product candidates, and these third parties may not perform satisfactorily, which could delay, prevent or impair our product development activities;

- we rely on third parties, including independent contract manufacturing organizations, or CMOs, to manufacture our product candidates for preclinical and clinical development, to manufacture our commercial supply of ARCALYST, and supply of drug substance and drug product for our products and product candidates; and if these third parties do not perform satisfactorily, including by producing insufficient commercial supply of ARCALYST to meet patient demand, or are impacted by delays or supply shortages, our product development activities, regulatory approval, and commercialization efforts may be delayed, prevented or impaired;

- the ongoing COVID-19 pandemic, and related measures taken in response, including measures imposed or re-imposed in light of new variants of the virus, may have an adverse impact on our business and operations as well as those of our manufacturers, CROs and other third parties with whom we conduct business or otherwise engage, including regulatory authorities;

- all of our products and product candidates have been licensed or acquired from other parties; if those parties did not adequately protect and we are unable to adequately protect such products and product candidates, or to secure and maintain freedom to operate, others could preclude us from commercializing our products and product candidates, if approved, or compete against us more directly;

- we face significant competition from other biotechnology and pharmaceutical companies, which may result in others discovering, developing or commercializing drugs before or more successfully than us;

- we may not successfully execute our growth strategy to identify, discover, develop, license or acquire additional product candidates or technologies, and our strategy may not deliver anticipated results or we may refine or otherwise alter our growth strategy;

- we may seek to acquire businesses or undertake business combinations, collaborations or other strategic transactions which may not be successful or on favorable terms, if at all, and we may not realize the intended benefits of such transactions; and

- concentration of ownership of the voting power of our common shares may prevent new investors from influencing significant corporate decisions and may have an adverse effect on the price of our Class A common shares.

INDUSTRY AND OTHER DATA

Unless otherwise indicated, certain industry data and market data included in this Quarterly Report were obtained from independent third-party surveys, market research, publicly available information, reports of governmental agencies and industry publications and surveys. All of the market data used in this Quarterly Report involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We believe that the information from these industry publications and surveys included in this Quarterly Report is reliable.

ARCALYST is a registered trademark of Regeneron Pharmaceuticals, Inc (“Regeneron”). Solely for convenience, trademarks, service marks, and trade names referred to in this Quarterly Report may be listed without identifying symbols.

Part I — Financial Information

Item 1. Financial Statements (unaudited)

KINIKSA PHARMACEUTICALS, LTD.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)
(Unaudited)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 63,324	$ 122,470
Short-term investments	82,253	59,731
Accounts receivable, net	29,440	3,985
Inventory	13,223	3,675
Prepaid expenses and other current assets	10,517	6,585
Total current assets	198,757	196,446
Property and equipment, net	2,475	2,834
Operating lease right-of-use assets	4,815	5,550
Other long-term assets	5,918	8,720
Intangible asset, net	19,000	19,250
Total assets	$ 230,965	$ 232,800
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 3,383	$ 1,868
Accrued expenses	38,887	38,031
Operating lease liabilities	3,311	3,381
Other current liabilities	4,773	1,544
Total current liabilities	50,354	44,824
Non-current liabilities:		
Non-current operating lease liabilities	2,096	2,669
Deferred revenue	12,000	—
Other long-term liabilities	271	270
Total liabilities	64,721	47,763
Commitments and contingencies (Note 14)		
Shareholders' equity:		
Class A common shares, par value of $0.000273235 per share; 34,270,445 shares and 34,059,725 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	9	8
Class B common shares, par value of $0.000273235 per share; 1,813,457 shares issued and outstanding as of March 31, 2022 and December 31, 2021	1	1
Class A1 common shares, $0.000273235 par value; 17,129,603 shares issued and outstanding as of March 31, 2022 and December 31, 2021	5	5
Class B1 common shares, $0.000273235 par value; 16,057,618 shares issued and outstanding as of March 31, 2022 and December 31, 2021	4	4
Additional paid-in capital	866,935	860,482
Accumulated other comprehensive loss	(103)	(66)
Accumulated deficit	(700,607)	(675,397)
Total shareholders' equity	166,244	185,037
Total liabilities and shareholders' equity	$ 230,965	$ 232,800

The accompanying notes are an integral part of these consolidated financial statements.

KINIKSA PHARMACEUTICALS, LTD.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2022	2021
Revenue:		
Product revenue, net	$ 22,189	$ —
Collaboration revenue	10,000	—
Total revenue	32,189	—
Costs and operating expenses:		
Cost of goods sold	4,219	—
Collaboration expenses	8,254	—
Research and development	20,817	28,683
Selling, general and administrative	22,218	20,600
Total operating expenses	55,508	49,283
Loss from operations	(23,319)	(49,283)
Interest income	34	9
Loss before provision for income taxes	(23,285)	(49,274)
Provision for income taxes	(1,925)	(210)
Net loss	$ (25,210)	$ (49,484)
Net loss per share attributable to common shareholders—basic and diluted	$ (0.36)	$ (0.72)
Weighted average common shares outstanding—basic and diluted	69,136,901	68,269,486
Comprehensive loss:		
Net loss	$ (25,210)	$ (49,484)
Other comprehensive loss:		
Unrealized gain (loss) on short-term investments and currency translation adjustments, net of tax	(37)	13
Total other comprehensive gain (loss)	(37)	13
Total comprehensive loss	$ (25,247)	$ (49,471)

The accompanying notes are an integral part of these consolidated financial statements.

KINIKSA PHARMACEUTICALS, LTD.
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(In thousands, except share amounts)
(Unaudited)

	Common Shares (Class A, B, A1 and B1)		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Shareholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balances at December 31, 2021	69,060,403	$ 18	$ 860,482	$ (66)	$ (675,397)	$ 185,037
Issuance of Class A common shares under incentive award plans	210,720	1	422	—	—	423
Share-based compensation expense	—	—	6,031	—	—	6,031
Unrealized loss on short-term investments and currency translation adjustments	—	—	—	(37)	—	(37)
Net loss	—	—	—	—	(25,210)	(25,210)
Balances at March 31, 2022	69,271,123	$ 19	$ 866,935	$ (103)	$ (700,607)	$ 166,244

	Common Shares (Class A, B, A1 and B1)		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Shareholders'
	Shares	Amount	Capital	Income	Deficit	Equity
Balances at December 31, 2020	68,215,022	$ 18	$ 829,424	$ (34)	$ (517,473)	$ 311,935
Issuance of Class A common shares under incentive award plans	115,012	—	1,106	—	—	1,106
Share-based compensation expense	—	—	7,126	—	—	7,126
Unrealized gain on short-term investments and currency translation adjustments	—	—	—	13	—	13
Net loss	—	—	—	—	(49,484)	(49,484)
Balances at March 31, 2021	68,330,034	$ 18	$ 837,656	$ (21)	$ (566,957)	$ 270,696

The accompanying notes are an integral part of these consolidated financial statements.

KINIKSA PHARMACEUTICALS, LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (25,210)	$ (49,484)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	656	312
Share-based compensation expense	6,031	7,126
Non-cash lease expense	735	593
Amortization of premiums and accretion of discounts on short-term investments	164	410
Deferred income taxes	—	10
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,932)	408
Accounts receivable, net	(25,455)	—
Inventory	(9,548)	—
Other long-term assets	2,755	(231)
Accounts payable	1,515	72
Accrued expenses and other current liabilities	4,085	1,079
Operating lease liabilities	(643)	(421)
Deferred revenue	12,000	—
Other long-term liabilities	1	4
Net cash used in operating activities	(36,846)	(40,122)
Cash flows from investing activities:		
Purchases of property and equipment	—	(54)
Purchases of short-term investments	(30,223)	(74,362)
Proceeds from the maturities of short-term investments	7,500	139,250
Intangible asset acquired	—	(20,000)
Net cash provided by (used in) investing activities	(22,723)	44,834
Cash flows from financing activities:		
Proceeds from issuance of Class A common shares under incentive award plans and employee share purchase plan	992	1,106
Payments in connection with Common Stock tendered for employee tax obligations	(569)	—
Net cash provided by financing activities	423	1,106
Net increase (decrease) in cash, cash equivalents and restricted cash	(59,146)	5,818
Cash, cash equivalents and restricted cash at beginning of period	122,470	114,248
Cash, cash equivalents and restricted cash at end of period	$ 63,324	$ 120,066

The accompanying notes are an integral part of these consolidated financial statements.

KINIKSA PHARMACEUTICALS, LTD
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share amounts)
(Unaudited)

1. Nature of the Business and Basis of Presentation

Kiniksa Pharmaceuticals, Ltd. (the "Company") is a biopharmaceutical company focused on discovering, acquiring, developing and commercializing therapeutic medicines for patients suffering from debilitating diseases with significant unmet medical need. The Company's portfolio of assets is based on strong biologic rationale or validated mechanisms, target underserved conditions and offer the potential for differentiation.

The Company is subject to risks and uncertainties common to early, commercial stage companies in the biopharmaceutical industry and global health, societal, economic and market conditions, including adverse impact from the coronavirus disease 2019 ("COVID-19") pandemic, the ongoing war in Ukraine, the Company's dependence on third parties, including CROs and CMOs, the Company's limited experience obtaining regulatory approvals, the potential failure of the Company to successfully complete research and development of its current or future product candidates, the potential inability of the Company to adequately protect its technology, potential competition, and the uncertainty that any current or future product candidates will obtain necessary government regulatory approval, that ARCALYST will continue to be commercially viable, and that any of the Company's current or future product candidates, if approved, will be commercially viable.

Risks and Uncertainties Related to COVID-19

The COVID-19 pandemic, and measures undertaken in response to the pandemic, or the easing of any of such measures, may cause significant disruptions in the Company's business or operations as well as in the business and operations of third parties with whom the Company conducts business or otherwise engages now or in the future. The COVID-19 pandemic may also adversely impact the Company's preclinical studies and clinical trials, which could impede, delay, limit or prevent the clinical development of the Company's product candidates and ultimately lead to the delay or denial of regulatory approval of its product candidates, which would materially adversely affect the Company's business and operations, including its ability to generate revenue. Moreover, the COVID-19 pandemic is impacting the global economy, and the U.S. economy in particular, with the potential for an economic downturn to be severe and prolonged. A severe or prolonged economic downturn could result in continued disruptions in the financial markets, which could adversely impact the Company's ability to raise additional capital when needed or on acceptable terms, if at all. While the Company has implemented certain workplace safety protocols and business contingency plans, there can be no assurance that such protocols or plans will be effective. The extent of the impact on the Company's business and operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, economic effects of the pandemic, new or emerging variants of the virus and the effectiveness of actions taken to contain and treat the disease.

Principles of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of the Company and its wholly owned subsidiaries, Kiniksa Pharmaceuticals Corp. ("Kiniksa US"), Primatope Therapeutics, Inc. ("Primatope") and Kiniksa Pharmaceuticals (UK), Ltd. ("Kiniksa UK") as well as the subsidiaries of Kiniksa UK, Kiniksa Pharmaceuticals (Germany) GmbH ("Kiniksa Germany"), Kiniksa Pharmaceuticals (France) SARL ("Kiniksa France"), and Kiniksa Pharmaceuticals GmbH ("Kiniksa Switzerland"), after elimination of all significant intercompany accounts and transactions.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of

expenses during the reporting period. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the recognition of revenue, the capitalization of inventory, the accrual for research and development expenses and the valuation of share-based awards. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Unaudited Interim Consolidated Financial Information

The accompanying unaudited consolidated financial statements have been prepared in accordance with GAAP for interim financial information. The accompanying unaudited consolidated financial statements do not include all of the information and footnotes required by GAAP for complete consolidated financial statements. The information included in this quarterly report on Form 10-Q should be read in conjunction with the Company's audited consolidated financial statements and the accompanying notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021 (the "2021 Form 10-K"). The Company's accounting policies are described in the Notes to Consolidated Financial Statements in the Company's 2021 Form 10-K and updated, as necessary, in this report. The accompanying year-end consolidated balance sheet was derived from audited financial statements but does not include all disclosures required by GAAP. The unaudited interim consolidated financial statements have been prepared on the same basis as the audited annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of March 31, 2022 and the results of its operations for the three months ended March 31, 2022 and 2021, the changes in its shareholders' equity for the three months ended March 31, 2022 and 2021 and its cash flows for the three months ended March 31, 2022 and 2021. The results for the three months ended March 31, 2022 are not necessarily indicative of results to be expected for the year ending December 31, 2022, any other interim periods or any future year or period.

Liquidity

The Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the consolidated financial statements are issued. As of March 31, 2022, the Company had an accumulated deficit of $700,607. During the three months ended March 31, 2022, the Company incurred a net loss of $25,210 and used $36,846 cash in operating activities. The Company expects to continue to generate operating losses and cash used in operations for the foreseeable future. As of March 31, 2022, the Company had cash, cash equivalents and short-term investments of $145,577.

Based on its current operating plan, the Company expects that its cash, cash equivalents and short-term investments will be sufficient to fund its operations and capital expenditure requirements for at least twelve months from the issuance date of these consolidated financial statements. The future viability of the Company beyond that point is dependent on its ability to fund its operations through sales of ARCALYST and/or raise additional capital, as needed. If the Company is unable to grow sales of ARCALYST in future periods, the Company would need to seek additional financing through public or private securities offerings, debt financings, government funding or grants, or other sources, which may include licensing, collaborations or other strategic transactions or arrangements. Although the Company has been successful in raising capital in the past, there is no assurance that it will be successful in obtaining such additional financing on terms acceptable to the Company, if at all. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate some or all of its commercialization efforts, research and development programs for product candidates or product portfolio expansion, which could adversely affect its business prospects, or the Company may be unable to continue operations.

KINIKSA PHARMACEUTICALS, LTD
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share amounts)
(Unaudited)

2. Summary of Significant Accounting Policies

Revenue Recognition

ASC Topic 606, Revenue from contracts with Customers ("ASC 606") outlines a five-step process for recognizing revenue from contracts with customers: (i) identify the contract with the customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the separate performance obligations in the contract, and (v) recognize revenue associated with the performance obligations as they are satisfied.

The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. Once a contract is determined to be within the scope of ASC 606, the Company determines the performance obligations that are distinct. The Company recognizes as revenues the amount of the transaction price that is allocated to each respective performance obligation when the performance obligation is satisfied. Generally, the Company's performance obligations are transferred to customers at a point in time, typically upon delivery of the product to the customer.

ASC 606 requires entities to record a contract asset when a performance obligation has been satisfied or partially satisfied, but the amount of consideration has not yet been received because the receipt of the consideration is conditioned on something other than the passage of time. ASC 606 also requires an entity to present a revenue contract as a contract liability in instances when a customer pays consideration, or an entity has a right to an amount of consideration that is unconditional (e.g., receivable), before the entity transfers a good or service to the customer.

Collaboration Revenue

The Company analyzes its collaboration arrangements to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities and therefore within the scope of ASC Topic 808, Collaborative Arrangements ("Topic 808"). This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of Topic 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of Topic 808 and which elements of the collaboration are more reflective of a vendor-customer relationship and therefore within the scope of Topic 606.

For elements of collaboration arrangements that are accounted for pursuant to ASC 606, we identify the performance obligations and allocate the total consideration we expect to receive on a relative standalone selling price basis to each performance obligation. Variable consideration such as performance-based milestones will be included in the total consideration if we expect to receive such consideration and if it is probable that the inclusion of the variable consideration will not result in a significant reversal in the cumulative amount of revenue recognized under the arrangement. Our estimate of the total consideration we expect to receive under each collaboration arrangement is updated for each reporting period, and any adjustments to revenue are recorded on a cumulative catch-up basis. We exclude sales-based royalty and milestone payments from the total consideration we expect to receive until the underlying sales occur because the license to our intellectual property is deemed to be the predominant item to which the royalties or milestones relate as it is the primary driver of value in our collaboration arrangements.

Key assumptions to determine the standalone selling price may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success. We recognize revenue associated with each performance obligation as the control over the promised goods or services transfer to our collaboration partner which occurs either at a point in time or over time. If control transfers over time, revenue is recognized by using a method of measuring progress that best depicts the transfer of goods or services. We

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evaluate the measure of progress and related inputs each reporting period and any resulting adjustments to revenue are recorded on a cumulative catch-up basis.

Consideration received that does not meet the requirements to satisfy ASC 808 or ASC 606 revenue recognition criteria is recorded as deferred revenue in the accompanying consolidated balance sheets, classified as either short-term (less than 12 months) or long-term (more than 12 months) deferred revenue based on our best estimate of when such revenue will be recognized.

There have been no other material changes to the significant accounting policies previously disclosed in the Company's 2021 Form 10-K.

Recently Adopted Accounting Pronouncements

Accounting standards that have been issued by the Financial Accounting Standards Board or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company's financial statements upon adoption.

3. Fair Value of Financial Assets and Liabilities

Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The following tables present information about the Company's financial instruments measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values:

	Fair Value Measurements as of March 31, 2022 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents — money market funds	$ 26,470	$ —	$ —	$ 26,470
Cash equivalents — U.S. Treasury notes	—	12,698	—	12,698
Short-term investments — U.S. Treasury notes	—	82,253	—	82,253
	$ 26,470	$ 94,951	$ —	$ 121,421

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	Fair Value Measurements as of December 31, 2021 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents — money market funds	$ 94,324	$ —	$ —	$ 94,324
Short-term investments — U.S. Treasury notes	—	59,731	—	59,731
	$ 94,324	$ 59,731	$ —	$ 154,055

During the three months ended March 31, 2022 and the year ended December 31, 2021 there were no transfers between Level 1, Level 2 and Level 3. The money market funds were valued using quoted prices in active markets, which represent a Level 1 measurement in the fair value hierarchy. The Company's cash equivalents and short-term investments as of March 31, 2022 and December 31, 2021 included U.S. Treasury notes, which are not traded on a daily basis and, therefore, represent a Level 2 measurement in the fair value hierarchy at each period end.

Cash equivalents and short-term investments as of March 31, 2022 and December 31, 2021 consisted of U.S. Treasury notes which investments were each due within six months of such date.

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Credit Losses	Fair Value
March 31, 2022					
Cash Equivalents - U.S. Treasury notes	$ 12,697	$ 1	$ —	$ —	$ 12,698
Short-term investments — U.S. Treasury notes	82,304	—	(51)	—	82,253
	$ 95,001	$ 1	$ (51)	$ —	$ 94,951

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Credit Losses	Fair Value
December 31, 2021					
Short-term investments — U.S. Treasury notes	$ 59,745	$ 1	$ (15)	$ —	$ 59,731
	$ 59,745	$ 1	$ (15)	$ —	$ 59,731

As of March 31, 2022, the Company held 18 securities that were in an unrealized loss position. The aggregate fair value of securities held by the Company in an unrealized loss position was $82,253 at March 31, 2022. As of December 31, 2021, the Company held 11 securities that were in an unrealized loss position. The aggregate fair value of securities held by the Company in an unrealized loss position was $49,739 at December 31, 2021. As of March 31, 2022 and December 31, 2021, these securities were held by the Company in an unrealized loss position for less than 12 months. The Company determined that there was no material change in the credit risk of these securities. As a result, the Company determined it did not hold any investments with an other-than-temporary impairment as of March 31, 2022 and December 31, 2021.

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4. Product Revenue, Net

ARCALYST

Following the approval by the U.S. Food and Drug Administration ("FDA") of ARCALYST on March 18, 2021, the Company began generating product revenue from sales of ARCALYST in April 2021.

	Three Months Ended March 31, 2022
Product revenue, net	$ 22,189

The following table summarizes balances and activity in each of the product revenue allowance and reserve categories for the three months ended March 31, 2022:

	Contractual Adjustments	Government Rebates	Returns	Total
Balance at December 31, 2021	$ 515	$ 719	$ 101	$ 1,335
Current provisions relating to sales in the current year	1,671	718	62	2,451
Adjustments relating to prior years	—	—	—	—
Payments/returns relating to sales in the current year	(553)	(89)	—	(642)
Payments/returns relating to sales in the prior years	(301)	(180)	—	(481)
Balance at March 31, 2022	$ 1,332	$ 1,168	$ 163	$ 2,663

Total revenue-related reserves as of March 31, 2022 and December 31, 2021, included in our consolidated balance sheets, are summarized as follows:

	March 31, 2022	December 31, 2021
Reduction of accounts receivable	$ (41)	$ (50)
Components of other current liabilities	2,704	1385
Total revenue-related reserves	$ 2,663	$ 1,335

Accounts receivable, net as of March 31, 2022 and December 31, 2021 related to product revenue was $7,339 and $3,910, respectively.

5. Inventory

During the year ended December 31, 2021, the Company commenced the capitalization of ARCALYST inventory in connection with receiving FDA approval of ARCALYST for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children 12 years and older.

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Inventory consisted of the following:

	March 31, 2022	December 31, 2021
Raw materials	$ —	$ —
Work-in-process	148	—
Finished Goods	13,075	3,675
	$ 13,223	$ 3,675

6. Property and Equipment, Net

Property and equipment, net consisted of the following:

	March 31, 2022	December 31, 2021
Furniture, fixtures and vehicles	$ 62	$ 62
Computer hardware and software	345	341
Leasehold improvements	3,931	3,931
Lab equipment	4,249	4,249
Construction in progress	162	166
Total property and equipment	8,749	8,749
Less: Accumulated depreciation	(6,274)	(5,915)
Total property and equipment, net	$ 2,475	$ 2,834

Depreciation expense was $359 and $290 during the three months ended March 31, 2022 and 2021, respectively.

7. Intangible Assets

Intangible assets, net of accumulated amortization, impairment charges and adjustments as of March 31, 2022 and December 31, 2021 are summarized in the following table.

	Estimated life	As of March 31, 2022			As of December 31, 2021		
		Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Regulatory milestone	20 years	$ 20,000	$ 1,000	$ 19,000	$ 20,000	$ 750	$ 19,250
		$ 20,000	$ 1,000	$ 19,000	$ 20,000	$ 750	$ 19,250

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8. Accrued Expenses

Accrued expenses consisted of the following:

	March 31, 2022	December 31, 2021
Accrued research and development expenses	$ 22,212	$ 24,977
Accrued employee compensation and benefits	4,934	8,916
Accrued legal, commercial and professional fees	11,412	3,768
Other	329	370
	$ 38,887	$ 38,031

9. Share-Based Compensation

The Company maintains several equity compensation plans, including the 2018 Incentive Award Plan (the "2018 Plan"), 2018 Employee Share Purchase Plan (the "2018 ESPP"), and Rilonacept Long-Term Incentive Plan ("RLTIP") which was approved under the 2018 Plan. Upon the effectiveness of the 2018 Plan, the Company ceased granting awards under its 2015 Equity Incentive Plan (as amended, the "2015 Plan" and together with the 2018 Plan, the "Plans").

2015 Plan

As of March 31, 2022, there were 2,172,447 Class A common shares subject to outstanding awards under the 2015 Plan and reserved for issuance thereunder pursuant to such awards.

2018 Plan

In May 2018, the Company's board of directors and shareholders approved the 2018 Plan, which became effective on May 23, 2018. The 2018 Plan provides for the grant of incentive share options, nonqualified share options, share appreciation rights, restricted shares, dividend equivalents, restricted share units ("RSUs") and other share- or cash- based awards. As of March 31, 2022, 4,092,732 shares remained available for future grant under the 2018 Plan.

2018 ESPP

In December 2021, the Company's board of directors approved an increase in the number of shares available for future issuance under the 2018 ESPP, as of January 1, 2022, of 90,000 shares. As of March 31, 2022, 554,801 Class A common shares were available for future issuance under the 2018 ESPP.

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Options

Share option activity under the Plans is summarized as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding as of December 31, 2021	9,226,846	$ 14.14
Granted	117,000	$ 10.91
Exercised	(58,155)	$ 9.76
Forfeited	(496,334)	$ 16.17
Outstanding as of March 31, 2022	8,789,357	$ 14.01
Share options exercisable as of March 31, 2022	5,148,927	$ 13.10
Share options unvested as of March 31, 2022	3,640,430	$ 15.29

As of March 31, 2022, total unrecognized compensation expense related to the unvested share option awards was $35,767 which is expected to be recognized over a weighted average remaining period of 2.35 years.

Restricted Share Units

Beginning in March 2021, the Company began granting RSUs with service conditions (“Time-Based RSUs”) to eligible employees as part of its equity incentive compensation. The Time-Based RSUs vest 25% on each of the first, second, third and fourth anniversaries of the date of grant, subject to continued employment through such dates.

During the years ended December 31, 2020 and 2019, the Company granted the first RSU awards (“First RLTIP RSU Awards”) as part of the RLTIP to eligible employees. During the year ended December 31, 2021, the FDA Milestone (as defined in RLTIP) was achieved (the date of such achievement, the “Achievement Date”) and (1) the number of Class A common shares issuable under the First RLTIP RSU Awards were determined in accordance with the RLTIP and vested in one installment on the first anniversary of the Achievement Date, subject to continued employment through such date, and (2) the Company granted a second set of RSU awards to eligible employees on the Achievement Date with respect to a number of shares determined in accordance with the RLTIP, which will vest on the second anniversary of the Achievement Date, subject to continued employment through such date.

During the three months ended March 31, 2022 and 2021, the Company recognized compensation expense of $619 and $1,452, respectively, related to RSUs including those granted in connection with the RLTIP.

The following table summarizes RSU activity, including the RSUs outstanding under the RLTIP for the three months ended March 31, 2022:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested RSUs as of December 31, 2021	885,021	$ 15.72
Granted	58,650	$ 10.91
Vested	(161,898)	$ 15.82
Forfeited	(116,003)	$ 14.43
Unvested RSUs as of March 31, 2022	665,770	$ 15.50

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As of March 31, 2022, total unrecognized compensation cost related to the RSU awards was $8,600 which is expected to be recognized over a weighted average remaining period of 3.12 years.

Share-Based Compensation

Share-based compensation expense was classified in the consolidated statements of operations and comprehensive loss as follows:

	Three Months Ended March 31,	
	2022	2021
Cost of goods sold	$ 180	$ —
Research and development expenses	1,976	2,634
Selling, general and administrative expenses	3,875	4,492
	$ 6,031	$ 7,126

10. Out-licensing Agreements

Huadong Collaboration Agreements

On February 21, 2022 (the "Effective Date"), the Company entered into two collaboration and license agreements (each, a "Collaboration Agreement" and together, the "Collaboration Agreements") with Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. ("Huadong"), pursuant to which the Company granted Huadong exclusive rights to develop and commercialize rilonacept and develop, manufacture and commercialize mavrilimumab (each, a "Licensed Product" and together, the "Licensed Products") in the following countries: People's Republic of China, Hong Kong SAR, Macao SAR, Taiwan Region, South Korea, Indonesia, Singapore, The Philippines, Thailand, Australia, Bangladesh, Bhutan, Brunei, Burma, Cambodia, India, Laos, Malaysia, Maldives, Mongolia, Nepal, New Zealand, Sri Lanka, and Vietnam (collectively, the "Territory"). The Company otherwise retained its current rights to the Licensed Products outside the Territory.

Under the Collaboration Agreements, the Company received a total upfront cash payment of $22,000, which includes $12,000 for the Territory license of rilonacept and $10,000 for the Territory license of mavrilimumab. The Company recorded these balances in accounts receivable as of March 31, 2022 and received payment subsequent to quarter end. In addition, the Company will be eligible to receive up to approximately $70,000 in payments for rilonacept, and up to approximately $576,000 in payments for mavrilimumab, including specified development, regulatory and sales-based milestones. Huadong will also be obligated to pay the Company tiered percentage royalties on a Licensed Product-by-Licensed Product basis ranging from the low-teens to low-twenties on annual net sales of each Licensed Product in the Territory, subject to certain reductions tied to rilonacept manufacturing costs and certain other customary reductions, with an aggregate minimum floor. Royalties will be payable on a Licensed Product-by-Licensed Product and country-by-country or region-by-region basis until the later of (i) 12 years after the first commercial sale of the applicable Licensed Product in such country or region in the Territory, (ii) the date of expiration of the last valid patent claim of the Company's patent rights or any joint collaboration patent rights that covers the applicable Licensed Product in such country or region in the Territory, and (iii) the expiration of the last regulatory exclusivity for the applicable Licensed Product in such country or region in the Territory.

Pursuant and subject to the terms of the Collaboration Agreements, Huadong has the exclusive right to conduct Territory-specific development activities for the Licensed Products in the Territory, the first right to support global development of the Licensed Products by serving as the sponsor of the global clinical trials conducted in the Territory and the exclusive right to commercialize the Licensed Products in the Territory. Huadong will be responsible for all costs of development activities and commercialization in the Territory. Both the Company and Huadong participate in a

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Joint Steering Committee ("JSC"), which coordinates and oversees the exploitation of the Licensed Products in the Territory.

The Company will supply certain materials to support development and commercialization activities for both mavrilimumab and rilonacept. Under the Collaboration Agreement for mavrilimumab, Huadong has the right to assume manufacturing responsibilities for materials in the Territory. Under the Collaboration Agreement for rilonacept, Huadong does not have rights to perform manufacturing activities in the Territory.

Absent early termination, each Collaboration Agreement will continue on a country-by-country or region-by-region basis until there are no more royalty payments owed to the Company in such country or region for the applicable Licensed Product. Huadong has the right to terminate each Collaboration Agreement at its discretion upon 12 months' notice and either party may terminate the applicable Collaboration Agreement in the event of an uncured material breach of the other party or in the case of insolvency of the other party. In addition, the Company may terminate the applicable Collaboration Agreement if Huadong or its affiliates or sublicensees challenges the scope, validity, or enforceability of the Company's patent rights being licensed to Huadong. If Huadong and its affiliates do not conduct any material development or commercialization activities with respect to a Licensed Product in the People's Republic of China for a continuous period of longer than six months, then, subject to certain exceptions, the Company may terminate the Collaboration Agreement applicable to such Licensed Product with 60 days' prior written notice. In addition, Huadong's rights under each Collaboration Agreement in certain regions within the Territory may be subject to termination upon failure by Huadong to perform certain clinical, development or commercialization activities, as applicable, with respect to the applicable Licensed Product in such regions.

The Company concluded that Huadong is a customer in these Collaboration Agreements, and as such, each Collaboration Agreement falls within the scope of the revenue recognition guidance in ASC 606.

The Company concluded that the Collaboration Agreements should not be combined and treated as a single arrangement for accounting purposes as the Collaboration Agreements were negotiated separately with separate and distinct commercial objectives, the amount of consideration in one Collaboration Agreement is not dependent on the price or performance of the other Collaboration Agreement, and the goods and services promised in the Collaboration Agreements are not a single performance obligation.

Accounting for Mavrilimumab Collaboration Agreement

As of the Effective Date, the Company identified the following material promises in the mavrilimumab Collaboration Agreement that were evaluated under the scope of ASC 606: delivery of (i) exclusive license for mavrilimumab in the Territory and (ii) clinical manufacturing supply of certain materials for mavrilimumab products in the Territory.

The Company also evaluated whether certain options outlined within the mavrilimumab Collaboration Agreement represented material rights that would give rise to a performance obligation and concluded that none of the options convey a material right to Huadong and therefore are not considered separate performance obligations within the mavrilimumab Collaboration Agreement.

The Company assessed the above promises and determined that the exclusive license for mavrilimumab in the Territory is reflective of a vendor-customer relationship and therefore represents a performance obligation within the scope of ASC 606. The exclusive license for mavrilimumab in the Territory is considered functional intellectual property and distinct from other promises under the Collaboration Agreement as Huadong can benefit from the license on its own or together with other readily available resources and the license is separately identifiable from the other promises. The clinical manufacturing supply of certain materials for mavrilimumab products in the Territory is considered distinct from the exclusive license for mavrilimumab as Huadong can benefit from the manufacturing services together with the

license transferred by the Company at the inception of the Collaboration Agreement. Therefore, each represents a separate performance obligation within a contract with a customer under the scope of ASC 606 at contract inception.

The Company determined the transaction price under ASC 606 at the inception of the mavrilimumab Collaboration Agreement and as of March 31, 2022 which includes $10,000, consisting of the upfront payment. The Company also includes an estimate of variable consideration associated with the clinical manufacturing supply of certain materials, when those materials are shipped. The Company determined that any variable consideration related to development and regulatory milestones is deemed fully constrained and therefore excluded from the transaction price due to the high degree of uncertainty and risk associated with these potential payments, as the Company determined that it could not assert that it was probable that a significant reversal in the amount of cumulative revenue recognized will not occur. The Company also determined that royalties and sales milestones relate solely to the licenses of intellectual property. Revenue related to these royalties and sales milestones will only be recognized when the associated sales occur, and relevant thresholds are met, under the sales or usage-based royalty exception of Topic 606.

As noted above, the Company identified two performance obligations in the mavrilimumab Collaboration Agreement: (i) the delivery of the exclusive license for mavrilimumab in the Territory; and (ii) the clinical manufacturing supply of certain materials for mavrilimumab products in the Territory. The selling price of each performance obligation in the mavrilimumab Collaboration Agreement was determined based on the Company's standalone selling price ("SSP") with the objective of determining the price at which it would sell such an item if it were to be sold regularly on a standalone basis. The Company allocated the variable consideration related to the manufacturing obligations to the future clinical supply of mavrilimumab products in the Territory and the remaining fixed and variable consideration to the license obligation. The Company recognizes revenue for the license performance obligations at a point in time, that is upon transfer of the license to Huadong. As control of the license was transferred on the Effective Date and Huadong could begin to use and benefit from the license, the Company recognized $10,000 of collaboration revenue during the three months ended March 31, 2022 under the mavrilimumab Collaboration Agreement. The Company will recognize revenue for the clinical manufacturing supply obligations at a point in time, that is upon each delivery of the supply to Huadong.

Accounting for Rilonacept Collaboration Agreement

As of the Effective Date, the Company identified the following material promises in the rilonacept Collaboration Agreement that were evaluated under the scope of ASC 606: delivery of (i) exclusive license for rilonacept in the Territory; (ii) clinical manufacturing supply of certain materials for rilonacept products in the Territory; and (iii) commercial manufacturing supply of certain material for rilonacept products in the Territory.

The Company also evaluated whether certain options outlined within the rilonacept Collaboration Agreement represented material rights that would give rise to a performance obligation and concluded that none of the options convey a material right to Huadong and therefore are not considered separate performance obligations within the rilonacept Collaboration Agreement.

The Company assessed the above promises and determined that there is one combined performance obligation for the exclusive license for rilonacept and clinical and commercial manufacturing obligations for rilonacept products in the Territory. Huadong cannot exploit the value of the exclusive license for rilonacept products in the Territory without receipt of supply as the exclusive license for rilonacept products in the Territory does not convey to Huadong the right to manufacture and therefore the Company has combined the exclusive license for rilonacept products in the Territory and the manufacturing obligations into one performance obligation.

The Company determined the transaction price under ASC 606 at the inception of the rilonacept Collaboration Agreement which includes $12,000, consisting of the upfront payment. The Company also includes an estimate of variable consideration associated with the clinical manufacturing supply of certain materials when those materials are shipped. The Company determined that any variable consideration related to development and regulatory milestones,

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sales milestones and royalties are deemed fully constrained and therefore excluded from the transaction price due to the high degree of uncertainty and risk associated with these potential payments, as the Company determined that it could not assert that it was probable that a significant reversal in the amount of cumulative revenue recognized will not occur. Royalties and sales milestones will be recognized as the Company delivers the commercial manufactured product to Huadong. Any changes in estimates may result in a cumulative catch-up based on the number of units of manufactured product delivered.

As noted above, the Company identified a single combined performance obligation in the rilonacept Collaboration Agreement consisting of the exclusive license for rilonacept and clinical and commercial manufacturing obligations for rilonacept products in the Territory. The Company recognizes revenue for the combined performance obligation consisting of the exclusive license for rilonacept and clinical and commercial manufacturing obligations for rilonacept products in the Territory at a point in time, upon which control of materials are transferred to Huadong for each delivery of the associated materials. The Company currently expects to recognize the revenue over the life of the agreement. This estimate considers the timing of development and commercial activities under the rilonacept License Agreement and may be reduced or increased based on changes in the various activities.

The Company has not recognized any revenue under the rilonacept License Agreement as of March 31, 2022 as there has been no delivery of materials under the rilonacept License Agreement to date. The full transaction price of $12,000 is recorded in long-term deferred revenue, based upon timing of anticipated future shipments.

The following table summarizes deferred revenue in connection with collaboration agreements for the three months ended March 31, 2022:

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Three Months ended March 31, 2022				
Huadong rilonacept	$ —	$ 12,000	$ —	$ 12,000
Deferred revenue	$ —	$ 12,000	$ —	$ 12,000

11. License, Acquisition and Collaboration Agreements

Biogen Asset Purchase Agreement

In September 2016, the Company entered into an asset purchase agreement (the “Biogen Agreement”) with Biogen MA Inc. (“Biogen”) to acquire all of Biogen’s right, title and interest in and to certain assets used in or relating to vixarelimab and other antibodies covered by certain patent rights, including patents and other intellectual property rights, clinical data, know-how, and clinical drug supply. In addition, Biogen granted to the Company a non-exclusive, sublicensable, worldwide license to certain background patent rights related to the vixarelimab program. The Company is obligated to use commercially reasonable efforts to develop and commercialize such acquired products.

Under the Biogen Agreement, the Company is obligated to make milestone payments to Biogen of up to $179,000 upon the achievement of specified clinical and regulatory milestones in multiple indications in various territories, of which $165,000 remains as of March 31, 2022. Additionally, the Company could be obligated to make up to an aggregate of up to $150,000 of payments upon the achievement of specified annual net sales milestones and to pay tiered royalties on escalating tiers of annual net sales of licensed products starting in the high single-digit percentages and ending below the teens.

The Company also agreed to pay certain obligations under third-party contracts retained by Biogen that relate to the vixarelimab program. Under these retained contracts, the Company paid a one-time upfront sublicense fee and is

obligated to pay insignificant annual maintenance fees as well as clinical and regulatory milestone payments of up to an aggregate of $1,575.

The Biogen Agreement will terminate upon the expiration of all payment obligations with respect to the last product in all countries in the territory. The Company has the right to terminate the agreement with 90 days' prior written notice. Both parties may terminate by mutual written consent or in the event of material breach of the agreement by the other party that remains uncured for 90 days (or 30 days for payment-related breaches).

During the three months ended March 31, 2022, the Company did not record any research and development expense in connection with the Biogen Agreement. During the three months ended March 31, 2021, the Company recorded research and development expense of $14, related to the annual maintenance fee in connection with the retained contracts.

Beth Israel Deaconess Medical Center License Agreement

In 2019, the Company exercised the call option under the stock purchase option agreement with Primatope and acquired all of the outstanding securities of Primatope (the "Primatope Acquisition"). As a result of the Primatope Acquisition, the Company acquired the rights to an exclusive license to certain intellectual property rights controlled by Beth Israel Deaconess Medical Center, Inc. ("BIDMC") to make, use, develop and commercialize KPL-404 (the "BIDMC Agreement"). Under the BIDMC Agreement, the Company is solely responsible for all development, regulatory and commercial activities and costs. The Company is also responsible for costs related to filing, prosecuting and maintaining the licensed patent rights. Under the BIDMC Agreement, the Company is obligated to pay an insignificant annual maintenance fee as well as clinical and regulatory milestone payments of up to an aggregate of $1,200 to BIDMC. The Company is also obligated to pay a low single-digit royalty on annual net sales of products licensed under the agreement.

During the three months ended March 31, 2022 and 2021, the Company did not record any research and development expense in connection with the BIDMC Agreement.

Regeneron License Agreement

In September 2017, the Company entered into a license agreement (the "Regeneron Agreement") with Regeneron Pharmaceuticals, Inc. ("Regeneron"), pursuant to which the Company has been granted an exclusive license under certain intellectual property rights controlled by Regeneron to develop and commercialize ARCALYST worldwide, excluding the Middle East and North Africa, for all indications other than those in oncology and local administration to the eye or ear. Upon receiving positive data in RHAPSODY, the Company's pivotal Phase 3 clinical trial of ARCALYST, Regeneron transferred the biologics license application, for ARCALYST to the Company. In March 2021, when the FDA granted approval of ARCALYST for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children 12 years and older, the Company assumed the sales and distribution of ARCALYST for Cryopyrin-Associated Periodic Syndromes and Deficiency of Interleukin-1 Receptor Antagonist in the United States.

The Company made a $20,000 payment in the first quarter of 2021 in connection with the achievement of a specified regulatory milestone event. The Company accounted for the acquisition of technology as an asset acquisition because it did not meet the definition of a business. The Company recorded the upfront payment as research and development expense in the consolidated statement of operations and comprehensive loss because the acquired technology represented in-process research and development and had no alternative future use.

The Company evenly splits profits on sales of ARCALYST with Regeneron, where profits are determined after deducting from net sales of ARCALYST certain costs related to the manufacturing and commercialization of

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ARCALYST. Such costs include but are not limited to (i) the Company's cost of goods sold for product used, sold or otherwise distributed for patient use by the Company; (ii) customary commercialization expenses, including the cost of the Company's field force, and (iii) the Company's cost to market, advertise and otherwise promote ARCALYST, with such costs identified in subsection (iii) subject to specified limits. In addition, should there be a transfer of technology related to the manufacture of ARCALYST, then, to the extent permitted in accordance with the Regeneron Agreement, the fully-burdened costs incurred by each of the Company and Regeneron in performing (or having performed) such technology transfer shall also be deducted from net sales of ARCALYST to determine profit. The Company also evenly splits with Regeneron any proceeds received by the Company from any licensees, sublicensees and distributors in consideration for the sale, license or other disposition of rights with respect to ARCALYST, including upfront payments, milestone payments and royalties. For the three months ended March 31, 2022, the Company recognized $8,254 of expenses related to the profit sharing agreement presented within collaboration expenses. For the three months ended March 31, 2021 the Company did not recognize any collaboration expenses related to the profit sharing agreement.

Pursuant to the Regeneron Agreement, in September 2017, the parties entered into a clinical supply agreement under which Regeneron agreed to manufacture materials solely for the Company's use in development activities. Pursuant to the Regeneron Agreement, during the year ended December 31, 2021, the Company entered into a commercial supply agreement under which Regeneron agreed to manufacture product for the Company's use, including for commercial sales. The commercial supply agreement terminates upon the termination of the Regeneron Agreement or the date of completion of the transfer of technology related to the manufacture of ARCALYST. During the three months ended March 31, 2022 and 2021, the Company did not incur any research and development expense related to the purchase of drug materials under the clinical supply agreement. As of March 31, 2022 and December 31, 2021, the Company recorded inventory of $13,223 and $3,675, respectively, related to the purchase of commercial product under the commercial supply agreement (see Note 5). As of March 31, 2022, the Company had non-cancelable purchase commitments under the commercial supply agreement (see Note 14).

The Regeneron Agreement will expire when the Company is no longer developing or commercializing any licensed product under the Regeneron Agreement. Either party may terminate the agreement upon the other party's insolvency or bankruptcy or for material breach of the agreement by the other party that remains uncured for 90 days (or 30 days for payment related breaches). Regeneron has the right to terminate the agreement if the Company suspends its development or commercialization activities for a consecutive 12 month period or does not grant a sublicense to a third party to perform such activities, or if the Company challenges any of the licensed patent rights. The Company may terminate the agreement at any time with one year's written notice. The Company may also terminate the agreement with three months' written notice if the licensed product is determined to have certain safety concerns.

MedImmune License Agreement

In December 2017, the Company entered into a license agreement (as amended from time to time, the "MedImmune Agreement") with MedImmune, Limited ("MedImmune"), pursuant to which MedImmune granted the Company an exclusive, sublicensable, worldwide license to certain intellectual property rights to make, use, develop and commercialize mavrilimumab. Under the MedImmune Agreement, the Company also acquired reference rights to relevant manufacturing and regulatory documents and MedImmune's existing supply of mavrilimumab drug substance and product. The Company is obligated to use commercially reasonable efforts to develop and commercialize the licensed products.

The Company is obligated to make clinical, regulatory and initial sales milestone payments of up to $72,500 in aggregate for the first two indications, of which $57,500 remain as of March 31, 2022. In addition, the Company is obligated to make clinical and regulatory milestone payments of up to $15,000 in the aggregate for each subsequent indication. In July 2020, the Company entered into an amendment to the MedImmune Agreement to establish a new coronavirus field and defer the payment of certain development and regulatory milestones as applied to the new coronavirus field. The Company is obligated to make milestone payments to MedImmune of up to $85,000 upon the achievement of annual net sales thresholds up to, but excluding, $1,000,000 in annual net sales as well as additional

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milestone payments aggregating up to $1,100,000 upon the achievement of additional specified annual net sales thresholds starting at $1,000,000 and higher. The Company has also agreed to pay tiered royalties on escalating tiers of annual net sales of licensed products starting in the low double-digit percentages and ending at twenty percent. Royalty rates are subject to reductions upon certain events.

The Company is solely responsible for all development, manufacturing, and commercial activities and costs of the licensed products, including clinical studies or other tests necessary to support the use of a licensed product. The Company is also responsible for costs related to the filing, prosecution and maintenance of the licensed patent rights.

The MedImmune Agreement will expire upon the expiration of the royalty term in the last country for the last indication, as defined in the agreement. Either party may terminate the agreement upon the other party's insolvency or bankruptcy or for material breach of the agreement by the other party that remains uncured for 90 days. MedImmune has the right to terminate the agreement if the Company challenges any of the licensed patent rights. The Company may terminate the agreement at any time upon 90 days' prior written notice.

During the three months ended March 31, 2022 and 2021, the Company did not record research and development expense in connection with milestone payments due under the MedImmune Agreement.

12. Net Loss per Share

The rights, including the liquidation and dividend rights, of the holders of Class A, Class B, Class A1 and Class B1 common shares are identical, except with respect to voting, transferability and conversion (see the Notes to Consolidated Financial Statements to our Form 10-K). As the liquidation and dividend rights are identical, losses are allocated on a proportionate basis, and the resulting net loss per share attributed to common shareholders will, therefore, be the same for the Class A, A1, B and B1 common shares on an individual or combined basis.

Basic and diluted net loss per share attributable to common shareholders was calculated as follows:

	Three Months Ended March 31,	
	2022	2021
Numerator:		
Net loss attributable to common shareholders	$ (25,210)	$ (49,484)
Denominator:		
Weighted average common shares outstanding—basic and diluted	69,136,901	68,269,486
Net loss per share attributable to common shareholders— basic and diluted	$ (0.36)	$ (0.72)

The Company's unvested RSUs have been excluded from the computation of basic net loss per share attributable to common shareholders.

The Company's potentially dilutive securities, which include options and unvested RSUs, have been excluded from the computation of diluted net loss per share attributable to common shareholders as the effect would be to reduce the net loss per share attributable to common shareholders. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common shareholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common shareholders for the periods indicated because including them would have had an anti-dilutive effect:

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	As of March 31,	
	2022	2021
Options to purchase common shares	8,789,357	10,355,433
Unvested RSUs	665,770	583,585
	9,455,127	10,939,018

13. Income Taxes

The Company is an exempted company incorporated under the laws of Bermuda. Under the current laws of Bermuda, income tax is not charged or levied on an exempted company's income. As a result, the Company has not recorded any income tax benefits from losses incurred in Bermuda during each reporting period, and no net operating loss carryforwards will be available to the Company for those losses. The Company's wholly owned U.S. subsidiaries, Kiniksa US and Primatope, are subject to federal and state income taxes in the United States. The Company's wholly owned subsidiary Kiniksa UK, and its wholly owned subsidiaries, Kiniksa Germany, Kiniksa France, and Kiniksa Switzerland are subject to taxation in their respective countries. Certain of the Company's subsidiaries, primarily Kiniksa US, operate under cost plus arrangements.

The income tax rate for the three months ended March 31, 2022 varied from the Bermuda statutory rate of zero primarily due to income subject to United States taxation under the Kiniksa US cost plus arrangements with the Company, and U.S. federal and state research tax credits ("R&D credits). Income tax provision for the three months ended March 31, 2022 was $1,925 primarily related to the tax impact from the current tax expense. The current income tax expense is primarily a result of the taxable income earned by Kiniksa US under its cost plus arrangement and required capitalization of R&D expenses offset in part by tax benefits from the U.S. federal and state research and development credits, the Foreign Derived Intangible Income ("FDII") deduction and share-based compensation taxable events.

Management examines all positive and negative evidence to estimate whether sufficient future taxable income will be generated to realize existing deferred tax assets. The Company previously determined it was more likely than not that a majority of its net deferred tax assets would not be realized and concluded that a valuation allowance was required, which eliminated its net deferred tax assets recorded in its balance sheet. In the future, if the Company believes that it is more likely than not that it will realize the benefit of these deferred tax assets, it will adjust the valuation allowance and recognize an income tax benefit. There are no material deferred tax assets in the jurisdictions outside Kiniksa US and Kiniksa UK.

14. Commitments and Contingencies

License Agreements

The Company entered into license agreements with various parties under which it is obligated to make contingent and non-contingent payments (see Note 11).

Manufacturing Commitments

The Company entered into a commercial supply agreement with Regeneron to provide both clinical supply and commercial product (see Note 11). The Company entered into agreements with several CMOs to provide the Company with preclinical and clinical trial materials. As of March 31, 2022, the Company had committed to minimum payments under these agreements totaling $36,613 of which $30,089 are due within one year.

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Indemnification Agreements

The Company is not aware of any claims under indemnification arrangements that are expected to have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of March 31, 2022 or December 31, 2021.

Legal Proceedings

The Company is not a party to any material litigation and does not have contingency reserves established for any litigation liabilities.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q, or Quarterly Report, and our audited consolidated financial statements and related notes for the year ended December 31, 2021 included in our Annual Report on Form 10-K, or Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that involve risks and uncertainties. As a result of many factors, including those factors set forth in the risks identified in Part II-Item 1A "Risk Factors" section of this Quarterly Report and our other filings with the Securities and Exchange Commission, or SEC, our actual results could differ materially from the results, performance or achievements expressed in or implied by these forward-looking statements.

Overview

We are a biopharmaceutical company focused on discovering, acquiring, developing and commercializing therapeutic medicines for patients suffering from debilitating diseases with significant unmet medical need. Our portfolio of assets, ARCALYST® (rilonacept), mavrilimumab, vixarelimab and KPL-404, are based on strong biologic rationale or validated mechanisms, target underserved conditions, and offer the potential for differentiation. These assets are designed to modulate immunological pathways across a spectrum of diseases.

ARCALYST is an interleukin-1α and interleukin-1β cytokine trap. In 2017, we licensed ARCALYST from Regeneron, who discovered and initially developed the drug. Our exclusive license to ARCALYST from Regeneron includes worldwide rights, excluding the Middle East and North Africa, for all applications other than those in oncology and local administration to the eye or ear. We received U.S. Food and Drug Administration, or FDA, approval of ARCALYST for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children 12 years and older in March 2021. Recurrent pericarditis is a painful inflammatory cardiovascular disease with an estimated U.S. prevalent population of approximately 40,000 patients seeking and receiving medical treatment. ARCALYST is commercially available through a distribution network of specialty pharmacies, which provide access across the United States. ARCALYST is also approved in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes, or CAPS, specifically Familial Cold Autoinflammatory Syndrome and Muckle-Wells Syndrome in adults and children 12 years and older, and the maintenance of remission in Deficiency of Interleukin-1 Receptor Antagonist, or DIRA, in adults and children weighing 10 kg or more. We are responsible for sales and distribution of ARCALYST in all approved indications in the United States, and evenly split profits on sales with Regeneron. In the fourth quarter of 2021, our ARCALYST collaboration with Regeneron achieved profitability after three quarters of commercial availability for recurrent pericarditis. In February 2022, we granted Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. ("Huadong") exclusive rights to develop and commercialize ARCALYST in the Asia Pacific region, excluding Japan.

Mavrilimumab is an investigational monoclonal antibody inhibitor targeting granulocyte-macrophage colony stimulating factor receptor alpha, or GM-CSFRα. In 2017, we licensed exclusive worldwide rights in all indications to mavrilimumab from MedImmune. We plan to focus mavrilimumab development on cardiovascular diseases where the GM-CSF mechanism has been implicated and that have synergies with our existing commercial infrastructure. In parallel, we may also explore the use of mavrilimumab through research collaborations in other development areas. We previously evaluated mavrilimumab in giant cell arteritis, or GCA, a chronic inflammatory disease of the medium-to-large arteries, and COVID-19-related acute respiratory distress syndrome, or ARDS. In October 2020, we announced that our Phase 2 proof-of-concept clinical trial for the study of mavrilimumab in GCA achieved both its primary and secondary efficacy endpoints with statistical significance. In September 2020, the FDA granted Orphan Drug designation for mavrilimumab for the treatment of GCA. In February 2022, we announced that we do not plan to initiate a Phase 3 trial of mavrilimumab in GCA. In December 2021, we announced that the Phase 3 portion of the global Phase 2/3 clinical trial of mavrilimumab in COVID-19-related ARDS did not meet its primary efficacy endpoint. We subsequently decided to not progress mavrilimumab in such indication. In February 2022, we granted Huadong exclusive rights to develop and commercialize mavrilimumab in the Asia Pacific region, excluding Japan.

Vixarelimab is an investigational monoclonal antibody inhibitor of signaling through oncostatin M receptor beta, or OSMRβ. We acquired worldwide rights to vixarelimab in all indications from Biogen MA Inc., or Biogen, in 2016. We are evaluating vixarelimab for the potential treatment of prurigo nodularis, a chronic inflammatory skin condition with an estimated U.S. prevalence of approximately 300,000 patients. In April 2020, we announced that our Phase 2a trial of vixarelimab in prurigo nodularis achieved its primary and secondary efficacy endpoints. In November 2020, the FDA granted Breakthrough Therapy designation for vixarelimab for the treatment of pruritus associated with prurigo nodularis. We are conducting a global Phase 2b dose-ranging clinical trial of vixarelimab in prurigo nodularis. This trial is designed to investigate efficacy, safety and pharmacokinetics. We expect to report top-line data from this trial in the second half of 2022.

KPL-404 is an investigational monoclonal antibody inhibitor of CD40-CD154 interaction. In 2019, we acquired all of the outstanding securities of Primatope Therapeutics, Inc., or Primatope, the company that owned or controlled the intellectual property related to KPL-404. In connection with our acquisition of Primatope, we acquired an exclusive world-wide license to KPL-404 from Beth Israel Deaconess Medical Center, Inc.. The CD40-CD154 interaction is a key T-cell co-stimulatory signal critical for B-cell maturation, immunoglobulin class switching and Type 1 immune response. We believe disrupting the CD40-CD154 interaction is an attractive approach to address multiple autoimmune disease pathologies such as rheumatoid arthritis, or RA, Sjogren's syndrome, Graves' disease, systemic lupus erythematosus and solid organ transplant graft rejection. In May 2021, we announced positive final data from our Phase 1 clinical trial of KPL-404 in healthy volunteers, which evaluated safety and pharmacokinetics, as well as receptor occupancy and T-cell dependent antibody response. In December 2021, we initiated a Phase 2 proof-of-concept clinical trial of KPL-404 in rheumatoid arthritis, which is designed to enable its potential development in a spectrum of autoimmune diseases believed to be mediated by the CD40-CD154 co-stimulatory interaction. The trial will evaluate pharmacokinetics, safety and efficacy of KPL-404 with subcutaneous administration. In January 2022, we provided KPL-404 to the University of Maryland School of Medicine, as part of an experimental immunosuppressive regimen in connection with a transplant of a genetically-modified pig heart into an adult human with end-stage heart disease who was not eligible for a standard allogeneic heart transplant.

Our future success is dependent on our ability to continue to commercialize ARCALYST and to develop, obtain regulatory approval for and successfully commercialize one or more of our current or future product candidates. Upon approval from the FDA of the commercial marketing of ARCALYST in the United States for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children 12 years and older in March 2021, we assumed the sales and distribution of ARCALYST for the previously approved indications in the United States and evenly split profits on ARCALYST sales with Regeneron. However, as a company we have limited experience obtaining marketing approval for product candidates, commercializing a therapeutic, supporting sales, marketing, and distribution activities and maintaining applicable infrastructure for these activities either directly and/or through agreements with third parties; as a result we may not be able to continue to commercialize ARCALYST or successfully commercialize any future approved product candidates, if any, thus potentially impairing the commercial potential of ARCALYST and our other product candidates.

We have incurred significant operating losses since inception. Our ability to generate product revenue sufficient to achieve corporate profitability will depend heavily on the continued commercialization of ARCALYST and the development and eventual commercialization of one or more of our current or future product candidates, if approved. In the fourth quarter of 2021, our ARCALYST collaboration with Regeneron achieved profitability, though such profits remain small compared to our total net losses and there is no guarantee that our ARCALYST collaboration with Regeneron will remain profitable in the future. For the three months ended March 31, 2022, our net losses were $25.2 million and we had an accumulated deficit of $700.6 million. We expect to continue to incur significant operating losses as we advance our product candidates through preclinical and clinical development and, ultimately, seek regulatory approval. In addition, we expect to continue to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution of ARCALYST. We may also incur expenses in connection with the in-licensing or acquisition of additional product candidates.

As a result, until such time as we can generate significant and sustained revenue, if ever from product sales of ARCALYST and one or more of our current or future product candidates, if approved, we expect to finance our operations through a combination of sales of ARCALYST, raising additional capital such as through debt or equity offerings or through other sources, which may include licensing, collaborations or other strategic transactions or arrangements. We may be unable to raise additional funds or enter into such other transactions or arrangements when

needed on favorable terms, or at all. If we fail to raise capital or enter into such transactions or arrangements as and when needed, we may have to significantly delay, scale back or discontinue the development of one or more of our current or future product candidates, delay our pursuit of potential in-licenses or acquisitions or scale back on commercialization activities for ARCALYST.

Because of the numerous risks and uncertainties associated with product development, including any impact from the COVID-19 pandemic, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain corporate profitability. Even if we are able to continue to commercialize ARCALYST and generate product sales from one or more of our current or future product candidates, if approved, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of March 31, 2022, we had cash, cash equivalents and short-term investments of $145.6 million. We believe that our existing cash, cash equivalents and short-term investments will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance of the unaudited consolidated financial statements included in this Quarterly Report. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "— *Liquidity and Capital Resources*." Our future viability is dependent on our ability to fund our operations through sales of ARCALYST and/or raise additional capital, such as through debt or equity offerings, as needed.

Components of Our Results of Operations

Product revenue, net

Following the FDA approval of ARCALYST in March 2021, we began generating product revenue from sales of ARCALYST in April 2021. ARCALYST is sold through a third party logistics provider that distributes primarily through a network of authorized specialty pharmacies and specialty distributors, collectively, the customers, which deliver the medication to patients by mail.

Net revenue from product sales is recognized at the transaction price when the customers obtain control of our product, which occurs at a point in time, typically upon shipment of the product from the third party logistics provider.

Our net revenues represent total revenues adjusted for discounts and allowances, including estimated cash discounts, chargebacks, rebates, returns, copay assistance, and specialty pharmacy and distributor fees. These adjustments represent variable consideration under ASC 606 and are estimated using the expected value method and are recorded when revenue is recognized on the sale of the product. These adjustments are established by management as its best estimate based on available information and will be adjusted to reflect known changes in the factors that impact such allowances. Adjustments for variable consideration are determined based on the contractual terms with customers, historical trends, communications with customers and the levels of inventory remaining in the distribution channel, as well as expectations about the market for the product and anticipated introduction of competitive products.

Collaboration revenue

Collaboration revenue includes amounts recognized related to upfront payments, royalty revenue, and milestone payments. On February 21, 2022, the Company entered into two collaboration and license agreements or the Collaboration Agreements, with Huadong, pursuant to which we granted Huadong exclusive rights to develop and commercialize rilonacept and mavrilimumab, referred to as the Licensed Products, in the Asia Pacific region excluding Japan, or the Territory. We otherwise retained our current rights to the Licensed Products outside the Territory.

Under the Collaboration Agreements, we received a total upfront cash payment of $22.0 million, which includes $12.0 million for the Territory license of rilonacept and $10.0 million for the Territory license of mavrilimumab. In addition, we will be eligible to receive contingent payments, including specified development, regulatory and sales-based milestones. Huadong will also be obligated to pay us tiered percentage royalties on a Licensed Product-by-Licensed Product basis ranging from the low-teens to low-twenties on annual net sales of each Licensed Product in the Territory, subject to certain reductions tied to rilonacept manufacturing costs and certain other

customary reductions, with an aggregate minimum floor. Royalties will be payable on a Licensed Product-by-Licensed Product and country-by-country or region-by-region basis until the later of (i) 12 years after the first commercial sale of the applicable Licensed Product in such country or region in the Territory, (ii) the date of expiration of the last valid patent claim of our patent rights or any joint collaboration patent rights that covers the applicable Licensed Product in such country or region in the Territory, and (iii) the expiration of the last regulatory exclusivity for the applicable Licensed Product in such country or region in the Territory. We recognized the $10.0 million related to the mavrilimumab license during the three months ended March 31, 2022. We deferred the $12.0 million related to the rilonacept license agreement as of March 31, 2022, as no materials were shipped during the three months ended March 31, 2022.

Operating Expenses

Cost of Goods Sold

Cost of goods sold includes production and distribution costs of ARCALYST, and amortization of the $20.0 million payment we made to Regeneron in the first quarter of 2021 upon achievement of a regulatory milestone, and other miscellaneous product costs associated with ARCALYST. Cost of goods sold also includes the allocations for the labor and overhead costs associated with the production of ARCALYST associated with quality control, quality assurance, and supply chain activities.

Collaboration expenses

Collaboration expenses consists of Regeneron's share of the profit related to ARCALYST sales under the license agreement with Regeneron, or the Regeneron Agreement. We evenly split profits on sales of ARCALYST with Regeneron, where profits are determined after deducting from net sales of ARCALYST certain costs related to the manufacturing and commercialization of ARCALYST. Such costs include but are not limited to (i) our cost of goods sold for product used, sold or otherwise distributed for patient use by us; (ii) customary commercialization expenses, including the cost of our field force, and (iii) our cost to market, advertise and otherwise promote ARCALYST, with such costs identified in subsection (iii) subject to specified limits. In addition, should there be a transfer of technology related to the manufacture of ARCALYST, then, to the extent permitted in accordance with the Regeneron Agreement, the fully-burdened costs of each of us and Regeneron incurred in performing (or having performed) such technology transfer shall also be deducted from net sales of ARCALYST to determine profit. We also evenly split with Regeneron any proceeds received by us from any licensees, sublicensees and distributors in consideration for the sale, license or other disposition of rights with respect to ARCALYST, including upfront payments, milestone payments and royalties.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the research and development of our product candidates. We expense research and development costs as incurred. These expenses may include:

- expenses incurred to conduct the necessary preclinical studies and clinical trials required to obtain regulatory approval;
- expenses incurred under agreements with contract research organizations, or CROs that are primarily engaged in the oversight and conduct of our clinical trials and contract manufacturing organizations, or CMOs that are primarily engaged to provide preclinical and clinical drug substance and product for our research and development programs for our product candidates;
- other costs related to acquiring and manufacturing preclinical and clinical trial materials, including manufacturing validation batches, as well as investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services;

- payments made in cash or equity securities under third-party licensing, acquisition and other similar agreements;
- employee-related expenses, including salaries and benefits, travel and share-based compensation expense for employees engaged in research and development functions;
- costs related to compliance with regulatory requirements; and
- allocated facilities-related costs, which include rent and utilities, depreciation and other expenses.

We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Our direct research and development expenses are tracked on a program-by-program basis for our product candidates and consist primarily of external costs, such as fees paid to outside consultants, CROs, CMOs and research laboratories in connection with our preclinical development, process development, manufacturing and clinical development activities. Our direct research and development expenses by program also include fees incurred under license, acquisition and other similar agreements. We do not allocate employee costs or facility expenses, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to conduct our research and discovery activities as well as for managing our preclinical and clinical development, process development and manufacturing clinical and preclinical materials.

Research and development activities are central to our business. Product candidates in later stages of clinical development generally have higher costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect that our research and development expenses will be substantial over the next several years as we conduct our ongoing and/or planned clinical trials for our product candidates as well as conduct other preclinical and clinical development, and make regulatory filings for our product candidates. We also expect to incur additional expenses related to milestone and royalty payments payable to third parties with whom we have entered into license, acquisition and other similar agreements to acquire the rights to our product candidates.

At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the clinical development of our current or future product candidates or when, if ever, we will realize significant revenue from product sales or be profitable. This uncertainty is due to the numerous risks and uncertainties, including those described in Part II, Item 1A. “Risk Factors” in this Quarterly Report.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and benefits, travel and share based compensation expense for personnel in selling, marketing, medical, executive, business development, finance, human resources, legal and support personnel functions. Selling, general and administrative expenses also include insurance and professional fees for legal, patent, consulting, accounting and audit services.

Upon approval from the FDA of the commercial marketing of ARCALYST in the United States for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children 12 years and older in March 2021, we assumed the sales and distribution of ARCALYST for the previously approved indications in the United States. We expect that our selling, general and administrative expenses will continue to increase in the future as we continue to

perform commercialization and sales activities. We also anticipate that we will continue to incur significant costs, including accounting, audit, legal, compliance and director and officer insurance costs as well as investor and public relations expenses, and that such costs will increase over time as the company continues to expand.

Interest Income

Interest income consists of income recognized from investments in money market funds and U.S. Treasury notes offset by expenses related to investments.

Income Taxes

As an exempted company incorporated under the laws of Bermuda, we are principally subject to taxation in Bermuda. Under the current laws of Bermuda, tax on a company's income is assessed at a zero percent tax rate. As a result, we have not recorded any income tax benefits from our losses incurred in Bermuda during each reporting period, and no net operating loss carryforwards are currently available to us for those losses, while our assets remain in Bermuda. Our wholly owned U.S. subsidiaries, Kiniksa US, and Primatope are subject to federal and state income taxes in the United States. Our wholly owned subsidiary Kiniksa UK, and its wholly owned subsidiaries, Kiniksa Pharmaceuticals (Germany) GmbH, Kiniksa Pharmaceuticals (France) SARL, and Kiniksa Pharmaceuticals GmbH are subject to taxation in their respective countries. Our provision for income taxes relates mainly to U.S. taxable income, generated by our wholly owned subsidiary Kiniksa US. In the first quarter of 2022 we transferred exclusive rights to develop and commercialize mavrilimumab in the Asia Pacific region, excluding Japan, to Kiniksa UK.

Results of Operations

Comparison of the Three Months Ended March 31, 2022 and 2021

The following table summarizes our results of operations for the three months ended March 31, 2022 and 2021:

	Three Months Ended March 31,		
	2022	2021	Change
		(in thousands)	
Revenue:			
Product revenue, net	$ 22,189	$ —	$ 22,189
Collaboration revenue	10,000	—	10,000
Total revenue	32,189	—	32,189
Costs and Operating expenses:			
Cost of goods sold	4,219	—	4,219
Collaboration expenses	8,254	—	8,254
Research and development	20,817	28,683	(7,866)
Selling, general and administrative	22,218	20,600	1,618
Total operating expenses	55,508	49,283	6,225
Loss from operations	(23,319)	(49,283)	25,964
Interest income	34	9	25
Loss before provision for income taxes	(23,285)	(49,274)	25,989
Provision for income taxes	(1,925)	(210)	(1,715)
Net loss	$ (25,210)	$ (49,484)	$ 24,274

Product Revenue, Net

Following the FDA approval of ARCALYST in March 2021, we began generating product revenue from sales of ARCALYST in April 2021. We recognize product revenue, net of ARCALYST at the transaction price when the customers obtain control of our products, which typically occurs upon shipment of the product from the third party

logistics provider. We recognized net revenue from the sale of ARCALYST of $22.2 million for the three months ended March 31, 2022.

Collaboration Revenue

Collaboration revenue for the three months ended March 31, 2022 was $10.0 million. The $10.0 million in revenue was recognized upon the signing of the mavrilimumab Collaboration Agreement in February of 2022. We expect to recognize the $12.0 million of deferred collaboration related to the rilonacept Collaboration Agreement over the development period.

Cost of Goods Sold

Upon the first sale commencing in April 2021, we began generating cost of goods sold associated with the sales of ARCALYST. We recognized cost of goods sold from the sale of ARCALYST of $4.2 million, which includes $0.3 million for the amortization of the payment we made to Regeneron in the first quarter of 2021 upon the achievement of a regulatory milestone, for the three months ended March 31, 2022.

Research and Development Expenses

	Three Months Ended March 31,		
	2022	2021	Change
	(in thousands)		
Rilonacept	$ 1,857	$ 2,801	$ (944)
Mavrilimumab	3,512	8,862	(5,350)
Vixarelimab	2,805	2,657	148
KPL-404	2,205	506	1,699
Unallocated research and development expenses:			
Personnel related (including share-based compensation)	6,970	9,734	(2,764)
Other	3,468	4,123	(655)
Total research and development expenses	$ 20,817	$ 28,683	$ (7,866)

Research and development expenses were $20.8 million for the three months ended March 31, 2022, compared to $28.7 million for the three months ended March 31, 2021, a decrease of $7.9 million.

The direct costs for our ARCALYST program were $1.9 million during the three months ended March 31, 2022, compared to $2.8 million during the three months ended March 31, 2021, a decrease of $0.9 million. The decrease in expenses incurred related primarily to the completion of RHAPSODY, our global, pivotal Phase 3 clinical trial in recurrent pericarditis, and transition to the long-term extension portion of the trial.

The direct costs for our mavrilimumab program were $3.5 million during the three months ended March 31, 2022, compared to $8.9 million during the three months ended March 31, 2021, or a decrease of $5.4 million. The decrease in expenses incurred related primarily to the wind-down activities of the Phase 3 clinical trial during the three months ended March 31, 2022, while during the three months ended March 31, 2021 expenses incurred related to the active enrollment of the Phase 2/3 clinical trial in COVID-19 related ARDS.

The direct costs for our vixarelimab program were $2.8 million during the three months ended March 31, 2022, compared to $2.7 million during the three months ended March 31, 2021, an increase of $0.1 million. Expenses incurred during the three months ended March 31, 2022 were primarily related to our continuation of the Phase 2b clinical trial in prurigo nodularis while during the three months ended March 31, 2021 expenses were primarily related to the initiation of our Phase 2b clinical trial in prurigo nodularis.

The direct costs for our KPL-404 program were $2.2 million during the three months ended March 31, 2022, compared to $0.5 million during the three months ended March 31, 2021, an increase of $1.7 million. The increase in

expenses incurred primarily related to the continuation costs of our Phase 2 trial in rheumatoid arthritis during the three months ended March 31, 2022 as compared to the limited clinical trial expenses for our Phase 1 trial of KPL-404 in healthy volunteers due to the completion of the patient portion of the clinical trial during the three months ended March 31, 2021.

Unallocated research and development expenses were $10.4 million for the three months ended March 31, 2022 compared to $13.9 million for the three months ended March 31, 2021, a decrease of $3.5 million. The decrease of $3.5 million in unallocated research and development expenses was primarily due to supply chain and quality related costs associated with our commercial ARCALYST program, which are now included as cost of goods sold. Personnel-related costs for the three months ended March 31, 2022 and 2021 included share-based compensation of $2.0 million and $2.6 million, respectively.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $22.2 million for the three months ended March 31, 2022 compared to $20.6 million for the three months ended March 31, 2021. The increase of $1.6 million was primarily due to an increase of $1.1 million in sales and marketing associated with the commercial operations of ARCALYST. Personnel-related costs for the three months ended March 31, 2022 and 2021 included share-based compensation of $3.9 million and $4.5 million, respectively.

Collaboration Expenses

Collaboration expenses were $8.3 million for the three months ended March 31, 2022. Our collaboration with Regeneron continued to be profitable for the three months ended March 31, 2022 after first achieving profitability in the fourth quarter of 2021, following three quarters of commercial availability of ARCALYST for recurrent pericarditis. The Collaboration expenses for the three months ended March 31, 2022 included $6.0 million due to Regeneron related to the upfront payment from the Huadong rilonacept Collaboration Agreement. We expect to continue to incur collaboration expenses associated with sales of ARCALYST.

Provision for Income Taxes

For the three months ended March 31, 2022, we recorded an income tax provision of $1.9 million relating primarily to the current tax expense due to income from our cost plus arrangements in the United States, net of R&D credits utilized. For the three months ended March 31, 2021, we recorded a provision for income taxes of $0.2 million relating primarily to the tax impact from the current tax expense due to income from our cost plus arrangements in the United States, net of R&D credits utilized offset by tax benefit related to the exercise of share options.

Liquidity and Capital Resources

As of March 31, 2022, our principle source of liquidity was cash, cash equivalents and short-term investments, which totaled $145.6 million. Our net losses were $25.2 million and $49.5 million for the three months ended March 31, 2022 and 2021, respectively. We expect to incur operating losses for the foreseeable future.

Under various agreements with third parties, we have agreed to make milestone payments, pay royalties, annual maintenance fees and to meet due diligence requirements based upon specified milestones. Under our license agreement with Regeneron, we have entered into supply agreements to provide both clinical and commercial product. We have committed to minimum payments to Regeneron of $36.4 million, of which $29.9 million are due within one year. We have entered into lease agreements for office and laboratory space, and vehicles, with total future lease payments of $5.6 million, of which $2.6 million are due within one year. These agreements impact our short-term and long-term liquidity and capital needs.

Cash Flows

The following table summarizes our cash flows for each of the periods presented:

	Three Months Ended March 31,	
	2022	2021
	(in thousands)	
Net cash used in operating activities	$ (36,846)	$ (40,122)
Net cash provided (used) by investing activities	(22,723)	44,834
Net cash provided by financing activities	423	1,106
Net increase (decrease) in cash and cash equivalents and restricted cash	$ (59,146)	$ 5,818

Operating Activities

During the three months ended March 31, 2022, operating activities used $36.8 million of cash, primarily resulting from our net loss of $25.2 million as well as net cash used by our operating assets and liabilities of $19.2 million offset by non-cash charges of $7.6 million. Net cash used by our operating assets and liabilities for the three months ended March 31, 2022 consisted primarily of a $25.5 million increase in account receivable primarily due to the Huadong Collaboration Agreements, a $9.5 million increase in inventory and a $3.9 million increase in prepaid expenses and other current assets, offset by an increase of $12.0 million in deferred revenue as a result of the rilonacept Huadong Collaboration Agreement, and a $4.1 million increase in accrued expenses and other current liabilities as a result of the upfront payment profit share of the Huadong Collaboration Agreement with Regeneron.

During the three months ended March 31, 2021, operating activities used $40.1 million of cash, primarily resulting from our net loss of $49.4 million offset by net cash provided by our operating assets and liabilities of $0.9 million and non-cash charges of $8.4 million. Net cash provided by our operating assets and liabilities for the three months ended March 31, 2021 consisted primarily of a $1.0 million increase in accrued expenses and other liabilities primarily due to increases related to our clinical trial costs and other general and administration accruals offset by our pre-commercialization activities of our ARCALYST program and the cash payment of the 2020 employee bonuses, offset by a $0.4 million decrease in operating lease liabilities due to monthly payments for our right-of-use assets.

Investing Activities

During the three months ended March 31, 2022 investing activities used $22.7 million of cash, consisting of $30.2 million of purchases of short-term investments, offset by $7.5 million of maturities of short-term investments.

During the three months ended March 31, 2021 investing activities provided $44.8 million of cash, consisting of $139.2 million from proceeds of maturities of short-term investments, partially offset by $74.4 million of purchases of short-term investments and $20.0 million related to the intangible asset acquired as a result of the milestone incurred under the Regeneron Agreement.

Financing Activities

During the three months ended March 31, 2022, net cash provided by financing activities was $0.4 million, consisting of proceeds from the exercise of share options.

During the three months ended March 31, 2021, net cash provided by financing activities was $1.1 million, consisting of proceeds from the exercise of share options.

Funding Requirements

We expect to incur significant expenses in connection with our ongoing and planned activities as we continue to commercialize ARCALYST and advance our current and future product candidates through preclinical and clinical

development, seek regulatory approval and commercialize one or more of our current or future product candidates, if approved. In addition, if we obtain marketing approval for any of our current or future product candidates, we expect to incur significant additional commercialization expenses related to such activities. We may also incur expenses in connection with the in-licensing or acquisition of additional product candidates. As a result, we expect to incur additional expenses related to milestone, royalty and other payments payable to third parties with whom we have entered into license, acquisition and other similar agreements to acquire the rights to our product candidates. Additionally, we expect to continue to incur costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses. We expect to incur expenses as we:

- conduct our current and planned clinical trials for our current and future product candidates;
- increase clinical and commercial manufacturing capabilities or make arrangements with additional third party manufacturers to successfully manufacture our products and product candidates;
- develop and timely deliver clinical grade and commercial grade product formulations that can be used in our clinical trials and for commercial sale;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- maintain, establish, and/or expand a sales, marketing, medical affairs and distribution infrastructure to commercialize ARCALYST or any of our current or future product candidates for which we may obtain marketing approval and intend to commercialize on our own;
- launch commercial sales of any of our current or future product candidates, if and when approved, whether alone or in collaboration with others;
- make milestone or other payments under any current or future license, acquisition, collaboration or other strategic transaction agreements;
- expand our operational, financial and management systems and increase personnel globally to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- maintain, expand and protect our intellectual property portfolio; and
- in-license or acquire other product candidates and technologies or their related businesses, if we determine to do so.

We believe that our existing cash, cash equivalents and short-term investments will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. The future viability of our company is dependent on our ability to fund our operations through sales of ARCALYST and/or raise additional capital, such as through debt or equity offerings, as needed. We anticipate that we may require additional capital if we choose to pursue in-licenses or acquisitions of other product candidates and technologies or their related businesses. We expect to continue to incur significant expenses related to product manufacturing, sales, marketing and distribution of ARCALYST. In addition, if we obtain regulatory approval for any of our current or future product candidates, pursue additional indications for our products or any of our current or future product candidates, we expect to incur significant expenses related to product development and manufacturing, sales, marketing and distribution, depending on where we choose to commercialize.

Because of the numerous risks and uncertainties associated with research, development and commercialization of biologic products, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements may be impacted by a number of factors, including those described in Part II, Item 1A. “Risk Factors” in this Quarterly Report.

Until such time, if ever, as we can generate substantial and sustained product revenue, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, or other sources, including, licensing, collaboration, marketing, distribution or other strategic transactions or arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our shareholders' ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect our shareholders' rights as a common shareholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, debt financing would result in fixed payment obligations.

If we raise funds through licensing, collaboration, marketing, distribution or other strategic transactions or arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates or future revenue streams, or otherwise agree to terms that may not be favorable to us. If we are unable to obtain funding, we could be forced to delay, reduce or eliminate some or all of our research and development programs for product candidates, product portfolio expansion or commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

During the three months ended March 31, 2022, we included the estimates associated with revenue recognition in our critical accounting policies. Our critical accounting policies are described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates" in the Annual Report and the notes to the consolidated financial statements included in Item 1, "Consolidated Unaudited Financial Statements," included in this Quarterly Report. We believe that of our critical accounting policies, the following accounting policies involve the most judgment and complexity:

- accrued research and development expenses;
- share-based compensation; and
- revenue recognition

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

We are exposed to market risk related to changes in interest rates. As of March 31, 2022, our cash, cash equivalents and short-term investments consisted of money market funds and U.S. Treasury notes. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. Further, the COVID-19 pandemic and the ongoing war in Ukraine have adversely impacted the U.S. and global economy and financial markets, and any prolonged impact may affect market interest rates. However, because of the short-term nature of the instruments in our portfolio, an immediate 10% change in market interest rates would not have a material impact on the fair market value of our investment portfolio or on our financial position or results of operations.

Item 4. Controls and Procedures.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act). Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2022.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended March 31, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

We are not party to any material legal proceedings.

Item 1A. Risk Factors.

You should carefully consider the risks described below, as well as the other information in this Quarterly Report, including our unaudited consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below could adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the market price of our Class A common shares could decline. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to Our Financial Position and Capital Needs

We are a biopharmaceutical company and have only started to generate revenue from product sales. We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. Typically, it takes many years to develop one new product from the time it is discovered to when it is available for treating patients and development may cease for a number of reasons. We have incurred operating losses in each year since our inception in 2015 and anticipate incurring losses for the foreseeable future. Our future success is dependent on our ability to develop, obtain regulatory approval for and successfully commercialize one or more of our product candidates. While the FDA approved ARCALYST® (rilonacept) for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children 12 years of age and older in March 2021, we may not be able to continue to commercialize ARCALYST or obtain significant and sustained revenue from such commercialization.

We have incurred significant losses related to expenses for research and development and our ongoing operations. For the three months ended March 31, 2022, our net losses were $25.2 million and as of March 31, 2022, we had an accumulated deficit of $700.6 million. We expect to continue to incur losses for the foreseeable future as a result of many factors, including:

- supporting our sales, marketing and distribution capabilities, infrastructure and organization to commercialize ARCALYST and any products candidates for which we may obtain marketing approval for indications in the United States;
- our research and preclinical and clinical development of our product candidates, including our Phase 2b dose-ranging study of vixarelimab in prurigo nodularis and Phase 2 proof-of-concept clinical trial for KPL-404 in RA;
- manufacturing our products and product candidates for clinical or commercial use, and increasing our manufacturing capabilities or adding additional manufacturers or suppliers;
- seeking regulatory and marketing approvals for our product candidates that successfully complete clinical trials, if any;
- initiating potential additional preclinical studies and clinical trials for our product candidates;
- making milestone or other payments under any current or future license, acquisition, collaboration or other strategic transaction agreement;

- seeking to identify, assess and study new or expanded indications for our products or product candidates, new or alternative dosing levels and frequency for our products or product candidates, or new or alternative administration of our products or product candidates, including method, mode or delivery device;
- seeking to identify, assess, acquire or develop additional product candidates;
- entering into licensing, acquisition, collaboration or other strategic transaction agreements;
- seeking to maintain, protect and expand our intellectual property portfolio;
- seeking to attract and retain skilled personnel;
- creating additional infrastructure to support our product development and commercialization efforts; and
- experiencing delays or encountering issues with any of the above, including but not limited to the impact of the COVID-19 pandemic and measures taken in response to the pandemic, failed trials, complex results, safety issues, regulatory challenges that require longer follow-up of existing trials, additional major trials, or additional supportive trials in order to pursue marketing approval.

See "*Risk Factors — Risks related to product development — The COVID-19 pandemic, and measures taken in response to the pandemic, could have an adverse impact on our current or planned preclinical studies and clinical trials, which could be significant*."

Further, the net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our shareholders' equity (deficit) and working capital.

We will require substantial additional financing, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, will force us to delay, limit, reduce or cease one or more of our product development plans, research and development programs for our product candidates, or other operations or commercialization efforts.

The development and commercialization of biopharmaceutical products is capital intensive. In 2021, we gained FDA approval for and commercially launched ARCALYST in the United States for the treatment of recurrent pericarditis. In addition, we are advancing our product candidates through research, preclinical and clinical development, including our Phase 2b dose-ranging study of vixarelimab in prurigo nodularis and our Phase 2 clinical trial with KPL-404 in RA.

Our expenses may increase in connection with our ongoing activities as we continue to support our sales, marketing and distribution capabilities, continue the research and development of our product candidates and expand our infrastructure and organization to support such activities. We also may incur significant additional commercialization expenses with respect to any future marketing approval of any of our product candidates related to manufacturing, product sales, marketing and distribution. As our product candidates progress through development and towards potential commercialization, we will need to make milestone payments and, if successful, eventually make royalty payments to the applicable licensors and other third parties from whom we have acquired our product candidates. Furthermore, we expect to continue to incur costs associated with operating as a public company.

Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed on acceptable terms, if at all, we will be forced to delay, limit, reduce or cease one or more of our product development plans, research and development programs for our product candidates, or commercialization efforts. We also may not be able to expand our operations or otherwise capitalize on our business opportunities, or may be required to relinquish rights to our product candidates or products.

Our business is highly uncertain, and we cannot estimate with certainty the actual amounts necessary to successfully market and sell products, or complete the development, regulatory approval process and commercialization of our product candidates. Our operating plans may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than expected, through public or private securities offerings, debt financings or other sources, including government funding or grants. Such factors that may significantly impact our funding requirements include:

- our ability to continue to commercialize ARCALYST or successfully commercialize any of our current or future product candidates, if approved, including the cost and timing of supporting our sales, marketing and distribution capabilities, infrastructure and organization expansion and entering into agreements with third parties to conduct one or more of these activities;

- the amount and timing of sales revenues from ARCALYST or any of our product candidates, if approved in the future, including the sales price and the availability of coverage and adequate third-party reimbursement;

- competitive and potentially competitive products and technologies and patients' and prescribers' receptivity to ARCALYST or any of our product candidates if approved in the future and the technology underlying them in light of competitive products and technologies;

- the costs and timing of payments for producing ARCALYST or any of our product candidates to support clinical trials as well as the potential commercial launch of any of our product candidates if approved in the future, reserving manufacturing slots, or transferring manufacturing technology to third-party manufacturers;

- the results from, and the time and cost necessary for development of our product candidates;

- the costs and timing of establishing and maintaining clinical trial sites for the development of our product candidates, both in the United States and in jurisdictions outside of the United States, including as a result of the COVID-19 pandemic and the ongoing war in Ukraine;

- the number, size and type of preclinical activities and any additional clinical trials;

- the costs, timing and outcomes of seeking and potentially obtaining approvals from regulatory authorities, including the potential for regulatory authorities to require that we conduct more studies than we currently plan to conduct and the costs of conducting post-marketing studies or implementing Risk Evaluation and Mitigation Strategy, or REMS, that could be required by regulatory authorities;

- the timing and amount of milestone and other payments we must make under our agreements with Regeneron, MedImmune, Limited, or MedImmune, Biogen MA Inc., or Biogen, BIDMC and the other third parties from whom we have acquired or in-licensed our products and product candidates or from whom we may in the future acquire or in-license products and product candidates;

- the timing and amount of milestone and other payments we may receive under our agreements with Huadong and any other third parties to whom we may in the future out-license products and product candidates;

- the costs to identify, assess and study new or expanded indications for our products and product candidates, new or alternative dosing levels or frequency for our products or product candidates, or new or alternative administration of our products or product candidates, including method, mode or delivery device;

- the costs of any future in-license, acquisition, development or discovery of additional product candidates, including in connection with any licensing, acquisition, collaboration or other strategic transaction agreements;
- the time and cost necessary to respond to technological and market developments;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- any product liability or other lawsuits related to our products and product candidates or any related activities;
- the ongoing costs associated with being a public company;
- our need and ability to hire and retain skilled personnel; and
- the receptivity of the capital markets to financings by biopharmaceutical companies generally and companies with a single commercial product and product candidates and technologies such as ours, specifically.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

In addition, the COVID-19 pandemic and the ongoing war in Ukraine continues to adversely impact the global economy, posing risks to our business and the business of third-parties upon whom we rely. See "*Risk Factors — General Risk Factors — The COVID-19 pandemic, and measures taken in response to the pandemic, could have an adverse impact that is significant on our business and operations as well as the business or operations of our manufacturers, CROs and other third parties with whom we conduct business or otherwise engage, including the FDA and other regulatory authorities, and has impacted and could continue to impact the global economy, which may have a material adverse effect on our business, operations and financial position"* and "*Risk Factors — General Risk Factors — The ongoing war in Ukraine, and actions taken against Russia as a result of its invasion of Ukraine, has and may continue to have an adverse impact on the global economy, equity capital markets and our clinical operations."*

Additionally, funds may not be available when we need them, on terms that are acceptable to us, or at all. If we are unable to obtain funding when needed, we will be forced to curtail, delay, limit, reduce or cease one or more of our product development plans, research and development programs for our product candidates, or commercialization efforts of any of our products or product candidates for which we obtain approval. We may also be unable to expand our operations or otherwise capitalize on our business opportunities or may be required to relinquish rights to our product candidates or products. Any of these occurrences could materially affect our business, financial condition and results of operations.

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates or products.

If and until such time as we can generate substantial and sustained product revenue from ARCALYST or any of our product candidates, if approved in the future, we expect to finance most of our cash needs through private or public securities offerings, debt financings, government funding or grants, or other sources, including licensing, collaboration or other strategic transactions or arrangements with third parties. The terms of any financing may adversely affect the holdings or the rights of our shareholders and our issuance of additional securities, whether equity or debt, or the possibility of such issuance, may cause the market price of our Class A common shares to decline. The sale of additional equity or convertible securities would dilute all of our shareholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and

other operating restrictions that could adversely impact our ability to conduct our business. Obtaining funds through licensing, collaboration or other strategic transactions or arrangements with third parties may require us to relinquish rights to some of our technologies, product candidates or future revenue streams, or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. If we raise funds through research grants, we may be subject to certain requirements, which may limit our ability to use the funds or require us to share information from our research and development. Raising additional capital through any of these or other means could adversely affect our business and the holdings or rights of our shareholders, and may cause the market price of our Class A common shares to decline.

Risks Related to Commercialization

We have limited experience as a company commercializing a therapeutic product and supporting sales, marketing, distribution and general infrastructure either directly and/or through agreements with third parties. As a result, we may not be able to continue to commercialize ARCALYST or be successful in commercializing any future approved product candidates, potentially impairing commercial potential for ARCALYST and our product candidates to generate any revenue.

The FDA approved ARCALYST for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children 12 years of age and older in March 2021. Upon approval by the FDA, we assumed the sales and distribution of ARCALYST for the previously approved indications in the United States, announcing the commercial availability of ARCALYST through Kiniksa in April 2021. To achieve commercial success for ARCALYST, we have established and expanded our internal capabilities, including but not limited to, sales, marketing, distribution, access and patient support services as well as contracting with third parties to perform certain services. Each aspect of commercialization on its own can be complex, expensive, and time consuming, and, collectively, the required effort for coordination is intensive. While we have begun the commercialization of ARCALYST and realized revenues from such efforts, there is no guarantee that we will be able to continue our commercialization of the product or be able to maintain significant and sustained revenues in the long-term.

In addition, our continued commercialization of ARCALYST or successful commercialization of any of our current or future product candidates, if approved, is subject to a number of foreseen and unforeseen factors, including:

- our inability to recruit, train and retain adequate numbers of effective sales, marketing, access, and payor and patient support personnel;
- the inability of sales personnel to obtain access to prescribers and accounts as well as for an adequate number of prescribers or accounts to prescribe any of our future products;
- the lack of complementary products to be supported by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- our inability to develop strong scientific-based relationships to drive disease awareness and education;
- our inability to establish the unmet medical need for a given disease;
- our inability to enable our products to be viewed as the product of choice within any indications for which they are approved;
- our inability or delay in gaining reimbursement and broad patient access at a price that reflects the value of ARCALYST or any of our future products;
- our inability to equip customer-facing personnel with effective materials, including medical and sales literature to help them educate physicians and other healthcare providers regarding applicable diseases relevant to ARCALYST or any of our future products;

- any delays in our ability to produce sufficient quantities of ARCALYST, or any of our future products, at an acceptable cost or quality, including such delays arising out of quality assurance concerns or those caused by our reliance on our third-party manufacturers;

- our inability and the inability of any third parties upon which we rely to effectively distribute products in a timely manner;

- our inability to provide prescribers and patients adequate support and training to build comfort around the preparation and administration process to initiate and continue to use ARCALYST or any of our future products;

- our inability to develop robust patient support programs to optimize the patient and customer experience with ARCALYST or any of our future products;

- our inability to develop or obtain and sustain sufficient operational functions and infrastructure to support our commercial activities; and

- unforeseen costs and expenses associated with creating and maintaining a sales, marketing, and access organization.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties, delays or unforeseen costs. If we experience any such factors that inhibit our efforts to commercialize ARCALYST or any of our product candidates, if approved, our business, results of operations, financial condition and prospects may be materially adversely affected. See "*Risk Factors — General Risk Factors — The COVID-19 pandemic, and measures taken in response to the pandemic, could have an adverse impact that is significant on our business and operations as well as the business or operations of our manufacturers, CROs and other third parties with whom we conduct business or otherwise engage, including the FDA and other regulatory authorities, and has impacted and could continue to impact the global economy, which may have a material adverse effect on our business, operations and financial position.*"

Our current products or future approved product candidates may not gain market acceptance by prescribers, patients, or third-party payors (e.g., governments and private health insurers), in which case our ability to generate product revenues will be impaired.

Even with FDA or any other regulatory authority approval of the marketing of ARCALYST or any of our other product candidates in the future (whether developed on our own or with a collaborator), prescribers, healthcare providers, patients, the medical community or third-party payors may not accept or use ARCALYST or any of our future product candidates, or may effectively block or limit their use in the case of third-party payors. While ARCALYST has seen near-term success, it is not certain we will be able to sustain such success over the long-term. If ARCALYST or any of our other product candidates, if approved, do not achieve an adequate level of sustained acceptance, we may not generate a sufficient level of product revenue or profits from operations, if at all. Sustained market acceptance of ARCALYST in the approved recurrent pericarditis indication, or any of our future approved product candidates and continued use of such products by our patients, will depend on a variety of factors, including:

- the timing of market introduction;

- disease awareness, including understanding the severity and epidemiology of the disease;

- the number and clinical profile of competing products, whether approved or not;

- the potential and perceived advantages or disadvantages of our product candidates relative to alternative treatments;

- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of regulatory authorities;
- limitations or warnings contained in the labeling approved by regulatory authorities;
- convenience and ease of administration, including relative to alternative therapies;
- pricing (including patient out-of-pocket costs), budget impact, affordability and cost effectiveness, particularly in relation to alternative treatments;
- the effectiveness of our sales, marketing and distribution activities;
- availability of adequate coverage, reimbursement and payment from health maintenance organizations and other insurers, both public and private, and the timing thereof; and
- other potential advantages over alternative treatment methods.

If ARCALYST or any of our future approved products, if any, fail to gain market acceptance, our ability to generate revenue will be adversely affected. Even if ARCALYST or any future approved product candidates achieve market acceptance, the relevant market may prove not to be large enough to allow us to generate significant and sustained revenue.

The successful commercialization of our products and future approved product candidates, if any, will depend in part on the extent to which third-party payors, including governmental authorities and private health insurers, provide funding, establish favorable coverage and pricing policies and set adequate reimbursement levels. Failure to obtain or maintain coverage and adequate reimbursement for our products and future approved product candidates, if any, could limit our ability to market those products and decrease our ability to generate revenue.

Our ability to continue to commercialize ARCALYST in the approved recurrent pericarditis indication and other approved indications in the United States or any of our future approved product candidates, if any, particularly in orphan or rare disease indications, will depend in part on the availability of favorable coverage, patient affordability and the adequacy of reimbursement for ARCALYST or the product candidate and alternative treatments from third-party payors (e.g., governmental authorities, private health insurers and other organizations). We continue to seek favorable coverage and reimbursement for ARCALYST in the approved recurrent pericarditis indication from third-party payors, which is contingent on our ability to execute payor value/benefit assessments and effectively negotiate favorable pricing and reimbursement terms.

We cannot be certain we will be able to effectively execute our coverage and reimbursement strategy in the markets we pursue, which could limit the commercial potential of ARCALYST in the approved recurrent pericarditis indication or any of our product candidates, if approved. As a result, our ability to generate projected revenue from ARCALYST or any of our product candidates, if approved, could be negatively impacted.

Governmental authorities, private health insurers and other third-party payors have attempted to control costs through a number of efforts, including by delaying the time to reimbursement, by restricting the breadth of coverage, by limiting the amount of reimbursement for particular products in terms of lower pricing and by increasing the proportion of the cost for which the patient is responsible. There may be significant delays in obtaining reimbursement for newly approved products or product indications, coverage may be limited to a subset of the patient population for which the treatment is approved by the FDA or similar regulatory authorities outside the United States, and reimbursement rates may vary according to the use of the product and the clinical setting in which it is used. Coverage and reimbursement barriers by payors may materially impact the demand for, or the price of, ARCALYST and any product candidate for

which we obtain marketing approval, if any. If coverage and reimbursement are not available, or available only at limited levels, or if such coverage will require patient out-of-pocket costs that are unacceptably high, we may not be able to successfully commercialize ARCALYST or any of the product candidates for which we obtain marketing approval. Moreover, any coverage or reimbursement that may be obtained may be decreased or eliminated in the future.

We may also be unable to adequately satisfy a third-party payor's value/benefit assessment. It is possible that third-party payors will select low-cost clinical comparators that serve as benchmarks for determining relative value, including generics, biosimilars and lower costs brands with or without the same approved indication. The result of such a change would be a more challenging value/benefit assessment caused by a more challenging basis for comparison and the potential for a worse relative outcome. Third-party payors may determine that we have failed to generate sufficient evidence to demonstrate the relative benefits of ARCALYST or any of our product candidates, if approved, and refuse to provide coverage and reimbursement entirely, or many find the evidence not sufficiently compelling to support the desired pricing and reimbursement. Similarly, payors may implement coverage criteria that further restricts the use of ARCALYST or any of our product candidates, if approved, beyond the approved label, which could adversely affect their commercial potential, including, for example, situations where a patient must be proven to not adequately respond to the lower-cost comparator.

Third-party payors are also introducing more challenging price negotiation methodologies, including in re-visiting established coverage and reimbursement parameters when new competitors, including branded drugs, generics and biosimilars enter the market. It is possible that a third-party payor may consider our products and product candidates, if approved, as substitutable and only be willing to cover the cost of the alternative product. Even if we show improved efficacy, safety or improved convenience of administration with ARCALYST or any of our product candidates, if approved, pricing of competitive products may limit the amount we will be able to charge for ARCALYST or any of our product candidates, if approved. Third-party payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. In some cases, when new competitor generic and biosimilar products enter the market, there are mandatory price reductions for the innovator compound. In other cases, payors employ "therapeutic category" price referencing and seek to lower the reimbursement levels for all treatment in the respective therapeutic category. Additionally, new competitor brand drugs can trigger therapeutic category reviews in the interest of modifying coverage and/or reimbursement levels. The potential of third-party payors to introduce more challenging price negotiation methodologies could have a negative impact on our ability to continue to commercialize ARCALYST or successfully commercialize any of our product candidates, if approved.

The incidence and prevalence for target patient populations of our products or product candidates have not been established with precision. If the market opportunities for our products and product candidates are smaller than we estimate, or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability may be materially adversely affected.

The precise incidence and prevalence for all the conditions we aim to address with our programs are not known with specificity. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our products and product candidates, if approved, are based largely on our extrapolation from available population studies and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, pharmacy claims analyses, large national surveillance databases or market research, and may prove to be incorrect. Further, new trials and therapeutic options may lead to changes in the estimated incidence or prevalence of these diseases, or relevant subpopulations thereof. As a result, the number of patients who may benefit from our products or product candidates, if approved, may turn out to be lower than expected.

The total addressable market for any of our products and approved product candidates in the future, if any, will ultimately depend upon, among other things, the diagnostic criteria and applicable patient population included in the final label for the product or product candidate approved for sale for its indication, the efficacy, safety and tolerability demonstrated by the product candidate in our clinical trials, acceptance by the medical community and patients, pricing, access and reimbursement. The number of addressable patients in the United States and other major markets outside of the United States may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our

products or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Further, even if we obtain significant market share for our product candidates, because the potential target populations are small for many of our approved and targeted indications, we may never achieve profitability despite obtaining significant market share.

Evolving health policy and associated legislative changes related to coverage and reimbursement aimed at lowering healthcare expenditure could impact the commercialization of our product candidates. Pharmaceutical pricing has been, and likely will continue to be, a central component of these efforts.

The regulations that govern regulatory approvals, pricing and reimbursement for new pharmaceutical products vary widely from country to country. In markets of some of the countries we may pursue outside of the United States, our products and product candidates, if approved, may be subject to extensive governmental price control or other price regulations. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price negotiations that delay our commercial launch of the product candidate in that country, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product candidate in that country.

Net prices for products may be reduced by mandatory discounts or legislated rebates that must be paid in order to participate in government healthcare programs or paid to other third-party payors. Mandatory discounts can be legislated at any time in any market. Similarly, some markets currently have pricing legislation that sets the price of a pharmaceutical product in their market by referencing the price of that product in other markets, known as international reference pricing. International reference pricing has the potential to impact price cut decisions in individual countries and the countries that reference the pricing of certain other individual countries.

Drug importation and cross-border trade, both sanctioned and unsanctioned, occurs when a pharmaceutical product from a market where the official price is set lower is shipped and made commercially available in a market where the official price is set higher. Any future relaxation of laws that presently restrict or limit drug importation or cross-border trade, including in the United States, could have a material negative impact on our ability to commercialize ARCALYST or any of our product candidates, if approved.

As a result of the foregoing, we may not be able to achieve or sustain favorable pricing for ARCALYST or any of our product candidates, if approved, and adequate reimbursement, which may hinder our ability to recoup our investment in such drugs.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of ARCALYST and any product candidates that we may develop, if approved.

We face an inherent risk of product liability exposure related to the commercialization of ARCALYST and the testing of our product candidates in clinical trials and other research activities. If we cannot successfully defend ourselves against claims that our products or product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates that we may develop or products we commercialize;
- injury to our reputation and significant negative media attention;
- regulatory investigations that could require costly recalls or product modifications;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;

- substantial monetary awards to trial participants or patients;
- loss of potential revenue;
- the diversion of management's attention away from managing our business; and
- the inability to commercialize any product candidates that we may develop, if approved.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur and is subject to deductibles and coverage limitations. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If we are unable to obtain insurance at acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may materially and adversely affect our business and financial position. These liabilities could prevent or interfere with our commercialization efforts.

If, in the future, we are unable to maintain our sales, marketing and distribution capabilities, infrastructure and organization directly and/or through agreements with third parties to sell and market our products and product candidates, if approved, their commercial potential may be impaired.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

If we enter into arrangements with third parties to perform sales, marketing, distribution and other commercial support services, our product revenues or the profitability of these revenues to us are likely to be lower than if we were to market and sell any approved product candidates ourselves. In addition, we may not be successful in entering into arrangements with third parties to market and sell our approved product candidates, if any, or may be unable to do so on terms that are favorable to us. Further, we will likely have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our approved product candidates effectively. However, developing a sales, marketing and access organization requires significant investment, is time consuming and if not completed as planned could delay the launch of our approved product candidates. Furthermore, we may not be able to adequately establish an effective sales, marketing, distribution and access organization in the European Union, or the EU, or other key markets in which we may obtain approval for the commercial marketing of our product candidates outside of the United States. If we are unable to maintain or establish sales, as applicable, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our approved product candidates, if any, and the approved product candidates' ability to generate any revenue may be impaired. Furthermore, our business, results of operations, financial condition and prospects will be materially adversely affected.

Our future growth may depend, in part, on our ability to penetrate markets outside of the United States, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability may depend, in part, on our ability to commercialize our product candidates in markets outside of the United States for which we may rely on collaborations with third parties.

We continue to evaluate the opportunities for the development and commercialization of our product candidates in certain markets outside of the United States, including through our Managed Access Program and collaborations with third parties, including Huadong. We and our collaborators are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that market, and we may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approval in

many other countries, we, or our collaborators, must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials, manufacturing and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we obtain approval of our product candidates and ultimately commercialize our product candidates in markets outside of the United States, we would be subject to additional risks and uncertainties, including:

- our ability to obtain reimbursement for our product candidates in such markets;
- our inability to directly control commercial activities because we may rely on third parties;
- the burden of complying with complex and changing regulatory, tax, accounting and legal requirements of such countries;
- exposure to increased regulatory risk, including those arising under the FCPA (as defined below);
- different medical practices and customs in such countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training and the need for language translations;
- reduced protection of intellectual property rights in such countries;
- the existence of additional potentially relevant third party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by laws of such country in the event of a contract dispute.

Sales of our product candidates outside of the United States could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

In some countries, particularly the countries in Europe, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, price negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain adequate reimbursement or favorable pricing approval in some countries, we may be required to conduct a clinical trial that compares our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

We may also be subject to burdensome pricing requirements. See "*Risk Factors – Risks Related to Commercialization –Evolving health policy and associated legislative changes related to coverage and reimbursement aimed at lowering healthcare expenditure could impact the commercialization of our product candidates. Pharmaceutical pricing has been, and likely will continue to be, a central component of these efforts.*"

We are subject to ongoing obligations, regulatory requirements and continued regulatory review, which may result in significant additional expense. Additionally, our products and future approved product candidates, if any, could be subject to unfavorable changes and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

We are subject to ongoing regulatory requirements for a number of our activities, including manufacturing, packaging, labeling, storage, distribution, advertising, promotion, sampling, record-keeping, adverse event reporting, conduct of post-marketing trials and submission of safety, efficacy and other post-market information for our products in the United States. Such obligations, along with continued regulatory review, may result in significant additional expense. Furthermore, if we seek and receive approval from regulatory authorities outside of the United States for products or any of our product candidates in the future, we will be subject to such authorities' requirements, which may be over and above our obligations in the United States.

Manufacturers and their facilities are required to comply with extensive requirements of regulatory authorities, including ensuring that quality control and manufacturing procedures conform to current good manufacturing practices, or cGMP, or similar foreign regulations. As such, we and our contract manufacturing organizations, or CMOs, will be subject to user fees and continual review and inspections to assess compliance with cGMP or similar foreign regulations and adherence to commitments made in any biologics license applications, or BLA, or Marketing Authorization Application, or MAA. Accordingly, we and our CMOs and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor safety and efficacy. For example, the holder of an approved BLA or similar foreign application must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets.

If our marketing approval would be obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm clinical benefit for our products. An unsuccessful post-marketing trial or failure to complete such a trial could result in the withdrawal of marketing approval. The FDA or foreign regulatory authority also may place other conditions on approvals including the requirement for a REMS or similar risk management measures, to assure the safe use of the product. If the FDA or foreign regulatory authority concludes a REMS or similar risk management measures are needed, the sponsor of the BLA or MAA must submit a proposed REMS or the similar risk management measures before it can obtain approval. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. We also will be required to report certain adverse reactions, production problems, inadequate efficacy and other issues, if any, to applicable regulatory authorities on an ongoing basis. In addition, the identification of new safety issues could lead to new labeling or restrictions on population or use of our products, diminishing the addressable market or sales or both. Such conditions, requirements or events may prove to be expensive and burdensome, and the reporting of such may cause the price of our Class A common shares to decrease.

Further, we must also comply with additional requirements concerning advertising and promotion for our products, which are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label.

If a regulatory agency discovers previously unknown problems with our product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we discover previously unknown problems with a product or product candidate, including adverse events of unanticipated severity or frequency, or with our manufacturing

processes, or fail to comply with regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our CMOs' facilities; or
- seize or detain products, or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time, cost and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

If there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or the manufacture of a product, or if we or one of our distributors, licensees, co-marketers or other third-parties operating on our behalf fails to comply with regulatory requirements, regulatory authorities could impose fines on us, instate restrictions on our product or its manufacture or require us to recall or remove the product from the market, in addition to withdrawing our marketing authorizations, or requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization. If any of these events occurs, our ability to sell our product may be impaired, and we may incur substantial additional expense to comply with such regulatory requirements.

The policies of the FDA and other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States, Europe or in other jurisdictions. In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement actions and we may not achieve or sustain profitability.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, physician and other healthcare professional payment and price transparency, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare professionals, physicians and third-party payors play a primary role in the recommendation and prescription of ARCALYST and any product candidates for which we obtain marketing approval. Our commercial arrangements may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may

constrain the business or financial arrangements and relationships through which we market, sell and distribute ARCALYST and our product candidates for which we obtain marketing approval.

Restrictions under applicable federal, state and foreign healthcare laws and regulations, include the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The U.S. federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand;

- the U.S. federal False Claims Act and civil monetary penalties laws, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the federal government. In addition, manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. Moreover, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the U.S. Foreign Corrupt Practices Act, or FCPA, which prohibits U.S. companies and their representatives from paying, offering to pay, promising to pay or authorizing the payment of anything of value to any foreign government official, government staff member, political party or political candidate for the purpose of obtaining or retaining business or to otherwise obtain favorable treatment or influence a person working in an official capacity abroad. In many countries, the healthcare professionals we interact with may meet the FCPA’s definition of a foreign government official. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect their transactions and to devise and maintain an adequate system of internal accounting controls;

- HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or service. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. federal physician payment transparency requirements, sometimes referred to as the “Sunshine Act”, which requires manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children’s Health Insurance Program to report to the Department of Health and Human Services information related to certain financial interactions with physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners including physician assistants and nurse practitioners, and teaching hospitals, as well as the ownership and investment interests of physicians and their immediate family members;

- analogous state laws and regulations, such as state antikickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by nongovernmental third-party payors, including private insurers; and some state laws require pharmaceutical

companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare professionals or marketing expenditures and pricing information; and

- similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

These laws and regulations, among other things, may constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements we may have with hospitals, prescribers or other potential purchasers of our products or product candidates, if approved. We have entered into consulting and advisory board agreements with physicians and other healthcare professionals and could be adversely affected if regulatory authorities determine our financial relationships with such prescribers violate applicable laws or create a conflict of interest. For example, investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Regulatory authorities may conclude that a financial relationship between us and a principal investigator or a clinical trial site has created a conflict of interest or otherwise affected interpretation of a study. Regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized, which could result in a delay in approval, or rejection, of our marketing applications by regulatory authorities and may ultimately lead to the denial of marketing approval of our product candidates. Furthermore, investigators for our clinical trials may become debarred by regulatory authorities, which may impact the integrity of our studies and the utility of the clinical trial itself may be jeopardized. Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations.

Interactions between biopharmaceutical companies and healthcare professionals are also governed by strict laws, regulations, industry self-regulation codes of conduct and healthcare professionals' codes of professional conduct. The provision of any inducements to healthcare professionals to prescribe, recommend, endorse, order, purchase, supply, use or administer a drug product is prohibited. A number of countries have established additional rules requiring pharmaceutical companies to publicly disclose their interactions with physicians and other healthcare professionals and to obtain approval from employers, professional organizations or competent authorities before entering into agreements with healthcare professionals.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including activities conducted by our sales team, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Further, defending against any such actions can be costly, time consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Risks Related to Product Development

We depend heavily on the success of one or more of our products and product candidates, which are in various stages of clinical development. If we are unable to advance our product candidates in clinical development, obtain regulatory approval and ultimately successfully commercialize one or more of our product candidates, or experience significant delays in doing so, our business will be significantly harmed.

We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable regulatory authorities outside of the United States. Our product candidates are in various stages of clinical development. Our assumptions about why our product candidates are worthy of future development and potential approval in the indications for which we are studying them, or any other indications, are based in part on indirect data collected by other companies and in part from data collected from our preclinical and clinical trials. We may not be able to demonstrate that they are safe or effective in the indications for which we are studying them, and they may not be approved.

We cannot be certain that any of our product candidates will be successful in their clinical trials or will receive regulatory approval even after completing a successful pivotal clinical trial. We may also determine that the potential product and commercial profile of any of our product candidates may not ultimately be commercially successful, or even if we believe they have the potential to be commercially successful, we may discontinue development of one or more of our product candidates or discontinue development in a specific indication for a particular product candidate, at any time for any reason. If we do not receive regulatory approvals for more than one of our product candidates, we may not be able to continue our operations.

While we received FDA approval of ARCALYST for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children 12 years of age and older, each of our product candidates requires substantial additional preclinical or clinical development and manufacturing support and, if approved, an organization to facilitate a successful product launch and commercialization before we will be able to generate any revenue from product sales. The success of our product candidates or potential future product candidates depends upon several factors, including the following:

- submission to and authorization to proceed with clinical trials by the FDA under investigational new drug applications, or INDs, and clinical trial applications to governmental authorities outside of the United States for our product candidates to commence planned clinical trials or future clinical trials;

- successful completion of preclinical studies, including toxicology studies, biodistribution studies and minimally efficacious dose studies in animals, conducted, where applicable, under the FDA's good laboratory practices, or GLP regulations;

- successful site activation for, enrollment in, and completion of clinical trials, the design and implementation of which are agreed to by the applicable regulatory authorities, and the ability of our CROs to successfully conduct such trials within our planned budget and timing parameters and without materially adversely impacting our trials;

- successful data from our clinical programs, including post-marketing trials, including those to satisfy regulatory commitments or for label expansion, with sufficient quality that support an acceptable risk-benefit profile of our products and product candidates for the targeted indications in the intended populations to the satisfaction of the applicable regulatory authorities;

- timely receipt, if at all, of regulatory approvals from applicable regulatory authorities and maintenance of any such approvals;

- as applicable, pediatric study plans acceptable regulatory authorities, and follow through of any pediatric study commitments, including development of pediatric formulations where indicated;

- establishment and maintenance of arrangements with third party manufacturers, as applicable, for continued clinical supply and commercial manufacturing;
- successful development of our manufacturing processes and transfer to third party facilities to support future development activities and commercialization that are operated by CMOs in a manner compliant with all regulatory requirements;
- successful manufacture of sufficient supplies of our product candidates within approved specifications for purity and efficacy from our facility and from our CMOs or other sole-source manufacturers in order to meet clinical or commercial demand, as applicable;
- establishment and maintenance of patent and trade secret protection or regulatory exclusivity for our product candidates;
- timely and successful commercial launch of our product candidates;
- acceptance of our products, if and when approved, by patients, patient-advocates, the medical community and third-party payors;
- effective competition with other therapies;
- establishment and maintenance of adequate healthcare coverage and reimbursement;
- enforcement and defense of intellectual property rights and claims;
- continued compliance with any postmarketing requirements imposed by regulatory authorities, including any required postmarketing clinical trial commitments or REMS or similar risk management measures; and
- maintenance of a continued acceptable safety profile of our product candidates following approval.

If we do not accomplish one or more of these factors in a timely manner or at all, including as a result of the COVID-19 pandemic and measures taken in response to the pandemic, we could experience significant delays in, or an inability to, timely or successfully commercialize our product candidates, which would materially harm our business. If we do not receive regulatory approvals for one or more additional product candidates, we may not be able to continue our operations. Failure to generate sufficient revenue from the commercialization of our current and future products, whether as a result of failing to obtain regulatory approvals or unsuccessfully commercializing such products would harm our ability to continue our operations. In such an instance, we may need to seek capital elsewhere. See "*Risk Factors – Risks Related to Our Financial Position and Capital Needs – We will require substantial additional financing, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, will force us to delay, limit, reduce or cease one or more of our product development plans, research and development programs for our product candidates, or other operations or commercialization efforts"* and "*Risk Factors – Risks Related to Our Financial Position and Capital Needs – Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates or products."*

Even though we received FDA approval for ARCALYST for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children 12 years of age and older, and assumed the sales and distribution of ARCALYST for the previously approved indications in the United States, we evenly split profits on ARCALYST sales with Regeneron, and the relevant markets for these indications may prove not to be large enough to allow us to generate significant and sustained revenue from these product sales. Moreover, even if we successfully obtain regulatory approvals to manufacture and market one or more product candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights, among other things. If the markets for patient subsets that we are targeting are smaller than we estimate, we may not generate projected revenue levels from sales of such product candidates, if approved.

Clinical drug development is a lengthy and expensive process with uncertain timelines and outcomes. We may encounter substantial delays in our clinical trials, or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities. We may therefore be unable to obtain required regulatory approvals and be unable to successfully commercialize our product candidates on a timely basis, if at all.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, time consuming and uncertain as to outcome.

Not all of our clinical trials have been conducted as initially planned or completed on our initial projected schedule, and accordingly, we cannot guarantee that any of our current or potential future clinical trials will be conducted as initially planned or completed on our initial projected schedule, if at all, including as a result of the COVID-19 pandemic and measures taken in response to the pandemic. For example, in December 2021, we announced that the primary efficacy endpoint of the Phase 3 clinical trial of mavrilimumab in COVID-19-related ARDS did not reach statistical significance. We subsequently decided to not progress mavrilimumab in the COVID-19-related ARDS indication. Clinical trials are a lengthy process that require the expenditure of significant money and human capital. Failing to achieve desired efficacy or identifying of a novel safety hazard in turn represents an inability to successfully recoup such expense via a potential commercialization of the product candidate, if approved. Sufficient inability to recoup clinical trial expense via successful development could pose material risks to our business. See "*Risk Factors – Risks Related to Product Development –We depend heavily on the success of one or more of our products and product candidates, which are in various stages of clinical development. If we are unable to advance our product candidates in clinical development, obtain regulatory approval and ultimately successfully commercialize one or more of our product candidates, or experience significant delays in doing so, our business will be significantly harmed*."

Commencing a clinical trial is subject to acceptance by the FDA of an IND or IND amendments, acceptance by competent authorities of the EU member states of a clinical trial application, or CTA, or acceptance by other applicable regulatory authorities, and finalizing the trial design based on discussions with the FDA, competent authorities of the EU member states or other applicable regulatory authorities. We have and may in the future receive feedback or guidance from regulatory authorities on our clinical trial design and protocols and, even after we incorporate such feedback or guidance from these regulatory authorities, such regulatory authorities may impose other requirements for our clinical trials, could disagree that we have satisfied their requirements to commence our clinical trials, disagree with our interpretation of data from the relevant preclinical studies, clinical trials or chemistry, chemistry, manufacturing and controls, or CMC, data, or disagree or change their position on the acceptability of our trial designs, including the proposed dosing level or schedule, treatment duration, our definitions of the patient populations or the clinical endpoints selected, which may require us to complete additional preclinical studies, clinical trials, CMC development, other studies or impose stricter approval conditions than we currently expect.

Commencing our planned clinical trials is also subject to approval by a central institutional review board, or IRB, and an IRB or ethics committee at each clinical trial site before a trial may be initiated, which approval could be delayed, rejected or suspended. Further, the IRBs of the institutions in which such trials are being conducted, the Data Safety Monitoring Board for such trial or regulatory authorities may impose a suspension or termination of our clinical trials even after approval and initiation of trial sites due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by regulatory authorities, unforeseen safety issues or adverse side effects that arise in the trial or failure to demonstrate a benefit from using a drug, any of which could result in the imposition of a clinical hold, as well as changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Successful completion of our clinical trials is a prerequisite to submitting a BLA or supplemental BLA, or sBLA, to the FDA and an MAA, to the European Medicines Agency, or EMA, or competent authorities of the EU member states, or other applicable regulatory authorities in other countries for each product candidate and, consequently, to obtaining approval and initiating commercial marketing of our current and any future product candidates. A failure of one or more of our current or future clinical trials can occur at any stage of testing, and our clinical trials may not be successful. We have experienced and may continue to experience delays in our ongoing clinical trials, and we do not know whether planned clinical trials will begin on time, be allowed by regulatory authorities, need to be redesigned, or if

we can activate sites or enroll patients on time, or if they will be completed on schedule, if at all. Events that have and may in the future delay or prevent commencement or successful completion of clinical development of our product candidates as planned and on schedule, if at all, include but are not limited to:

- inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of human clinical trials;
- delays or failure in reaching a consensus with regulatory agencies on trial design or implementation, including the appropriate dosage levels, frequency of dosing, or treatment period in clinical trials;
- delays or failure in reaching agreement on acceptable terms with prospective CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- difficulties in obtaining required IRB or ethics committee approval at each clinical trial site;
- delays or failure in obtaining regulatory approval to commence a trial, or imposition of a clinical hold by regulatory authorities;
- difficulty in identifying and enrolling suitable patients in a particular trial, which may reduce the power of a clinical trial to detect statistically significant results;
- amendments to clinical trial protocols impacting study criteria, endpoints or design, including amendments that either we initiate or are requested by regulatory authorities;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, medical institutions, or other third parties we contract with in connection with our clinical trials to adhere to clinical trial requirements or to perform their obligations in a timely or manner compliant with all applicable laws and regulations, including FCPA;
- failure to perform in accordance with the FDA's good clinical practices, or GCPs, or applicable comparable regulatory guidelines in other countries;
- patients not completing a clinical trial or not returning for post-treatment follow-up, in either case including as a result of trial demands on participants as a result of the COVID-19 pandemic and measures taken in response to the pandemic or otherwise, among other things;
- clinical trial sites withdrawing from or being unable to conduct activities, or patients withdrawing from clinical trials, including as a result of the COVID-19 pandemic or the ongoing war in Ukraine, among other things;
- participating patients experiencing serious adverse events or undesirable side effects or being exposed to unacceptable health risks;
- participating patients failing to experience confirmed pre-specified events during the clinical trial within an expected timeframe, if at all;
- safety issues, including occurrence of adverse events associated with a product candidate, that are viewed to outweigh its potential benefits;
- changes in regulatory requirements, policies and guidance that require amending or submitting new clinical protocols;

- the cost of clinical trials being greater than we anticipate;
- strategic decisions regarding clinical study priority for capital preservation purposes;
- failure by us, our CROs, or other third parties with whom we contract to properly collect, analyze, and/or assess clinical data, including the performance of assays, analyses and other activities;
- clinical trials of our product candidates producing negative, inconclusive or uncompetitive results, which may result in us deciding, or regulatory authorities requiring us, to conduct additional clinical trials or modify or cease development programs for our product candidates;
- failure to replicate safety, efficacy or other data from earlier preclinical studies and clinical trials conducted by us or third parties, including the companies from whom we have licensed or acquired or may in the future license or acquire our product candidates, in our later clinical trials;
- the occurrence of adverse or other events not observed in earlier studies;
- suspensions or terminations of our clinical trials by us or the IRBs of the institutions in which our clinical trials are being conducted, the Data Safety Monitoring Board for such trials or the FDA or comparable regulatory authorities;
- failure of manufacturers, or us, to produce phase-appropriate supplies of our product candidates for use in our clinical trials in accordance with cGMP requirements and regulations or applicable comparable regulatory guidelines in other countries;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing either as a result of quality assurance or due to our reliance on third party manufacturers; and
- disruptions to our business operations, including our manufacturing operations, and the business operations of our third-party manufacturers, CROs upon whom we rely to conduct our clinical trials, or other third parties with whom we conduct business or otherwise engage, as well as disruptions in supply chain distribution and business travel into and within the countries in which we conduct our clinical trials, our manufacturers produce our product candidates or we otherwise conduct business or engage with other third parties, now or in the future as a result of the impact of the COVID-19 pandemic.

Delays in the commencement or completion of our planned and ongoing clinical trials of our product candidates have occurred and may continue to occur. Consequences of delays have increased and may in the future increase our costs of developing our product candidates, slow down the development and approval of our product candidates, delay or jeopardize our ability to commence product sales and generate revenue, if any, from our product candidates and harm their commercial prospects. Furthermore, disruptions caused by the COVID-19 pandemic have increased and may continue to increase the likelihood that we encounter such difficulties or delays in commencing or completing our planned and ongoing clinical trials or other development. In addition, many of the factors that cause, or lead to, difficulties and delays in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates or us deciding to modify or cease development of our product candidates.

Clinical trial delays could also shorten any periods during which our products have patent protection or shorten any periods during which we have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, which could impair our ability to obtain orphan exclusivity for our products that potentially qualify for this designation and to successfully commercialize our product candidates, and may harm our business and results of operations. Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue and harm our business, financial condition and prospects significantly.

Furthermore, clinical trials must be conducted in accordance with the laws, rules and regulations, guidelines and other requirements of the FDA, EU institutions, the European Medicines Agency, or EMA and other applicable regulatory authorities outside of those jurisdictions and are subject to oversight by these regulatory authorities and IRBs or ethics committees at the medical institutions where the clinical trials are conducted. Further, conducting global clinical trials, as we do for certain of our product candidates, may require that we coordinate among the legal requirements and guidelines of regulatory authorities across a number of jurisdictions, including the United States, EU and countries outside of those jurisdictions, which could require that we amend clinical trial protocols or determine not to conduct a trial in one or more jurisdictions or to run separate trials in various jurisdictions due to the inability, cost or delay in harmonizing divergent requests from such regulatory authorities, all of which could increase costs. In addition, clinical trials that are conducted in countries outside the United States and the EU may subject us to risks associated with the engagement of non-United States and non-EU CROs who are unknown to the FDA or the EMA, or the EU member states' regulatory authorities and may have different standards of diagnosis, screening and medical care, as well as risks associated with further delays and expenses as a result of increased shipment costs (including as a result of local quality release or in-country testing of a product candidate supply produced in a different jurisdiction for our clinical trials) and political and economic risks relevant to such countries outside the United States and the EU.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate CTA to be submitted in each member state, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials whose CTA was made under the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors may still choose to submit a CTA under either the Clinical Trials Directive or the CTR until January 31, 2023 and, if authorized, those will be governed by the Clinical Trials Directive until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR.

It is currently unclear to what extent the United Kingdom, or UK will seek to align its regulations with the EU. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation).

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

Further, the ongoing war in Ukraine may also materially affect our clinical activities and our product candidate development timeline. See "*Risk Factors – General Risk Factors – The ongoing war in Ukraine, and actions taken against Russia as a result of its invasion of Ukraine, has and may continue to have an adverse impact on the global economy, equity capital markets and our clinical operations*."

The COVID-19 pandemic, and measures taken in response to the pandemic, could have an adverse impact on our current or planned preclinical studies and clinical trials, which could be significant.

The COVID-19 pandemic, and measures taken in response to the pandemic, have had and could continue to have an impact on our current or planned preclinical studies and clinical trials. If the COVID-19 pandemic and measures undertaken in response to the pandemic are reinstated, including as a result of the emergence of new variants of the virus, we may experience significant disruptions that could materially impact our preclinical studies and clinical trials, including by:

- impeding, delaying, limiting or preventing the production, delivery or release of our product candidates to our clinical trial sites or patients, including due to interruptions in the supply of raw materials or global shipping that may affect the transport of our product candidates or clinical trial materials, or the reprioritization by third parties or the U.S. government for any products or potential products related to the treatment or prevention of COVID-19;

- impeding, delaying, limiting or preventing the production, delivery or release of the supply of our product candidates, including due to disruptions at manufacturing facilities that produce our product candidates, staffing shortages, reprioritizations, production slowdowns or stoppages or interruptions in global shipping;

- impeding, delaying, limiting or preventing clinical trial investigators, other critical staff, or patients from traveling to our clinical trial sites or visiting nurses traveling to patients;

- impeding, delaying, limiting or preventing key clinical trial activities, including patient screening, clinical trial site monitoring, patient dosing, study procedures (such as biopsies, which may be deemed non-essential), collection of clinical data and samples as well as cleaning and verification of clinical data, which could affect the integrity of clinical trial data;

- diverting healthcare resources away from the conduct of clinical trials or reprioritizing the focus of such resources on clinical trials for product candidates with the potential for treatment or prevention of COVID-19 related conditions;

- timing of COVID-19 and other vaccinations received by potential patients for our clinical trials may impede, delay, limit or prevent such potential patients from enrolling in our clinical trials;

- impeding, delaying, limiting or preventing clinical trial site initiation, including difficulties in recruiting clinical site investigators and clinical site staff, and enrollment or retention of patients in our clinical trials;

- increasing the risk that participants enrolled in our clinical trials will contract COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;

- interrupting or delaying preclinical studies due to restricted or limited operations at our research and development laboratory facility;

- causing interruptions or delays at the FDA, or other regulatory authorities, which could result in delays in review and approval of our submissions and applications, including INDs, clinical trial protocols and BLAs and similar applications for our product candidates;

- resulting in the refusal of the FDA or foreign regulatory authorities to accept data from clinical trials in affected geographies;

- prompting changes in local regulations as part of a response to the COVID-19 pandemic, or any emerging variants, which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or cause us to pause or discontinue one or more of our current or planned clinical trials altogether;

- delaying necessary interactions with local regulatory authorities, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and

- limiting employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire or requirement of employees to avoid contact with large groups of people.

Any one of the foregoing could significantly impede, delay, limit or prevent the clinical development of our product candidates and ultimately lead to the delay or denial of regulatory approval of our product candidates. While we continuously look to identify business-critical activities and to develop contingencies and mitigation strategies for those activities to potentially minimize the impact of the COVID-19 pandemic on our business and operations, there can be no assurance that we will be able to identify all such activities or that any identified contingencies and mitigation strategies will be effective. If the clinical development of our product candidates is significantly impeded, delayed, limited or is prevented, it could ultimately lead to the delay or denial of regulatory approval of our product candidates which would materially adversely affect our business and operations, including our ability to generate revenue.

We may find it difficult to enroll patients in our clinical trials in a timely manner given the limited number of patients who have the diseases for which our product candidates are being studied, our particular enrollment criteria or competing clinical studies in the same patient population.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends in part on the speed at which we can recruit a sufficient number of patients to participate in testing our product candidates, particularly given that many of the conditions for which we are evaluating our current product candidates or may evaluate them in the future are in small disease populations. In addition, the eligibility criteria of our clinical trials will further limit the pool of available trial participants, as we will require patients to have specific characteristics that we can evaluate based on the primary and secondary endpoints of the study. Further, our product candidates modulate the immune system and carry risks associated with immunosuppression, including the risk of serious infections, potential interference with vaccines, and other potential serious health risks. Additionally, certain indications for our product candidates may present challenges that may prevent us or third parties from conducting well-controlled studies.

Our clinical trials have competed and may continue to compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates. This competition may further reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which would reduce the number of patients who are available for our clinical trials at such clinical trial site.

Accordingly, when we encounter these or other difficulties in enrollment, we have experienced and may continue to experience delays or we may be prevented from completing our clinical trials. Patient enrollment depends on many factors, including:

- the size and nature of the patient population;
- the severity of the disease being studied;
- patient referral practices of prescribers;
- patient eligibility criteria for the clinical trial and evolving standards of care;
- the proximity of patients to clinical sites;
- the complexity of the design and nature of the clinical protocol and trial;
- the availability and nature of competing clinical trials;

- the availability of standard of care or new drugs approved for the indication the clinical trial is investigating;
- failure to obtain and maintain or timely amend patient consents;
- our ability to recruit clinical trial investigators with applicable competencies and experience;
- the risk that patients enrolled in clinical trials will withdraw from the trials before completion of their treatment or follow-up period (in either case including as a result of trial demands on participants among other things);
- clinicians' and patients' perceptions as to the safety and potential advantages of the product candidate being studied in relation to other available therapies; and
- the occurrence of adverse events or undesirable side effects attributable to our product candidates.

The process of finding and enrolling patients may prove costly, especially since we are looking to identify a subset of the patients eligible for our studies from a relatively small patient population for many of the diseases we are studying. If patients are unable or unwilling to participate in our clinical trials for any reason, or we experience difficulties in patient enrollment for any other reasons, such as due to the COVID-19 pandemic, our costs may significantly increase and the timeline for recruiting patients, conducting trials and obtaining regulatory approval of our product candidates may be significantly delayed or prevented, the commercial prospects of our product candidates may be harmed, and our ability to commence product sales and generate product revenue from any of these product candidates, if approved, could be delayed or prevented. Any of these occurrences may harm our business, financial condition, and prospects significantly.

Our products and product candidates may cause undesirable side effects or have other safety risks that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences, including withdrawal of approval, following any potential marketing approval.

Treatment with our products and product candidates may produce undesirable side effects or adverse reactions or events. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in more restrictive labels or the delay or denial of regulatory approvals by regulatory authorities.

Our products and product candidates modulate the immune system and carry risks associated with immunosuppression, including the risk of serious infections and other potential serious health risks.

For mavrilimumab, there is a theoretical risk for the development of pulmonary alveolar proteinosis, or PAP, with chronic use. PAP is a rare lung disorder in which surfactant-derived lipoproteins accumulate excessively within pulmonary alveoli due to loss of GM-CSF function. The disease can range in severity from a sub-clinical reduction in diffusion capacity to significant dyspnea during mild exertion. In preclinical studies conducted by MedImmune, certain effects were observed in the lungs of non-human primates, which led the FDA to issue a clinical hold with respect to MedImmune's proposed clinical trial in RA. Preclinical data generated to-date suggest mavrilimumab at clinically relevant doses does not reach the lungs in sufficient quantities to induce PAP, and human trials thus far have not shown a clinical effect on pulmonary function tests attributable to mavrilimumab.

However, if the results of our clinical trials reveal an unacceptable severity and prevalence of certain side effects, the FDA or applicable regulatory authority outside of the United States may suspend or terminate our clinical trials, or not authorize us to initiate further trials. In addition, if other molecules in the same or related class in development by third parties show the same or similar side effects as those we observed in our trials but to a greater degree or reported new previously unreported side effects, it could have an impact on the entire class of molecules in development; the applicable regulatory agency may suspend or terminate our clinical trials, or not authorize us to initiate

further trials with our molecule in that class. Regulatory authorities could order us to cease further development of, or deny or withdraw any approval of, any of our products or product candidates for any or all targeted indications.

In addition, the compassionate use of our product candidates, or evaluation of our product candidates by third parties via scientific collaborations or investigator initiated studies could increase the possibility of generating adverse safety results that impact our development of such product candidates. Such adverse safety results, when reported to regulatory authorities, may negatively impact the safety profile of the drug studied as a class effect and could result in the imposition of clinical holds on all clinical trials involving such product candidate regardless of the indication studied.

Further, clinical trials by their nature utilize a sample of the potential patient population. Certain rare and severe side effects associated with our products or product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidates. If we or others later identify undesirable side effects caused by our product or any of our product candidates, if approved, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such product and require us to take it off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, contraindications or field alerts to prescribers and pharmacies;
- we may be required to create a registry or a REMS plan or similar risk management measures, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers or other elements to assure safe use;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we promote the product, or sales of the product may decrease significantly;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product or product candidate, if approved, and could significantly harm our business, results of operations and prospects.

Interim, preliminary, and "top-line" data from our clinical trials that we announce or publish from time to time may change as more patient data become available following the release of the interim data; preliminary data are subject to audit and verification procedures, and deeper analysis of the data beyond the topline data may provide more color and context to the data, all of which could result in material or other changes that are reflected in the final data.

From time to time, we may disclose interim data from our preclinical studies or clinical trials, which are based on an interim analysis of then-available data from ongoing studies or trials. Interim data from our preclinical studies and clinical trials that we may complete are subject to the risk that one or more of the clinical observations may materially change as patient enrollment continues and more patient data become available from the particular study or trial. As a result, interim data should be viewed with caution until final data are available. Adverse differences between interim data and final data could significantly harm the development of our product candidate and our business prospects with respect thereto.

Further, from time to time we may announce or publish topline or preliminary data from our preclinical studies or clinical trials, which are based on a preliminary analysis of data from a completed study. Preliminary and topline data from our clinical trials are subject to change following a more comprehensive review of the data from the particular clinical trial. We also make assumptions, estimations, calculations and conclusions as part of our preliminary analyses of the data, and we may not have received, or had the opportunity to evaluate fully and carefully, all of the data. As a result, preliminary and topline data remain subject to audit and verification procedures that may result in the final data being different from the preliminary data we previously announced or published.

Third parties, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and our business prospects. In addition, the information we announce or publish regarding a particular preclinical study or clinical trial may represent only a portion of extensive information generated from that study or trial, and our shareholders or other third parties may not agree with what we determine is material, important or otherwise appropriate information to include in our disclosure.

If the interim, preliminary, or topline data that we report differ materially from final results, or if third parties, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business prospects, operating results or financial condition. Further, announcement of preliminary, interim or top-line data by us or differences between that data and the final data could result in volatility in the price of our Class A common shares.

Risks Related to Marketing Approval and Regulatory Matters

Regulatory approval processes are lengthy, time consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our current or future product candidates or if we fail or otherwise cease to advance their development, we will be delayed in commercializing or will not be able to commercialize, our current or future product candidates and our ability to generate additional revenue will be materially impaired.

Before we can commercialize any of our current or future product candidates, we must obtain marketing approval from regulatory authorities. We may not be able to receive approval to market any of our current or future product candidates from regulatory authorities in our desired indications in any jurisdiction and it is possible that none of our product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. We may need to rely on third-party CROs and regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the biologic manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authorities. Our current or future product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. The FDA and other regulatory authorities have substantial discretion in the approval process, including determining when or whether regulatory approval will be obtained for a product candidate. Even if we believe the data collected from clinical trials are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority. In addition to the United States, we may seek regulatory approval to commercialize our product candidates in other jurisdictions. While the scope of regulatory approval is similar in many countries, to obtain separate regulatory approval in multiple countries will require us to comply with numerous and varying regulatory requirements of each such country or jurisdiction regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution, and we cannot predict success in any such jurisdictions.

The process of obtaining regulatory approvals, both in the United States and in other countries, is time consuming, expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted BLA, or equivalent application types, may cause delays in the approval or rejection of an application. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. A proposal for revision of several legislative instruments related to medicinal products (potentially revising the duration of regulatory exclusivity, eligibility for expedited pathways, etc.) is expected to be adopted by the European Commission by the end of 2022. The proposed revisions, once they are agreed and adopted by the European Parliament and European Council (not expected before the end of 2024) may have a significant impact on the biopharmaceutical industry in the long term.

Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical studies or clinical or other trials for our current or future product candidates. Our current and future product candidates could be delayed in receiving, or fail to receive, regulatory approval or we may fail or cease to advance their development for many reasons, including the following:

- regulatory authorities may disagree with the number, design or implementation of our clinical trials to support further development or approval;
- we may be unable to demonstrate to the satisfaction of regulatory authorities that a product candidate is safe and effective for its proposed indication or that its clinical and other benefits outweigh its safety risks;
- regulatory authorities could require us to collect additional data or conduct additional clinical trials;

- the results of clinical trials may produce negative, inconclusive or uncompetitive results, which may result in us deciding, or regulatory authorities requiring us, to conduct additional clinical trials or to modify or cease development programs for our product candidates;

- the results of clinical trials may not meet the primary or secondary endpoints of the applicable trial or the level of statistical significance required by regulatory authorities;

- regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA, sBLA or other submission or to obtain regulatory approval in the United States or elsewhere;

- regulatory authorities could require us to conduct additional clinical trials to compare our product candidates to other therapies for the treatment of the same indication;

- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or we may fail to recruit suitable patients to participate in a trial;

- our third-party contractors may fail to comply with data quality and regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- regulatory authorities may not believe that we have sufficiently demonstrated our ability to manufacture the products to the requisite level of quality standards, including that such material is sufficiently comparable to material used in previous clinical trials, or they may fail to approve our manufacturing processes or facilities, or the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;

- regulatory authorities may not believe that their on-site inspections and data audits have sufficiently demonstrated the quality and integrity of the clinical trial conduct and of data submitted to regulatory authorities in support of our new product approvals and marketing applications;

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;

- our product candidates may have undesirable side effects, toxicities or other unexpected characteristics, causing us or our investigators, regulatory authorities or IRBs to reject, suspend or terminate the clinical trials; and

- the approval policies or regulations of regulatory authorities may significantly change in a manner rendering our clinical data, biologic manufacturing process and other supporting information insufficient for approval.

In addition, even if we were to obtain approval for one or more of our current or future product candidates, regulatory authorities may approve any of our current or future product candidates for fewer indications or more limited patient populations than we request. For example, in connection with our vixarelimab program, regulatory authorities may recognize a narrower patient population as having prurigo nodularis, define the disease differently than we do or classify the drug as a different line of therapy. Furthermore, regulatory authorities may not approve the price we intend to charge, may grant approval contingent on the performance of costly post-marketing clinical trials, may impose certain post-marketing requirements that impose limits on our marketing and distribution activities, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful

commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our current or future product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of or to advance our current or future product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate additional revenue will be materially impaired.

Our products, current product candidates and any of our future product candidates regulated as biologics in the United States may face biosimilar competition sooner than anticipated.

In the United States, the BPCIA created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first approved under a BLA by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product for the same therapeutic indication if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty.

For example, although ARCALYST was approved as a biological product under a BLA for the treatment of CAPS in February 2008, and we believe it qualified for the 12-year period of exclusivity against any biosimilars, such 12-year period of exclusivity has lapsed. The FDA approved ARCALYST for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children 12 years of age and older in March 2021. However, the 12-year exclusivity period does not attach to the approval of an sBLA, potentially creating the opportunity for biosimilar competition, subject to any Orphan Drug exclusivity under the U.S. Orphan Drug Act (See "*Risk Factors — Risks Related to Marketing Approval and Regulatory Matters — We may seek Orphan Drug designation for our product candidates in the United States, as well as for any of our product candidates in the EU, and we may be unsuccessful, or may be unable to maintain the benefits associated with Orphan Drug designation, including the potential for market exclusivity, for any product candidate for which we obtain Orphan Drug designation.")*. If we obtain FDA approval for any of our other biological product candidates, we expect any such product candidates to qualify for the 12-year period of exclusivity under the BPCIA. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider any such approved product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated.

Even if we obtain marketing authorization of our current or future product candidates in a major pharmaceutical market such as the United States, or the EU, we may not seek or obtain approval or commercialize our current products or product candidates in other markets, which would limit our ability to realize their full market potential.

In order to market any products in a country or territory, we must establish and comply with numerous and varying regulatory requirements of such country or territory regarding safety and efficacy. Regulatory requirements can vary widely from country to country, and clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation, additional administrative review periods, and additional preclinical studies or clinical trials, which would be costly and time consuming and could delay or prevent the introduction of our current or future product candidates, or ARCALYST, in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries.

We may seek Orphan Drug designation for our product candidates in the United States, as well as for any of our product candidates in the EU, and we may be unsuccessful, or may be unable to maintain the benefits associated with

Orphan Drug designation, including the potential for market exclusivity, for any product candidate for which we obtain Orphan Drug designation.

We have received Orphan Drug designation in the United States for mavrilimumab for the treatment of GCA, and we may seek Orphan Drug designation for certain of our other product candidates in the United States as well as for any of our product candidates in the EU. We may be unsuccessful in obtaining such designation for any of our other product candidates or unable to maintain the associated benefits for any of our other current or future product candidates that are granted Orphan Drug designation, if any. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs or biologics intended to treat relatively small patient populations as Orphan Drug products. Under the U.S. Orphan Drug Act, the FDA may designate a drug or biologic as an Orphan Drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States.

In the EU, the European Commission grants Orphan Drug designation after receiving the opinion of the EMA's Committee for Orphan Medicinal Products on an Orphan Drug designation application. In the EU, Orphan Drug designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the EU and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, Orphan Drug designation is granted for drugs intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug. In the EU, Orphan Drug designation entitles a party to financial incentives such as reduction of fees or fee waivers, as well as potential marketing exclusivity.

In addition, if a drug or biologic with an Orphan Drug designation subsequently receives the first marketing approval for the disease or condition for which it has such designation, the drug or biologic is entitled to a period of marketing exclusivity, which precludes a regulatory authority from approving another marketing application for the same drug and disease or condition for that time period, except in limited circumstances. If our competitors are able to obtain Orphan Drug exclusivity prior to us, for products that constitute the "same drug" and treat the same diseases or conditions as our product candidates, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time. The applicable period is seven years in the United States and ten years in the EU. The EU exclusivity period can be reduced to six years if, at the end of the fifth year, it is established that a drug no longer meets the criteria for Orphan Drug designation including where it is shown that the drug is sufficiently profitable not to justify maintenance of market exclusivity.

In connection with the FDA's approval of ARCALYST in the recurrent pericarditis indication, we received seven years of Orphan Drug exclusivity for ARCALYST for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and pediatric patients 12 years and older. Even if we obtain Orphan Drug exclusivity for any of our product candidates, that exclusivity may not effectively protect those product candidates from competition because different drugs can be approved for the same disease or condition. Even after an Orphan Drug is approved, the FDA can subsequently approve a later application for the same drug for the same disease or condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer in a substantial portion of the target populations, more effective or makes a major contribution to patient care. In addition, a designated Orphan Drug may not receive Orphan Drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, Orphan Drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Foreign regulatory authorities may also make the same determination. Orphan Drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

We may seek Breakthrough Therapy designation or Fast Track designation by the FDA, for one or more of our product candidates, which we may not receive. Such designation may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

We received Breakthrough Therapy designation for vixarelimab for the treatment of pruritis associated with prurigo nodularis, and we may seek Breakthrough Therapy or Fast Track designation for one or more of our other product candidates. A Breakthrough Therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Separately, if a product candidate is intended for the treatment of a serious or life-threatening condition and clinical or preclinical data demonstrate the potential to address unmet medical needs for this condition, the sponsor may apply for Fast Track designation. Both Fast Track designation and Breakthrough Therapy designations offer sponsors the potential for rolling review of a BLA, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

The FDA has broad discretion whether or not to grant Fast Track and Breakthrough Therapy designations, and even if we believe a particular product candidate is eligible for such designations, we cannot be certain that the FDA would decide to grant them. Even if we obtain such designations for one or more of our product candidates, we may not experience a faster development process, review or approval compared to non-expedited FDA review procedures. In addition, the FDA may withdraw Fast Track or Breakthrough Therapy designations if it believes that such designations are no longer supported. Although product candidates receiving Fast Track and Breakthrough Therapy designation are generally eligible for the FDA's priority review procedures, receiving such designations does not guarantee that the BLA for such product candidates will receive priority review.

We may seek PRIME designation by EMA or other designations, schemes or tools in the EU, including the conditional marketing authorization or marketing authorization under exceptional circumstances, for one or more of our product candidates, which we may not receive. Such designations may not lead to a faster development or regulatory review or approval process and do not increase the likelihood that our product candidates will receive marketing authorization.

We may seek EMA PRIME (Priority Medicines) designation or other designations, schemes or tools for one or more of our product candidates. In the European Union, innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIME scheme, which provides incentives similar to the Breakthrough Therapy designation in the United States. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. The benefits of a PRIME designation include the appointment of a rapporteur before submission of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process.

Even if we believe one of our product candidates is eligible for PRIME, the EMA may disagree and instead determine not to make such designation. The EMA PRIME scheme or other schemes, designations, or tools, even if obtained or used for any of our product candidates may not lead to a faster development, regulatory review or approval process compared to therapies considered for approval under conventional procedures and do not assure ultimate approval. In addition, even if one or more of our product candidates is eligible to the PRIME scheme, the EMA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for review or approval will not be shortened.

Product developers that benefit from PRIME designation may be eligible for accelerated assessment (in 150 days instead of 210 days), which may be granted for medicinal products of major interest from a public health perspective or that target an unmet medical need, but this is not guaranteed.

Moreover, in the EU, a "conditional" marketing authorization may be granted in cases where all the required safety and efficacy data are not yet available. A conditional marketing authorization is subject to conditions to be fulfilled for generating missing data or ensuring increased safety measures. A conditional marketing authorization is valid for one year and has to be renewed annually until fulfillment of all relevant conditions. Once the applicable pending studies are provided, a conditional marketing authorization can become a "standard" marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA, the marketing authorization will cease to be renewed. Furthermore, marketing authorizations may also be granted "under exceptional circumstances" when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to the introduction of specific procedures. This may arise when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This type of marketing authorization is close to a conditional marketing authorization as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a marketing authorization. However, unlike a conditional marketing authorization, the applicant does not have to provide the missing data and will never have to. Although a marketing authorization "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the marketing authorization may be withdrawn where the risk-benefit ratio is no longer favorable.

The competent regulatory authorities in the EU have broad discretion whether to grant such an accelerated assessment, conditional marketing authorization or marketing authorization under exceptional circumstances, and, even if such assessment or authorization is granted, we may not experience a faster development process, review or authorization compared to conventional procedures. Moreover, the removal or threat of removal of such marketing authorizations may create uncertainty or delay in the clinical development of our product candidates and threaten the commercialization prospects of our products and product candidates, if approved. Such an occurrence could materially impact our business, financial condition and results of operations.

We have limited experience obtaining marketing approvals, and we may be unable to successfully do so for any of our current or future product candidates. Failure to successfully complete another pivotal clinical trial or obtain marketing approval in a timely manner for any of our current or future product candidates could have a material adverse impact on our business and financial performance.

Conducting pivotal clinical trials and preparing, and obtaining marketing approval for, a product candidate is a complicated process. As a company, we have only limited experience in obtaining marketing approval for our product candidates. As a result, in the future, obtaining marketing approval for any of our current or future product candidates may require more time and expense than we anticipate. Failure to successfully complete, or delays in, any of our eventual other pivotal trials or related regulatory submissions would prevent us from, or delay us in, obtaining regulatory approval for our current or future product candidates. It is possible that regulatory authorities may refuse to accept for substantive review any regulatory submissions that we submit for our product candidates or may conclude after review of our applications for any of our current or future product candidates that the submissions are insufficient to obtain marketing approval for such product candidates. Regulatory authorities may also require that we conduct additional clinical, preclinical or manufacturing validation trials and submit that data before they will reconsider our applications. Depending on the extent of these or any other required trials, approval or receipt of any marketing authorization may be delayed by several years or may require us to expend more resources than we have available. It is also possible that additional trials, if performed and completed, may not be considered sufficient by regulatory authorities to approve or grant marketing authorizations. Any delay in obtaining, or an inability to obtain, marketing approvals would delay or prevent us from commercializing any of our current or future product candidates, generating additional revenue and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to modify or cease our development efforts for one or more of our product candidates, which could significantly harm our business.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies, such as the EMA following its relocation to Amsterdam and resulting staff changes, may also slow the time necessary for new biologics or modifications to approved biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed inspections at facilities from March 2020 until July 2021. Even though the FDA has since resumed standard inspection operations of domestic facilities, it is nonetheless faced with a significant backlog as a result of its earlier suspension. It is unclear when, if ever, the FDA will fully recover from its COVID-19-related backlog and until such time its operations may be significantly hindered. Further, the FDA has continued to monitor and implement changes to its inspection activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic. Any resurgence of the virus may cause additional postponements, exacerbating the previously discussed risks.

Regulatory authorities outside the United States have adopted similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of such regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Manufacturing and Our Reliance on Third Parties

We contract with third parties for manufacturing our commercial supply of ARCALYST and clinical supply for our product candidates and for certain research and other preclinical development and expect that we will continue to do so in the future. This reliance on third parties increases the risk that we may not have sufficient quantities of ARCALYST or our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our research and development or commercialization efforts.

We do not currently own or operate any late-stage or commercial manufacturing facilities. Although we have built a development and manufacturing facility to produce drug substance to support certain research, preclinical and other clinical development for our product candidates, we rely, and expect to continue to rely, on third parties for the manufacture of our late-stage product candidates and certain early-stage product candidates for the majority of our clinical development efforts, as well as for the commercial manufacture of ARCALYST or any of our current or future product candidates, if approved, as well as label and packaging activities. We rely on these third parties to produce ARCALYST and our product candidates at sufficient quality and quantity to support our commercialization and research and development efforts.

Our reliance increases the risk that we will have insufficient quantities of ARCALYST and our product candidates or that ARCALYST and our product candidates are not produced at an acceptable cost or quality, which could delay, prevent or impair our commercialization or research and development efforts. For example, in the second half of 2021, events were identified in the ARCALYST manufacturing process that prevented distribution of certain

ARCALYST material as previously planned. While we were ultimately able to source sufficient ARCALYST material to cover our current commercial needs, if we encounter events in the future that prevent additional material from being distributed in a timely manner or within specifications and we are unable to source additional commercial supply of ARCALYST, if needed, or should additional manufacturing or supply chain issues arise, we may be unable to adequately meet patient demand for ARCALYST or may be required to effect a recall, any of which would adversely affect our business, results of operations and financial condition. In addition, we may have difficulty sourcing an adequate supply of ARCALYST to cover our commercial and clinical needs, should we decide to develop ARCALYST in one or more additional indications.

Regeneron and its CMOs are the sole manufacturers of ARCALYST, and we have a contract with Regeneron to produce ARCALYST on an exclusive basis, subject to limited exceptions. However, Regeneron is not obligated to accept our forecasts or purchase orders that are not in line with accepted forecasts and Regeneron may not have sufficient manufacturing capacity to meet our commercial or clinical demand for ARCALYST. Regeneron, in turn, relies upon CMOs or other third parties to conduct fill/finish operations for ARCALYST. In the event that a particular batch of ARCALYST fails to meet specifications, whatever the cause, we are nonetheless obligated to pay for such material pursuant to the terms of the Supply Agreement. As a result of our reliance on Regeneron and its CMOs as our sole manufacturers, we do not have control over their manufacturing operations and scheduling, which may impact our ability to meet commercial or clinical demand for ARCALYST. We may also be subject to unexpected costs arising from any manufacturing or supply chain disruptions, which may materially impact our business, results of operations and financial condition.

Under certain circumstances, we or Regeneron could initiate a technology transfer to either us or another CMO to manufacture ARCALYST. Finding new CMOs or third-party suppliers to produce ARCALYST would add additional costs and require significant time and focus from our management and technical teams. We may also not be able to identify a suitable CMO that can meet our manufacturing timeline requirements. Even if we were to find a CMO, such CMO would need to produce ARCALYST at a different manufacturing site, potentially using a different or more costly process, or at a different scale. We cannot provide any assurance that the technology transfer from Regeneron to us or to another CMO will be successful in producing ARCALYST in sufficient quantities or of acceptable quality, if at all, or that we or another CMO will produce a comparable product to the satisfaction of regulatory authorities, which could delay, prevent or impair the further development, if any, or commercialization of ARCALYST. Further, we may be unable to establish a new agreement with another CMO on acceptable terms, if at all. In addition, there is typically a transition period when a new CMO commences work. Failure to produce sufficient quantities of ARCALYST could result in supply shortages for our patients, result in lost revenue and impact our ability to hold sufficient quantities of safety stock to be properly positioned to address unexpected disruptions to the ARCALYST supply chain.

We also have CMOs manufacture vixarelimab drug substance and drug product, entered into an agreement with a CMO to produce mavrilimumab beyond our current inventory and have qualified two CMOs to produce KPL-404 drug product. While we have built a manufacturing facility to support early development for our product candidates, we and our CMOs may not be able to produce sufficient quantities of our product candidates or produce them at an acceptable quality, including as a result of the COVID-19 pandemic, which could delay, prevent or impair our development or commercialization efforts and increase costs.

Our suppliers may also be negatively impacted by the COVID-19 pandemic. See "*Risk Factors — General Risk Factors — The COVID-19 pandemic, and measures taken in response to the pandemic, could have an adverse impact that is significant on our business and operations as well as the business or operations of our manufacturers, CROs and other third parties with whom we conduct business or otherwise engage, including the FDA and other regulatory authorities, and has impacted and could continue to impact the global economy, which may have a material adverse effect on our business, operations and financial position.*"

If we make manufacturing or formulation changes to our products or product candidates or change manufacturers or manufacturing processes, we may be unsuccessful in producing products or product candidates comparable to those used in prior clinical trials. Therefore, we may need to conduct additional process development or additional clinical trials to bridge our prior clinical results to those resulting from the new manufacturing process, which could impact the timing and subsequent success of our planned clinical trials. In addition, as we plan to produce clinical

trial and commercial material at a CMO, the CMO may be required to adopt different manufacturing protocols or processes. For example, although Regeneron has produced ARCALYST for commercial use for over ten years, regulatory authorities may reevaluate ARCALYST's current manufacturing processes or route of administration in connection with evaluating whether to approve ARCALYST for any new indication in the future or in connection with a technology transfer from Regeneron to us or another CMO.

The facilities used by our CMOs to manufacture ARCALYST and our current and future product candidates may be inspected by regulatory authorities in connection with the submission of our marketing applications to, and review by, regulatory authorities or based on their work for other clinical trial sponsors. While we provide oversight of manufacturing activities, we do not and will not control the manufacturing process of, and will be completely dependent on, our CMOs for compliance with cGMPs and other regulatory requirements in connection with the manufacture of ARCALYST and our product candidates. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of regulatory authorities, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. While we review the compliance history and performance of our CMOs and have the ability to audit their compliance and performance, we have no direct control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel other than through quality monitoring in accordance with our agreements with the CMOs. If regulatory authorities do not approve these facilities for the manufacture of our product candidates or if they withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market ARCALYST or our current or future product candidates, if approved. Further, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products or product candidates, if approved, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our products or product candidates.

Our product candidates may also compete with other product candidates and approved products for access to and capacity within manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Furthermore, given the limited number of available manufacturing slots and the long lead times needed to reserve them, manufacturers require monetary commitments in connection with such reservations as well as fees for changes or cancellations in the reserved manufacturing slots. As a result, we may wait to reserve manufacturing slots until we can be informed by data from the clinical trials of our product candidates, which may be several months from the time we request manufacturing slots. Any significant delay in the supply of clinical materials for our product candidates could considerably delay conducting our clinical trials and potential regulatory approval of our product candidates. Alternatively, we may project when we may need additional clinical material for our product candidates and reserve manufacturing time-slots "at-risk" prior to our product candidates having generated data from their then current clinical trials.

In addition, given the lead times we must provide to Regeneron with respect to the commercial supply of ARCALYST, we must place purchase orders based on projected demand, in advance of knowing the market acceptance of ARCALYST for the treatment of recurrent pericarditis. Such projections involve risks and uncertainties. For example, we may be unable to swiftly accommodate for unforeseen increases in commercial demand for ARCALYST given the lead times we must provide to Regeneron and limitations on Regeneron's manufacturing capacity for ARCALYST. These risks may result in additional costs or delays in manufacturing clinical materials for our product candidates when and if we actually need them and commercial materials for ARCALYST and may result in having too little or too much of our product candidates or ARCALYST in inventory to meet actual demand.

Any performance failure on the part of our existing or future manufacturers could delay, as applicable, clinical development or marketing approval or commercialization efforts for ARCALYST and our product candidates, if approved. If our current CMOs cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement. In addition, we may not be able to establish new agreements on acceptable terms, if at all, with such alternative manufacturers. Further, Regeneron has an exclusive right to produce ARCALYST, subject to limited exceptions, which could impact our ability to find a

replacement manufacturer for ARCALYST in a short period of time, if needed. Additionally, establishing a replacement manufacturer for ARCALYST or our product candidates, if required, is unlikely to be accomplished in a timely or cost-effective manner, if at all. Furthermore, despite our efforts, we may be unable to procure a replacement supplier or do so on commercially reasonable terms, which could have a material adverse impact upon our business, results of operations and financial condition. If we or our CMOs are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory approval, which could result in further delay.

Our business involves the use of hazardous materials, and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of ARCALYST or our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' and suppliers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that our safety procedures and the safety procedures utilized by our third-party manufacturers and suppliers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources, and state or federal or other applicable authorities may curtail our use of certain materials or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

Manufacturing or supply issues could cause product shortages, disrupt or delay our clinical trials or regulatory approvals, delay or stop commercialization of our products and product candidates, and adversely affect our business.

The manufacture of ARCALYST and our product candidates is highly regulated, complex and difficult, requiring a multi-step and controlled process, and even minor problems or deviations could result in ARCALYST or our product candidates failing to meet approved specifications, failed batches or other failures, such as defective products or manufacturing failures. We have limited experience overseeing the manufacturing processes of ARCALYST, mavrilimumab, vixarelimab, and KPL-404. Due to the highly technical requirements of manufacturing ARCALYST and our product candidates and the strict quality and control specifications, we and our third-party providers may be unable to manufacture or supply ARCALYST or our product candidates despite our and their efforts. Failure to produce sufficient quantities of our product candidates could delay their development, result in supply shortages for our patients, result in lost revenue, if any, and diminish our potential profitability, as applicable, which may lead to lawsuits or could delay the introduction of our product candidates to the market.

The manufacture of ARCALYST and our product candidates is at high risk of product loss due to contamination, equipment malfunctions, human error or raw material variability or shortages. Deviations from established manufacturing processes could result in reduced production yields, failed batches and other supply disruptions and increased costs. If microbial, viral or other contaminations are discovered in ARCALYST or our product candidates or manufacturing facilities, any related production lot could be lost and the relevant manufacturing facilities may need to close for an extended period of time to investigate and remediate the contaminant. The involvement of our third-party manufacturers, including Regeneron, may exacerbate such effects, which has required and may in the future require us to reject lots for quality control purposes. See "*Risk Factors—We contract with third parties for manufacturing our commercial supply of ARCALYST and clinical supply for our product candidates and for certain research and other preclinical development and expect that we will continue to do so in the future. This reliance on third parties increases the risk that we may not have sufficient quantities of ARCALYST or our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.*"

Many additional factors could cause production interruptions at our facilities or at the facilities of our third-party providers, as well as disruptions in travel, shipping or delivery capabilities into and within the countries in which we or our manufacturers produce ARCALYST or our product candidates or disruptions to production capabilities, including due to the impact of natural disasters, accidents, boycotts, labor disputes, political and economic instability, such as acts of terrorism or war, including the ongoing war in Ukraine, and an epidemic or pandemic or other outbreak of disease, including the COVID-19 pandemic. The occurrence of any such event could adversely affect our ability to satisfy the required supply for any of ARCALYST or our product candidates or successfully complete preclinical and clinical development, which would result in additional costs to us or impair our ability to generate revenue and would harm our business, financial condition and prospects significantly.

Supply chain issues related to important ancillary products may also adversely affect our business. For example, we contract with a network of specialty pharmacies who distribute ARCALYST as well as peripheral supplies that are required to reconstitute and self-administer ARCALYST, such as sterile water for injection, syringes and needles. A delay or shortage in the supply or the distribution of the peripheral supplies required to administer ARCALYST may impact patient access to ARCALYST and could cause us to lose potential revenue, reduce our potential profitability, and damage our reputation.

We also contract with third parties to source specialized placebo for use in our clinical trials which cannot be easily replaced as it must be nearly indistinguishable from our product candidates to ensure proper clinical trial blinding. If we encounter shortages of such placebo, our clinical trials may be substantially delayed unless and until we can source suitable replacements.

In addition, our third-party providers may fail to comply with cGMP and other stringent regulatory requirements related to the manufacturing process. See "*Risk Factors—We contract with third parties for manufacturing our commercial supply of ARCALYST and clinical supply for our product candidates and for certain research and other preclinical development and expect that we will continue to do so in the future. This reliance on third parties increases the risk that we may not have sufficient quantities of ARCALYST or our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts*."

We and our third-party providers are required to maintain compliance with cGMP and other stringent requirements and are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm such compliance. If we or any of our third-party providers are not able to establish and maintain procedures and processes sufficient to satisfy cGMP or similar foreign standards, we could experience a delay, interruption or other issues in our manufacture, fill-finish, packaging, storage or delivery of ARCALYST or our product candidates, and any related failure of the facilities or operations of third parties to pass any regulatory agency inspection could significantly impair our ability to supply our products and product candidates. Significant noncompliance could also result in the imposition of monetary penalties or other civil or criminal sanctions and damage our reputation.

Any adverse developments affecting the operations of our third-party providers, such as any impact due to the COVID-19 pandemic including shortages or reprioritizations of raw materials, reprioritization by third parties or the U.S. government for any products or potential products related to the treatment or prevention of COVID-19, could result in a shortage of commercial products or product candidates, the imposition of additional commercial product requirements by regulatory authorities, the withdrawal of our product candidates or approved products, shipment delays, lot failures or recalls. We may also have to write off inventory and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Such manufacturing issues could increase our cost of goods, cause us to lose potential revenue, reduce our potential profitability or damage our reputation.

The third parties upon whom we rely for the supply of the drug substance and drug product used in ARCALYST and our product candidates are our sole source of supply, and the loss of any of these suppliers could significantly harm our business.

The drug substance and drug product used in ARCALYST, mavrilimumab and vixarelimab are supplied to us from single single-source suppliers and we obtain the drug substance and drug product used in KPL-404 from a limited

number of sources. Regeneron has a contractual right to be our sole source manufacturer of ARCALYST unless they have a persistent failure to satisfy our supply needs. Our ability to continue to commercialize ARCALYST, to develop our product candidates, and to ultimately supply our commercial products in quantities sufficient to meet market demand, depends in part on our ability to obtain the drug substance and drug product for ARCALYST and these product candidates in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. With respect to ARCALYST, mavrilimumab and vixarelimab, we do not currently have arrangements in place for a redundant or second-source supply of any such drug substance and drug product in the event any of our current suppliers of such drug substance and drug product cease their operations or stop offering us sufficient quantities of these materials for any reason. With respect to KPL-404, while we anticipate having more than one source for drug substance and drug product, such sources are nonetheless limited and subject to similar risks as our other products and product candidates.

We are not certain that our single-source suppliers will be able to meet our demand for our products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand on a timely basis in the past, they may subordinate our needs in the future to their other customers.

In addition to manufacturing our products and product candidates in the quantities that we believe would be required to meet anticipated market demand, our third-party manufacturers may need to increase manufacturing capacity and, in some cases, alternative sources of commercial supply may need to be secured, which could involve significant challenges and may require additional regulatory approvals. In addition, the development of commercial-scale manufacturing capabilities may require us and our third-party manufacturers to invest substantial additional funds and hire and retain the technical personnel who have the necessary manufacturing experience. Neither we nor our third-party manufacturers may successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all.

Moreover, our ability to progress our preclinical and clinical programs or successfully commercialize our products could be materially and adversely impacted if any of the third-party suppliers upon which we rely for raw materials and preclinical and clinical stage product candidate and commercial stage product supply were to experience a significant business challenge, disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating to other customers such as regulatory or quality compliance issues, or other financial, legal, regulatory or reputational issues. Additionally, any damage to or destruction of our manufacturing facilities or equipment or those of our third-party manufacturers' or suppliers' facilities or equipment may significantly impair our ability to manufacture our products and product candidates on a timely basis.

Establishing additional or replacement suppliers for the drug substance and drug product used in ARCALYST or our product candidates, if required, is unlikely to be accomplished quickly and can take several years, if at all. Furthermore, despite our efforts, we may be unable to procure a replacement supplier or do so on commercially reasonable terms, which could have a material adverse impact upon our business. If we or our CMOs are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory approval, which could result in further delay. While we and our CMOs may seek to maintain adequate inventory of the drug substance and drug product used in ARCALYST or our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain such drug substance and drug product from alternate sources of comparable quality at acceptable prices in a timely manner could impede, delay, limit or prevent our development or commercialization efforts, which could harm our business, results of operations, financial condition and prospects.

Certain of the materials required in the manufacture and the formulation of our products and product candidates are derived from biological sources. Such materials are difficult to procure and may be subject to contamination or recall. Access to and supply of sufficient quantities of raw materials which meet the technical specifications for the production process is challenging, and often limited to single-source suppliers. Finding an alternative supplier could take a significant amount of time and involve significant expense due to the nature of the products and the need to obtain regulatory approvals. If we or our manufacturers are unable to purchase the materials necessary for the manufacture of ARCALYST or our product candidates on acceptable terms, in a timely manner, at sufficient quality levels, or in

adequate quantities, if at all, our ability to produce sufficient quantities of our products for clinical or commercial requirements would be negatively impacted. A material shortage, contamination, recall or restriction on the use of certain biologically derived substances or any other material used in the manufacture of our products and product candidates could adversely impact or disrupt manufacturing, which would increase costs and impair our ability to generate revenue from the sale of ARCALYST or our product candidates, if approved.

We rely, and expect to continue to rely, on third parties, including independent investigators and CROs, to activate sites, conduct and otherwise support our research activities, preclinical studies, clinical trials and other trials for our product candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates, and our business could be substantially harmed.

We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to activate sites, conduct or otherwise support our preclinical studies and clinical trials for our product candidates properly and on time. We also rely on third parties to conduct other research related to our product candidates. We expect to rely heavily on these parties for such site activation, execution of and otherwise supporting clinical trials for our product candidates. While we have agreements governing their activities and we review the compliance history and performance of our CROs as well as have the ability to audit such activities, we have no direct control over their activities and have limited influence over their actual performance other than through quality monitoring in accordance with our agreements with the CROs. The third parties with whom we contract for execution of our preclinical studies and our clinical trials play a significant role in the conduct of these trials and the subsequent collection and analysis of data. Except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third parties to conduct our preclinical studies and clinical trials in accordance with applicable GLP or GCP requirements, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not and will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our preclinical studies or clinical trials, we could be subject to warning letters or enforcement actions that may include civil penalties and criminal prosecution.

We and our CROs are required to comply with regulations, including GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product candidates produced under cGMPs or similar foreign regulations. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action. We also are required to register certain clinical trials and post the results of completed clinical trials on a government-sponsored database within certain timeframes. Failure to do so when required can result in fines, adverse publicity and civil and criminal sanctions.

Although we have and intend to continue to design the clinical trials for our product candidates, CROs will activate sites and conduct and oversee all of the clinical trials together with the various clinical trial sites that we engage to conduct the studies. As a result, many important aspects of our development programs for our product candidates, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to activate sites and conduct future clinical trials will also result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;

- have disruptions to their business and operations, including as a result of the impact from an epidemic or pandemic disease outbreak, including COVID-19 (see "*Risk Factors — Risks related to product development — The COVID-19 pandemic, and measures taken in response to the pandemic, could have an adverse impact on our current or planned preclinical studies and clinical trials, which could be significant*") or as the result of war, conflict or terrorism as with the ongoing war in Ukraine (see "*Risk Factors – General Risk Factors – The ongoing war in Ukraine, and actions taken against Russia as a result of its invasion of Ukraine, has and may continue to have an adverse impact on the global economy, equity capital markets and our clinical operations*");

- fail to comply with contractual obligations;

- have difficulty controlling the performance of their subcontractors;

- experience regulatory compliance issues;

- undergo changes in priorities or become financially distressed; or

- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to activate sites and conduct and oversee our clinical trials and may subject us to unexpected cost increases that are beyond our control. If the CROs, their subcontractors or the clinical trial sites do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our product candidates may be delayed, we may not be able to obtain regulatory approval and commercialize our product candidates, or our development program may be materially and irreversibly harmed. If we are unable to rely on clinical data collected by our CROs, their subcontractors or the clinical trial sites, we could be required to repeat, extend the duration of or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

Further, if our CROs, their subcontractors or the clinical trial sites fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of our product candidates. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information is misappropriated.

If the third parties conducting our preclinical studies or our clinical trials do not perform their contractual duties or obligations, experience significant business challenges, disruptions or failures, such as due to the impact of the COVID-19 pandemic, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or to GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated. As a result, we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable product candidate, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to develop and manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, invention assignment agreements, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees, independent contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the

rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may harm our business. To the extent that we share trade secrets of third parties that are licensed to us, unauthorized use or disclosure could expose us to liability.

See also, "*Risk Factors – Risks Related to Intellectual Property – If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed.*"

Risks Related to Competition, Executing our Strategy and Managing Growth

We face substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than we do.

The development and commercialization of new drugs and biologics is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell drugs or biologics or are pursuing the development of therapies in the fields in which we are interested. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

We are not aware of any FDA-approved therapies for recurrent pericarditis, but are aware of one program (RPH-104) being developed by R-Pharm International, which inhibits IL-1α/IL-1β-induced signaling and is in Phase 2 development in recurrent pericarditis subjects. Anakinra (KINERET), marketed by Swedish Orphan Biovitrum AB, is currently approved for use in RA, CAPS and DIRA. We are not aware of any active, industry sponsored development programs using anakinra seeking a label for recurrent pericarditis. Canakinumab (ILARIS), marketed by Novartis Pharmaceuticals Corporation, is currently approved for use in CAPS, Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS), Mevalonate Kinase Deficiency (MKD) and Familial Mediterranean Fever (FMF), Still's Disease and Systemic Juvenile Idiopathic Arthritis (SJIA). We are not aware of any active, industry sponsored development programs using canakinumab seeking a label for recurrent pericarditis. Additionally, Novartis is also developing gevokizumab for use in oncologic indications. There are other therapies which modulate IL-1α in preclinical and clinical development for diseases other than recurrent pericarditis from Johnson & Johnson and XBIOTECH USA, INC. We are not aware of any active, industry sponsored development programs for these programs seeking a label for recurrent pericarditis.

There are five other programs in clinical development in various indications that modulate GM-CSF signaling from GlaxoSmithKline plc, or GSK (otilimab), I-MAB Biopharma (plonmarlimab), Roivant Sciences Ltd. (gimsilumab and namilumab) and Humanigen, Inc. (lenzilumab). All of these competitive programs target the GM-CSF ligand itself versus targeting the GM-CSF receptor like mavrilimumab.

We are not aware of any therapies currently approved by the FDA for the treatment of prurigo nodularis, however multiple therapies are in development for prurigo nodularis, and any that receive FDA approval for this indication will be likely competitors to vixarelimab. We are also not aware of any programs in preclinical or clinical development targeting OSMRβ antagonism. Trevi Therapeutics, Inc., is conducting a Phase 2/3 study with their k-opioid antagonist, nalbuphine ER; Galderma SA is conducting a Phase 3 study with their IL-31 specific antagonist nemolizumab; Incyte Corporation is conducting a Phase 2 study with INCB054707, a JAK1 inhibitor; and, Regeneron / Sanofi SA have conducted Phase 3 studies with their IL-4 antagonist dupilumab (Dupixent).

There are various programs in clinical development antagonizing the CD40 / CD154 costimulatory pathway, however KPL-404 is the only program designed to be administered subcutaneously. Certain programs are designed for intravenous administration only. Astellas Pharma Inc. is developing bleselumab (anti-CD40); Horizon Therapeutics plc is developing the Tn3 fusion protein, dazodalibep (anti-CD40L); Biogen, Inc. and UCB S.A. are developing dapirolizumab pegol (anti-CD40L); and, Eledon Pharmaceuticals, Inc. are developing AT-1501 (anti-CD40L). Certain other programs pose the potential for subcutaneous administration. Novartis A.G. is developing CFZ-533, or iscalimab (anti-CD40), Sanofi S.A./ImmuNext Inc. are developing SAR441344 (anti-CD40L), Bristol Myers-Squibb is developing BMS-986325 (anti-CD40); and Abbvie, Inc., Boehringer Ingelheim International GmbH are developing ravagalimab (anti-CD40), and H. Lundbeck A/S is developing Lu AG22515 (anti-CD40L).

Further, the results of clinical trials for our product candidates may produce negative, inconclusive or uncompetitive results compared to those produced by any of these or other companies in the indications we are studying, which may result in us deciding, or regulatory authorities requiring us, to conduct additional clinical trials or modify or cease development programs for our product candidates. We may also determine that the potential product and commercial profile of any of our product candidates may not ultimately be commercially successful or even if they have the potential to ultimately be successful, we may not have sufficient recourses, which in either case could lead us to discontinue its development in certain indications, or we may determine to not support further development of any of our product candidates at any time for any reason.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the effectiveness of companion diagnostics in guiding the use of related products, market acceptance by prescribers and patients, the level of generic competition and the availability of reimbursement from government and other third-party payors.

We may not be successful in executing our growth strategy to identify, discover, develop, in-license or acquire additional product candidates or technologies, and our growth strategy may not deliver the anticipated results or we may refine or otherwise alter our growth strategy. We may seek to acquire businesses or undertake business combinations, collaborations or other strategic transactions which may not be successful or on favorable terms, if at all, and we may not realize the intended benefits of such transactions.

We have acquired or in-licensed our existing product candidates, and as part of our strategy we plan to identify new product candidates or technologies that we believe are complementary to our existing product candidates. We may do this through our internal discovery program, or by acquiring the rights to product candidates and technologies through a variety of transaction types, including in-licensing, strategic transactions, mergers or acquisitions. If we are unable to identify, discover, develop, in-license or otherwise acquire and integrate product candidates, or their related companies, in accordance with this strategy, our ability to pursue this component of our growth strategy would be limited and we may need to refine or otherwise alter this strategy. We cannot be certain that we will be successful in such efforts, and even if we are successful in such efforts, we cannot be certain that such discovery or transaction will be on favorable terms, or that, following any such discovery or transaction, we will be able to realize the intended benefits of it.

Research programs and business development efforts to identify new product candidates and technologies require substantial technical, financial and human resources. We may focus our efforts and resources on potential product candidates, technologies or businesses that ultimately prove to be unsuccessful. In-licensing and acquisitions of product candidates, technology or businesses often require significant payments and expenses and consume additional resources. We will need to continue to devote a substantial amount of time and personnel to research, develop and commercialize any such in-licensed or acquired product candidate or technology, or integrate any new business, and we may decide to reprioritize our efforts even after having expended resources on a particular prospect. Our research programs and business development efforts, including businesses or technology acquisitions, collaborations or licensing attempts, may fail to yield additional complementary or successful product candidates for clinical development and commercialization or successful business combinations for a number of reasons, including, but not limited to, the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates or businesses with a high probability of success for development progression;
- we may not be able or willing to assemble sufficient resources or expertise to in-license, acquire or discover additional product candidates or acquire businesses or undertake business combinations, collaborations, or other strategic transactions;
- we may not be able to agree to acceptable terms with potential licensors or other partners or with respect to business acquisitions; and
- any product candidates or technologies to which we acquire the rights or that we discover may not allow us to leverage our expertise and our development and commercial infrastructure as currently expected.

If any of these events occurs, we may not be successful in executing our growth strategy to identify, discover, develop, in-license or acquire additional product candidates or technologies or to acquire businesses or undertake business combinations, collaborations, or other strategic transactions, or our growth strategy or strategic transactions may not deliver the anticipated results or we may refine or otherwise alter this strategy.

The consummation or performance of any acquisition, business combination, collaboration or other strategic transaction we may undertake in furtherance of our growth strategy or any refined or otherwise altered strategy, may involve additional risks, such as difficulties in assimilating different workplace cultures, retaining personnel and integrating operations, which may be geographically dispersed, increased costs, exposure to liabilities, incurrence of indebtedness, or use a substantial portion of our available cash for all or a portion of the consideration or cause dilution to our existing shareholders if we issue equity securities for all or a portion of the consideration. If any of these events occurs or we are unable to meet our strategic objectives for any such transaction, we may not be able to achieve the expected benefits from the transaction and our business may be materially harmed.

We may seek to enter into collaboration, licensing or other strategic transactions or arrangements to further develop, commercialize or otherwise attempt to realize value from one or more of our product candidates, and any such transactions or arrangements that we may enter into may not be successful or be on favorable terms, which could adversely affect our ability to develop, commercialize or attempt to realize value from our product candidates.

We have entered into and may seek to enter into collaboration, licensing or other strategic transactions or arrangements to further develop, commercialize or otherwise attempt to realize value from one or more of our product candidates instead of developing or commercializing our product candidates ourselves. For example, in February 2022, we granted Huadong exclusive rights to develop and commercialize rilonacept and mavrilimumab in the Asia Pacific region, excluding Japan. In addition, we may seek to jointly develop, commercialize or otherwise exploit one or more of our product candidates with a third party. To the extent that we decide to enter into such transactions or arrangements, we may face significant competition in seeking appropriate collaborators, licensees or other strategic partners. Moreover, these transactions and arrangements are complex and time consuming to negotiate, document, implement and to close or maintain. We may not be successful in our efforts to establish collaborations, licenses or other strategic transactions or

arrangements should we choose to do so. The terms of any such transactions or arrangements that we may establish may have unfavorable tax consequences for our shareholders in the United States. Further, granting territory-specific rights for our products and product candidates may reduce their attractiveness for subsequent business development activity. In addition, our right to grant a sublicense of intellectual property licensed to us under certain of our current agreements requires the consent of the applicable licensor.

Any current or future collaborations, licenses or other strategic transactions or arrangements that we enter into may not be successful. The success of these potential collaboration, license arrangements and other strategic transactions or arrangements may depend heavily on the efforts and activities of our collaborators, sublicensees or other strategic partners. We have experienced collaboration failure in the past and may experience similar failures in the future. Collaborations, licenses or other strategic transactions or arrangements are subject to numerous risks, which may include risks that the collaborator, licensee or other strategic partner, as applicable:

- may have significant discretion in determining the efforts and resources that they will apply;
- may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out its activities;
- may not properly prosecute, maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- may own or co-own intellectual property covering products that results from our arrangement with them, that is not properly prepared, prosecuted, maintained or defended in a way that could impact that patentability of the intellectual property or validity for any granted patent, which could shorten the term during which we are owed royalties on such intellectual property
- may own or co-own intellectual property covering products that results from our arrangement with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property, and even if we are able to license such exclusive rights, we may have to enter into a license agreement that include obligations to make milestone, royalty or other payments under such agreement; and
- may conduct sales and marketing activities or other operations that may not comply with applicable laws, resulting in civil or criminal proceedings.

In addition, disputes may arise with respect to the ownership of any intellectual property developed pursuant to these arrangements. These arrangements may also be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

We need to continue to develop our company and expand our scope of operations, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

We expect to continue to develop our company and expand the scope of our operations. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational and financial systems and infrastructure, expand our facilities over time and continue to recruit and train qualified personnel. Also, our executive and senior management teams have and may continue to divert a disproportionate amount of their attention away from their day-to-day activities and devote a substantial amount of time to managing these development and expansion activities. For example, in January 2021, we implemented select components of a new ERP system that will enable the organization to manage the complexity of operating a commercial organization more efficiently. As with any implementation, this new system will require specific skills and expertise to setup, maintain and utilize the system. We may not be able to develop these skills internally or in sufficient time and capacity, which could require us to expend additional resources to acquire them. Due to our limited resources, certain employees have and may continue to perform activities that are beyond their regular scope of work, and we may not be able to effectively manage the development of

our company, expansion of our operations or recruit and train qualified personnel. This may result in weaknesses of our systems and infrastructure, give rise to managerial, operational and financial mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The development of our company and expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of one or more of our product candidates. If our executive and senior management teams are unable to effectively manage our anticipated development and expansion, our expenses may increase more than expected, our ability to generate revenue could be reduced and we may not be able to implement our business strategy as planned, including with respect to our commercialization of ARCALYST in recurrent pericarditis. Our future financial performance and our ability to commercialize our product candidates, if approved, and to compete effectively will depend, in part, on our ability to effectively manage the future development of our company and expansion of our operations.

Risks Related to Intellectual Property

If we are unable to adequately protect our proprietary technology or obtain and maintain patent protection for our technology and products, if the scope of the patent protection obtained is not sufficiently broad, or if the terms of our patents are insufficient to protect our product candidates for an adequate amount of time, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be materially impaired.

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection in the United States and other countries for our products and product candidates, including ARCALYST, mavrilimumab, vixarelimab, and KPL-404. We seek to protect our proprietary and intellectual property position by, among other methods, filing patent applications in the United States and abroad related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position.

We acquire, in-license and file patent applications directed to our products and product candidates in an effort to establish intellectual property positions directed to their compositions of matter and manufacture as well as uses of these products and product candidates in the treatment of diseases. Our intellectual property includes patents and patent applications that we own as well as patents and patent applications that we in-license. For example, we have a field-specific exclusive license under a license agreement with Regeneron to patent applications and patents relating to ARCALYST, an exclusive license under the MedImmune Agreement to patent applications and patents relating to mavrilimumab, and an exclusive license under our license agreement with Beth Israel Deaconess Medical Center to patent applications and patents related to KPL-404.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We or our licensors have not pursued or maintained, and may not pursue or maintain in the future, patent protection for our products or product candidates in every country or territory in which we may sell our products or product candidates, if approved. In addition, we cannot be sure that any of our pending patent applications or pending trademark applications will issue or that, if issued, they will be in a form that is advantageous to us. The United States Patent and Trademark Office, or the USPTO, international patent offices or judicial bodies may deny or significantly narrow claims made under our patent applications and our issued patents may be successfully challenged, may be designed around or may otherwise be of insufficient scope to provide us with protection for our commercial products. Further, the USPTO, international trademark offices or judicial bodies may deny our trademark applications and, even if published or registered, these trademarks may not effectively protect our brand and goodwill. Like patents, trademarks also may be successfully opposed or challenged.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. The degree of patent protection we require to successfully commercialize our product candidates may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our owned or in licensed patents have, or that any of our owned or in-licensed pending patent applications that mature into issued patents will have, claims with a scope sufficient to protect ARCALYST, mavrilimumab, vixarelimab, KPL-404, or any future products and product candidates. A U.S. patent covering ARCALYST as a composition of matter expired in 2020, and relevant composition of matter patents issued outside of the United States are expected to expire by 2023, not including any patent term extensions. A U.S. patent covering methods of using ARCALYST in the treatment of recurrent pericarditis issued in June 2021 and has a statutory term that expires in 2038, not including any patent term adjustment. The composition of matter patents for mavrilimumab generally have statutory expiration dates in 2027, not including any extensions or adjustments. The issued composition of matter patents for vixarelimab have statutory expiration dates in 2034, not including any extensions. The issued composition of matter patents for KPL-404 have statutory expiration dates in 2036, not including any extensions. The issued composition of matter patents licensed from Beth Israel Deaconess Medical Center related to KPL-404 have statutory expiration dates in 2032, not including any patent term extensions or adjustments. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions and adjustments may be available; however, the life of a patent, and the protection it affords, is limited. The actual protection afforded by a patent varies on a product-by-product basis, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. For example, the applicable regulatory exclusivity period is often triggered by the date a product candidate obtains regulatory approval, and we cannot predict with any certainty whether and if so, when, the applicable product would receive regulatory approval in any given jurisdiction. Furthermore, the type, scope and duration of such exclusivities will vary on a country-by-country basis depending on the jurisdiction in which a product candidate is approved and the particular regulatory exclusivity for which the product is eligible as of the time of approval in such jurisdiction.

Patents may be eligible for limited patent term extension in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. Similar patent extensions exist in the EU and Japan, subject to the applicable laws in those jurisdictions. In most countries, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO, in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier expiring patent. In certain countries, the term of a patent that covers a drug product may also be eligible for patent term extension when regulatory approval is granted, provided the legal requirements are met. We may not receive an extension if we fail to apply within applicable deadlines or fail or are unable to apply prior to expiration of relevant patents. For example, no patent term extension was obtained in the United States following the FDA's approval of ARCALYST for the treatment of CAPS in 2008, and the deadline for applying for such extension has passed. Accordingly, patent term extension in the United States based on the FDA's approval of ARCALYST for CAPS, or any other indication for which the FDA may grant approval in the future, is unavailable. Further, while patent term extension was awarded for relevant patents in certain European countries following the EMA's approval of ARCALYST for the treatment of CAPS, in 2012 the marketing authorization for CAPs was withdrawn. Patent term extensions may no longer be in effect or available, subject to the applicable laws in those countries as well as other factors, such as whether a marketing approval for ARCALYST is reissued and whether such reissuance is prior to the expiration of the patent's natural 20-year patent term. Moreover, the length of the extension could be less than we request. In addition, the laws of other countries may not protect our rights to the same extent as the laws of the United States. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner, impacting our revenue.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized, thereby limiting protection such patent would afford the respective product and any competitive advantage such patent may provide. In some cases, an in-licensed patent portfolio may have undergone a considerable loss of patent term prior

to our initiation of development and commercialization of the product or product candidate. For example, the patents in the United States covering ARCALYST as a composition of matter have expired, and patents covering ARCALYST as a composition of matter in Europe have a term that expires in 2023, not including any patent term extensions, and the patents covering mavrilimumab as a composition of matter have a term that expires in 2027 in the United States, not including any patent term adjustments (an adjustment to the term of a U.S. patent to compensate the patentee for delays caused by the USPTO during the examination process) or patent term extensions, and in 2027 in Europe, not including any patent term extensions. We may not receive any patent term extension for patents covering mavrilimumab as a composition of matter if such patent in an applicable jurisdiction expires before mavrilimumab would be eligible to receive regulatory approval in such jurisdiction. As a result, our owned and in-licensed patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar or identical to our product candidates. In such cases, we expect to rely on regulatory exclusivity for our product candidates. The expiration date of regulatory exclusivity is determined on a country-by country-basis if the applicable product is approved in such country and if any applicable regulatory exclusivity applies and is granted. The actual expiration date of any such regulatory exclusivity, however, is subject to significant uncertainty. For instance, the applicable regulatory exclusivity period is often triggered by the date a product candidate obtains regulatory approval, and we cannot predict with any certainty whether and if so, when, the applicable product would receive regulatory approval in any given jurisdiction. Furthermore, the type, scope and duration of such exclusivities will vary on a country-by-country basis depending on the jurisdictions in which a product candidate is approved and the particular regulatory exclusivity for which the product is eligible as of the time of approval.

Other parties may have developed or may develop technologies that may be related or competitive to our own, and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our patent applications or issued patents, with respect to either the same methods or formulations or the same subject matter, in either case, that we may rely upon to dominate our patent position in the market. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights cannot be predicted with any certainty.

In addition, the patent prosecution process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO is often significantly narrowed by the time they issue, if at all. The claims of our issued patents or patent applications when issued may not cover our product candidates, proposed commercial technologies or the future products that we develop, or even if such patents provide coverage, the coverage obtained may not provide any competitive advantage. Further, it is possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we in-license from, or out-license to, third parties. Therefore, these patents and applications may not be prepared, prosecuted, enforced or maintained in a manner consistent with the best interests of our business. In the case of our field-limited license from Regeneron, another licensee may have the right to enforce patents covering the product in their field. As a result, we may need to coordinate prosecution, enforcement or maintenance with another party, and the other party could prosecute, enforce or maintain the patents in a manner adverse to our interests or otherwise put the patents at risk of invalidation.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or license may fail to result in issued patents in the United States or in other countries. Even if we acquire patent protection that we expect should enable us to maintain a competitive advantage, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. The issuance of a patent is not conclusive as to its inventorship, scope, validity, enforceability or term, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third-party submission of prior art to the USPTO challenging the priority of an invention claimed within one of our patents, which submissions may also be

made prior to a patent's issuance, precluding the granting of any of our pending patent applications. We may become involved in contested proceedings challenging our patent rights or the patent rights of others from whom we have obtained licenses to such rights. For example, patents granted by the USPTO may be subject to third-party challenges such as (without limitation) derivation, re-examination, interference, post-grant review or *inter partes* review proceedings, and patents granted by the European Patent Office may be challenged by any person in an opposition proceeding within nine months from the publication of the grant. Similar proceedings are available in other jurisdictions, and in some jurisdictions third parties can raise questions of validity with a patent office even before a patent has granted. Competitors may claim that they invented the inventions claimed in our issued patents or patent applications prior to us, or may file patent applications before we do. In such case, we may have to participate in interference or derivation proceedings in the USPTO, to determine which party is entitled to a patent on the disputed invention. We may also become involved in similar opposition proceedings in the European Patent Office or similar offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology.

Such proceedings can be expensive, time consuming and may divert the efforts of our technical and managerial personnel, which could in turn harm our business, whether or not we receive a determination favorable to us. We may not be able to correctly estimate or control our future operating expenses in relation to such proceedings, which could affect operating expenses. Our operating expenses may fluctuate significantly in the future as a result of a variety of factors, including the costs of such proceedings.

Since patent applications are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to our product candidates. Competitors may also contest our patents, if issued, by showing the patent examiner that the invention was not original, was not novel or was obvious. In litigation, a competitor could claim that our patents, if issued, are not valid or enforceable for a number of reasons. If a court agrees, rights to those challenged patents may be diminished or lost.

In addition, we may in the future be subject to claims by our or our licensors' former employees or consultants asserting an ownership right in our patents or patent applications as a result of the work they performed on our or their behalf, respectively. Although we generally require all of our employees and consultants and any other partners or collaborators who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we or our licensors have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy.

An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, without payment to us, or could limit the duration of the patent protection covering our technology and product candidates. Such challenges may also result in our inability to manufacture or commercialize our product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if they are unchallenged, our issued patents and our pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. For example, a third party may develop a competitive drug that provides benefits similar to one or more of our product candidates but that has a different composition that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, or if the breadth, strength or term (including any extensions or adjustments) of protection provided by the patents and patent applications we hold or pursue with respect to our product candidates or any future product candidates is successfully challenged, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business. Further, if we

encounter delays in our clinical trials, the period of time during which we could market our product candidates or any future product candidates under patent protection would be reduced.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. If we breach any of the agreements related to our product candidates, we could lose the ability to continue the development and commercialization of the related product. Additionally, our current licensing and acquisition agreements contain limitations and restrictions that could limit or adversely affect our ability to develop and commercialize other products in the future.

We entered into agreements to acquire the rights to develop and commercialize ARCALYST and our product candidates, mavrilimumab, vixarelimab and KPL-404. In September 2017, we entered into a license agreement with Regeneron to obtain an exclusive license under certain intellectual property rights controlled by Regeneron to develop and commercialize ARCALYST. In December 2017, we entered into the MedImmune Agreement to obtain exclusive worldwide rights to research, develop, manufacture, market and sell mavrilimumab and any other products covered by the licensed patent rights. In September 2016, pursuant to the Biogen Agreement, we acquired all of Biogen's right, title and interest in and to certain assets used in or relating to vixarelimab, including patents and other intellectual property rights, clinical data, know-how and inventory. In connection with our acquisition of Primatope in March 2019, we acquired an exclusive world-wide license with Beth Israel Deaconess Medical Center for certain patent applications and patents related to KPL-404. Each of these agreements requires us to use commercially reasonable efforts to develop and commercialize the related product candidates, make timely milestone and other payments, provide certain information regarding our activities with respect to such product candidates and indemnify the other party with respect to our development and commercialization activities under the terms of the agreements. These agreements and any future such agreements that we enter into impose a variety of obligations and related consequences.

We are a party to license and acquisition agreements of importance to our business and to our current product candidates, and we expect to be subject to additional such agreements in the future. Disputes may arise between us and any of these counterparties regarding intellectual property subject to and each parties' obligations under such agreements, including:

- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the scope of rights granted under the agreement and other interpretation-related issues;
- our obligations to make milestone, royalty or other payments under those agreements;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the agreement;
- our right to sublicense patent and other rights to third parties;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners;
- our right to transfer or assign the license; and
- the effects of termination.

These or other disputes over our obligations or intellectual property that we have licensed or acquired may prevent or impair our ability to maintain our current arrangements on acceptable terms, or may impair the value of the arrangement to us. Any such dispute could have an adverse effect on our business.

If we fail to meet our obligations under these agreements in a material respect, the respective licensor/seller would have the right to terminate the respective agreement and upon the effective date of such termination, have the right to re-obtain the related technology as well as aspects of any intellectual property controlled by us and developed during the period the agreement was in force that relate to the applicable technology. This means that the licensor/seller to each of these agreements could effectively take control of the development and commercialization of our product candidates after an uncured, material breach of the agreement by us. This would also be the case if we voluntarily elected to terminate the relevant agreement, which we have the right to do under each of these agreements. While we would expect to exercise our rights and remedies available to us in the event we fail to meet our obligations under these agreements in any material respect, including seeking to cure any breach by us, and otherwise seek to preserve our rights under the technology licensed to or acquired by us, we may not be able to do so in a timely manner, at an acceptable cost or at all. Any uncured, material breach under the license could result in our loss of exclusive rights and may lead to a complete termination of our product development and any commercialization efforts for each of our product candidates. Termination of one of these agreements for any reason, and the related discontinuation of the development or commercialization of a product candidate could impair our ability to raise additional capital, generate revenue and may significantly harm our business, financial condition and prospects.

The FDA approved ARCALYST for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children 12 years of age and older in March 2021. Upon receipt of this approval, we assumed the sales and distribution of ARCALYST for the previously approved indications in the United States. We evenly split profits on ARCALYST sales with Regeneron. Regeneron retains worldwide rights to develop and commercialize ARCALYST for local administration to the eye and ear and oncology. Additionally, Regeneron retains the right to develop and commercialize ARCALYST for all applications in the Middle East and North Africa. The development of ARCALYST in other fields could increase the possibility of identification of adverse safety results that impact the commercialization of ARCALYST for the treatment of recurrent pericarditis.

Certain of our agreements may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, under the Regeneron Agreement, Regeneron has a right of first negotiation over the assignment or sale of our rights to any product we develop under the Regeneron Agreement to third parties and we must obtain Regeneron's prior consent to assign or sublicense our rights under such agreement to a third party. Under the MedImmune Agreement, we cannot sublicense the rights licensed or sublicensed to us without the consent of MedImmune and certain applicable third-party licensors, if required by agreements between MedImmune and such third-party licensors. Under the Biogen Agreement, Biogen has a right of first negotiation under certain circumstances to purchase the assets we acquired from Biogen or to obtain a license to exploit the applicable products. This right of first negotiation remains in effect until the earlier of 12 years from the date of the agreement or the first commercial sale of a product under the agreement, and applies to a variety of transactions, including licensing transactions and the sale of our company. In addition, under the Biogen Agreement, we are subject to an exclusivity obligation, pursuant to which we may not conduct any activity alone or through a third party related to a product that modulates the oncostatin M receptor (other than for the development and commercialization of products that are the subject of the Biogen Agreement). This exclusivity obligation runs from the earlier of the eighth anniversary of the agreement or the first commercial sale of a product that is the subject of the Biogen Agreement.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our products and product candidates, if approved, and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and frequent litigation regarding patents and other intellectual property rights. We cannot assure you that our products, product candidates or any future product candidates, including methods of making or using these product candidates, will not infringe existing or future third-party patents. We may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our products and product candidates and technology, including contested proceedings before the USPTO. Our competitors or other third parties may assert infringement claims against us, alleging that our products are covered by their patents.

Given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. Many companies have filed, and continue to file, patent applications related to immunomodulation. Some of these patent applications have already been allowed or issued, and others may issue in the future. For example, we are aware of third-party patents that contain claims potentially relevant to mavrilimumab, vixarelimab and KPL-404. If the claims of any of these patents are asserted against us, we do not believe our proposed activities related to mavrilimumab, vixarelimab and KPL-404 would be found to infringe any valid claim of these patents. While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent. If we were to challenge the validity of any issued U.S. patent in court, we would need to overcome a statutory presumption of validity that attaches to every U.S. patent. This means that in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. In order to avoid infringing these or any other third-party patents, we may find it necessary or prudent to obtain licenses to such patents from such third-party intellectual property holders. However, we may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use processes or other intellectual property rights from third parties that we identify as necessary for our current or future product candidates. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may also pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property or maintain the existing intellectual property rights we have, we may have to cease development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Since our product candidates are being developed for use in fields that are competitive and of strong interest to pharmaceutical and biotechnology companies, we will likely seek to file additional patent applications and may have additional patents granted in the future, based on our future research and development efforts. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications of third-parties now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. Regardless of when filed, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third-party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes our product candidate infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product candidate that is the subject of the actual or threatened suit.

If we are found to infringe a third-party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our product candidates and technology. Under any such license, we would most likely be required to pay various types of fees, milestones, royalties or other amounts. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non-exclusive terms, thereby providing our competitors and other third parties access to the same technologies licensed to us. Without such a license, we could be forced, including by court order, to cease developing and commercializing the infringing technology or product candidate, or forced to redesign it, or to cease some aspect of our business operations. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed such third-party patent rights. We may be required to indemnify collaborators or contractors against such claims. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Even if we are successful in defending against such claims, litigation can be expensive and time consuming and would divert management's attention from our core business. Any of these events could harm our business significantly.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights.

Competitors and other third parties may infringe, misappropriate or otherwise violate our patents and other intellectual property rights, whether owned or in-licensed. To counter infringement or unauthorized use, we or our current or future collaborators may be required to file infringement claims against these infringers. A court may disagree with our allegations, however, and may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the third-party technology in question. Further, such third parties could counterclaim that we infringe their intellectual property or that a patent we have asserted against them is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims challenging the infringement, validity, enforceability or scope of asserted patents are commonplace. In addition, third parties may initiate legal proceedings against us to assert such challenges to our intellectual property rights. The outcome of any such proceeding is generally unpredictable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, or foreign equivalents thereof. Patents may be unenforceable if someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. It is possible that prior art of which we or our licensors and the patent examiner were unaware during prosecution exists, which could render our patents invalid. Moreover, it is also possible that prior art may exist that we are aware of but do not believe is relevant to our current or future patents, but that could nevertheless be determined to render our patents invalid or unenforceable.

Some of our competitors may be able to devote significantly more resources to intellectual property litigation, and may have significantly broader patent portfolios to assert against us if we assert our rights against them. Further, because of the substantial discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be disclosed or otherwise compromised during litigation.

An adverse result in any litigation proceeding could put one or more of our patents, whether owned or in-licensed, at risk of being invalidated or interpreted narrowly. If a defendant were to prevail on a legal assertion of invalidity or unenforceability of our patents covering one of our product candidates, we would lose at least part, and perhaps all, of the patent protection covering such product candidate. Competing products may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a patent lawsuit outside of the United States, alleging our infringement of a competitor’s patents, we could be prevented from marketing our products in one or more such countries. Any of these outcomes would have a materially adverse effect on our business.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our Class A common shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various governmental patent agencies outside of the United States require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and patent agencies outside of the United States over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we, our licensors or our licensees fail to maintain the patents and patent applications covering our products or technologies, we may not be able to stop a competitor from marketing products that are the same as or similar to our product candidates, which would have a material adverse effect on our business. In addition, if we or our licensees fail to apply for applicable patent term extensions or adjustments, we will have a more limited time during which we can enforce our granted patents, or receive royalties from a licensee. In addition, if we are responsible for patent prosecution and maintenance of patent rights in-licensed to us, any of the foregoing could expose us to liability to the applicable patent owner.

We may not be able to effectively enforce our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly in developing countries. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in intellectual property laws outside of the United States. In addition, the patent laws of some such countries do not afford intellectual property protection to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain jurisdictions outside of the United States. Varying filing dates in international countries may also permit intervening third parties to allege priority to patent applications claiming certain technology. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many countries outside of the United States have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against certain parties, including government agencies or government contractors. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our or our licensees' technologies in jurisdictions where we have not obtained patent protection, or where we have obtained patent protection, but such jurisdictions do not favor the enforcement of patents and other intellectual property rights, to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Proceedings to enforce our patent rights, whether owned or in-licensed, in jurisdictions outside of the United States, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to pursue protection for our intellectual property rights in the major markets for our product candidates, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and other countries may affect our ability to obtain and enforce adequate intellectual property protection for our technology.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or Leahy-Smith Act, signed into law on September 16, 2011, contribute to those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that have affected the way patent applications are prosecuted, and have redefined prior art and provided more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a first-to-file system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that has filed a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This requires us to be cognizant of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (1) file any patent application related to our product candidates or (2) invent any of the inventions claimed in our patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license.

Among some of the other changes introduced by the Leahy-Smith Act are changes that (i) affect the way patent applications are prosecuted, (ii) redefine prior art, and (iii) provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include changes that limit where a patentee may file a patent infringement suit and provide new opportunities for third parties to challenge issued patents in the USPTO. We may be subject to the risk of third-party prior art submissions on pending applications or become a party to opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patents. There is a lower standard of evidence necessary to invalidate a patent claim in a USPTO proceeding relative to the standard in U.S. district or federal court. This could lead third parties to challenge and successfully invalidate our patents that would not otherwise be invalidated if challenged through the court system. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation increase the uncertainties and costs surrounding the prosecution of our or our future licensors' patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain or maintain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents; enforce or shorten the term of our existing patents and patents that we might obtain in the future; shorten the term that has been lengthened by patent term adjustment of our existing patents or patents that we might obtain in the future; or challenge the validity or enforceability of our patents that may be asserted against us by our competitors or other third parties. Any of these outcomes could have a material adverse effect on our business.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed.

In addition to the protection afforded by patents, we may rely upon unpatented trade secret protection, unpatented know-how and continuing technological innovation to develop and maintain our competitive position. Although we seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our collaborators, scientific advisors, contractors, employees, independent contractors and consultants, and invention assignment agreements with our independent contractors, consultants, scientific advisors and employees, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation (e.g., in countries that do not favor the enforcement of intellectual property rights), and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

We cannot be certain that the steps we have taken will prevent unauthorized use or unauthorized reverse engineering of our technology. Monitoring unauthorized use of our intellectual property is difficult and costly. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. The steps we have taken to protect our proprietary rights may not be adequate to prevent misappropriation of our intellectual property.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached. Detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. We may in the future rely on trade secret protection, which would be subject to the risks identified above with respect to confidential information.

Our trade secrets could otherwise become known or be independently discovered by our competitors. Competitors could purchase our product candidates and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If our trade secrets are not adequately protected so as to protect our market against competitors' products, our competitive position could be adversely affected, as could our business.

See also "*Risk Factors – Risks Related to Manufacturing and Our Reliance on Third Parties – Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed*."

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names in the United States or jurisdictions outside of the United States, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

We have not yet registered trademarks for a commercial trade name for our product candidates in the United States or jurisdictions outside of the United States and failure to secure such registrations could adversely affect our business.

We have not yet registered trademarks for a commercial trade name for some of our product candidates in the United States or any jurisdiction outside of the United States. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many jurisdictions outside of the United States, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Moreover, any name we propose to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

General Risk Factors

The ongoing war in Ukraine, and actions taken against Russia as a result of its invasion of Ukraine, has and may continue to have an adverse impact on the global economy, equity capital markets and our clinical operations.

In February 2022, Russia invaded Ukraine to the condemnation of the international community. Although the length, impact and outcome of the ongoing military conflict in Ukraine is highly unpredictable, this conflict could lead to significant market and other disruptions, including significant volatility in commodity prices and supply of energy resources, instability in financial markets, supply chain interruptions, political and social instability, changes in consumer or purchaser preferences as well as increases in cyberattacks and espionage. In response to Russia’s invasion and perpetration of war crimes, western nations, including the United States and the EU, instated severe economic sanctions against Russia, including the suspension of Russian banks from the global SWIFT system, travel bans, personal sanctions against the Russian elite and boycotts of Russian goods and commodities. Private organizations responded similarly, with many companies choosing to suspend their Russian operations or end them entirely.

The situation is rapidly evolving, and the United States, the EU, the UK and other countries may implement additional sanctions, export controls or other measures against Russia, Belarus and other countries, regions, officials, individuals or industries in the respective territories. Such sanctions and other measures, as well as the existing and potential further responses from Russia or other countries to such sanctions, tensions and military actions, could adversely affect the global economy and financial markets and could adversely affect our business, operations and financial position. The prices of certain commodities have and will likely continue to increase in the wake of the conflict.

U.S. capital markets have seen significant volatility as a result of the conflict. The war may also pose risks to global supply chains, further threatening the global and U.S. economy. The price of our shares and the shares of other biopharmaceutical companies may fluctuate or otherwise be impacted, especially if the war or governmental responses thereto result in a prolonged economic downturn. As a result of such disruptions, we may be unable to raise additional capital when needed or on acceptable terms, if at all. These risks may also be compounded with the effects of the COVID-19 pandemic, and measures taken in response to the pandemic, on U.S. and global capital markets. See "*Risk Factors – General Risk Factors – The COVID-19 pandemic, and measures taken in response to the pandemic, could have an adverse impact that is significant on our business and operations as well as the business or operations of our manufacturers, CROs and other third parties with whom we conduct business or otherwise engage, including the FDA and other regulatory authorities, and has impacted and could continue to impact the global economy, which may have a material adverse effect on our business, operations and financial position.*"

The conflict in Ukraine has and may continue to adversely affect our clinical development efforts. We conduct clinical trials at sites across the globe, including in Eastern Europe. In the aftermath of the invasion we terminated planned clinical trial operations in Ukraine and Russia. While we anticipate being able to secure alternative clinical trial sites in Western Europe, there is no guarantee that such sites will be able to provide a sufficient number of patients to satisfy our clinical need and at a reasonable cost. Further, should the conflict escalate beyond Ukraine, we may need to take further actions. In such an instance, we may be unable to secure alternative clinical sites when needed or on acceptable terms, if at all. The foregoing may cause significant delays or disruptions to our clinical development efforts, which could have a material impact on our business, operations and financial position.

Furthermore, due to the political uncertainty involving Russia and Ukraine, there is also an increased likelihood that we or our CROs or other third parties with whom we conduct business or otherwise engage, may also be subject to retaliatory cyberattacks perpetrated by Russia or others at its direction in response to economic sanctions and other actions taken against Russia as a result of its invasion of Ukraine. See "*Risk Factors – General Risk Factors – Our information technology systems, or those of our third party CMOs, CROs or other contractors, consultants and service providers, may fail or suffer cyberattacks or security breaches, which could result in a material disruption of our or such third-party's business or operations and our development programs for our product candidates or loss of other assets, including funds*."

The COVID-19 pandemic, and measures taken in response to the pandemic, could have an adverse impact that is significant on our business and operations as well as the business or operations of our manufacturers, CROs and other third parties with whom we conduct business or otherwise engage, including the FDA and other regulatory authorities, and has impacted and could continue to impact the global economy, which may have a material adverse effect on our business, operations and financial position.

The COVID-19 pandemic, and measures taken in response to the pandemic, could cause significant disruption in our business and operations and could cause significant disruption in the business and operations of our manufacturers, CROs upon whom we rely to conduct our clinical trials, clinical trial sites, and other third parties with whom we conduct business or otherwise engage, including the FDA and other regulatory authorities.

The federal and state governments in the United States and the governments of other countries around the globe have implemented various measures in response to the COVID-19 pandemic, including significant restrictions on businesses as well as travel into and within the countries in which our manufacturers produce our product candidates or where we conduct our clinical trials or otherwise conduct business or engage with other third parties. And while certain of such restrictive measures have since been loosened or repealed following the widespread distribution of COVID-19 vaccines and the reduction in global cases in mid-2021, the loosening of such restrictions have been and may in the future be subject to abrupt reversal in the presence of new variants of COVID-19, including the Delta and Omicron variants, which may lengthen or exacerbate the pandemic's effect on our business, financial condition and results of operations. In addition, government restrictions and policies remain unpredictable and varied across jurisdictions, introducing significant uncertainty and compliance difficulty.

If the COVID-19 pandemic is prolonged, including through the emergence of new variants of the virus, and measures undertaken in response to the pandemic are reinstated, , we may experience and our manufacturers, CROs or

other third parties with whom we conduct business or otherwise engage, may experience or continue to experience staffing shortages or reprioritizations, production slowdowns or stoppages, and disruptions in delivery systems now or in the future. For example, the COVID-19 pandemic and measures taken in response to the pandemic, including business and travel restrictions and social distancing to halt the spread of the pandemic, has had an impact on certain aspects of our commercialization strategy, including interacting with third-party payors, prescribers and patient advocacy groups to build disease awareness, and conducting in-person market research as well as recruiting qualified candidates to enhance our commercial operations and support commercialization, which, if prolonged, may impede the effective commercialization of our products and product candidates, if approved, and result in lower than anticipated future revenue.

In response to the COVID-19 pandemic and measures introduced by state and federal governments in the United States, we implemented workplace protocols at our facilities. We have required all employees entering our workplaces in the United States to be fully vaccinated against COVID-19, subject to a reasonable accommodation process. We have also established additional safety measures at our facilities, including providing and requiring the use of personal protective equipment, testing prior to returning to the office after an exposure and/or onset of symptoms, enforcing occupancy limits, and implementing enhanced contact tracing tools. These safety measures do not, however, guarantee that COVID-19 will not spread amongst our employees through workplace contact, and the sickness of employees may have a significant adverse impact on our business. We continue to monitor the developments, restrictions and requirements in jurisdictions where we have offices, and plan to update the protocols for our offices as applicable.

The COVID-19 pandemic may also have a significant adverse impact on our preclinical studies and clinical trials, which could significantly impede, delay, limit or prevent the clinical development of our product candidates and ultimately lead to the delay or denial of regulatory approval of our product candidates, which would materially adversely affect our business and operations, including our ability to generate revenue. See "*Risk Factors — Risks related to product development — The COVID-19 pandemic, and measures taken in response to the pandemic, could have an adverse impact on our current or planned preclinical studies and clinical trials, which could be significant.*"

Further, the COVID-19 pandemic may impact our ability to successfully commercialize ARCALYST and our current and future product candidates, if approved. The COVID-19 pandemic and measures taken in response to the pandemic, including business and travel restrictions and social distancing to halt the spread of the pandemic, has had an impact on businesses, healthcare systems, regulatory authorities and other organizations and conferences. These measures may result in limitations on certain aspects of our commercialization strategy, including our specialty cardiology salesforce having limited, or zero, access to prescriber offices and other high-volume accounts in person, which if prolonged, may impede the effective commercialization of ARCALYST and result in lower than anticipated future revenue.

As a result of the COVID-19 pandemic, existing and any new third party CMOs or suppliers may be unable to produce or supply our current or future products and product candidates or obtain certain raw or fill-finish materials, including vials and stoppers, needed to produce or supply such products and product candidates. Such parties may also experience delays, restrictions or limitations in the production, delivery or release of our products and product candidates or the raw or fill-finish materials needed to produce them, including due to disruptions at their respective facilities, staffing shortages, production slowdowns, stoppages or reprioritizations, including as a result of reprioritization by third parties or the U.S. government for any products or potential products related to the treatment or prevention of COVID-19, or interruptions in global shipping. Any failure to source sufficient quantities of our products and product candidates could prevent us from successfully commercializing our approved products and/or delay or force us to cancel our clinical activity.

Moreover, the COVID-19 pandemic is impacting the global economy, and the U.S. economy in particular, with the potential for an economic downturn to be severe and prolonged. A severe or prolonged economic downturn could result in a variety of risks to our business, including disruptions in the financial markets. For example, the trading prices of biopharmaceutical companies have been and continue to be highly volatile as a result of the COVID-19 pandemic's effect on capital markets. These disruptions could adversely impact our ability to raise additional capital when needed or on acceptable terms, if at all.

The United Kingdom's withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business.

Following a national referendum and enactment of legislation by the government of the UK, the UK formally withdrew from the EU and ratified a trade and cooperation agreement governing its future relationship with the EU , referred to as Brexit. The agreement, which was being applied provisionally from January 1, 2021 and entered into force on May 1, 2021, addresses trade, economic arrangements, law enforcement, judicial cooperation and a governance framework including procedures for dispute resolution, among other things. Because the agreement merely sets forth a framework in many respects and will require complex additional bilateral negotiations between the UK and the EU as both parties continue to work on the rules for implementation, significant political and economic uncertainty remains about how the precise terms of the relationship between the parties will differ from the terms before withdrawal.

Since January 1, 2021, however the UK operates under a distinct regulatory regime to the EU. EU pharmaceutical laws only apply in respect of the UK to Northern Ireland (as set out in the Protocol on Ireland/Northern Ireland). EU laws which have been transposed into UK law through secondary legislation continue to be applicable as "retained EU law". While the UK has indicated a general intention that new laws regarding the development, manufacture and commercialization of medicinal products in the UK will align closely with EU law, there are limited detailed proposals for future regulation of medicinal products. The trade and cooperation agreement includes specific provisions concerning medicinal products, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued (such mutual recognition can be rejected by either party in certain circumstances), but does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations. For example, it is not clear to what extent the UK will adopt legislation aligned with, or similar to, the EU CTR which became applicable on January 31, 2022 and which significantly reforms the assessment and supervision processes for clinical trials throughout the EU. On January 17, 2022, the Medicines and Healthcare products Regulatory Agency, or MHRA, launched an eight-week consultation on reframing the UK legislation for clinical trials. The consultation closed on March 14, 2022 and aims to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The outcome of the consultation will be closely watched and will determine whether the UK chooses to align with the regulation or diverge from it to maintain regulatory flexibility. A decision by the UK not to closely align its regulations with the new approach that will be adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries and/or make it harder to seek a marketing authorization in the EU for our product candidates on the basis of clinical trials conducted in the UK.

Therefore, there remains political and economic uncertainty regarding to what extent the regulation of medicinal products will differ between the UK and the EU in the future. Any divergences will increase the cost and complexity of running our business, including with respect to the conduct of clinical trials. Brexit also materially impacted the regulatory regime with respect to the approval of our product candidates. Great Britain is no longer covered by the EU's procedures for the grant of marketing authorizations (Northern Ireland is covered by the centralized authorization procedure and can be covered under the decentralized or mutual recognition procedures). As of January 1, 2021, all existing centralized marketing authorizations were automatically converted into UK marketing authorizations effective in Great Britain and issued with a United Kingdom marketing authorization number on January 1, 2021 (unless marketing authorization holders opted out of this scheme). A separate marketing authorization is now required to market drugs in Great Britain. It is currently unclear whether the regulator in the UK, the MHRA is sufficiently prepared to handle the increased volume of marketing authorization applications that it is likely to receive. The UK's withdrawal from the EU and the associated uncertainty has had and may continue to have a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Asset valuations, currency exchange rates and credit ratings may be especially subject to increased market volatility. Any of these factors could have a significant adverse effect on our business, financial condition, results of operations and prospects.

Further, the UK's withdrawal from the EU has resulted in the relocation of the EMA from the UK to the Netherlands. This relocation has caused, and may continue to cause, disruption in the administrative and medical scientific links between the EMA and the MHRA, including delays in granting clinical trial authorization or marketing authorization,

disruption of importation and export of active substance and other components of new drug formulations, and disruption of the supply chain for clinical trial product and final authorized formulations. The cumulative effects of the disruption to the regulatory framework may add considerably to the development lead time to marketing authorization and commercialization of products in the EU and/or the UK.

Such a situation could hinder our ability to conduct current and planned clinical trials and commercialize our products and product candidates, if approved, including ARCALYST, adversely affecting our business, financial condition and results of operations. Additionally, political instability in the EU as a result of Brexit may result in a material negative effect on credit markets and foreign direct investments in the EU and UK.

These developments, or the perception that any related developments could occur, have had and may continue to have a material adverse effect on global economic conditions and the financial markets, and may significantly reduce global market liquidity, restrict the ability of key market participants to operate in certain financial markets or restrict our access to capital. Any of these factors could have a material adverse effect on our business, financial condition and results of operations and reduce the price of our shares.

If we fail to comply with reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in governmental programs that impose extensive drug price reporting and payment obligations on pharmaceutical manufacturers. Medicaid is a joint federal and state program that is administered by the states for low-income and disabled beneficiaries. Under the MDRP, as a condition of federal funds being made available for our covered outpatient drugs under Medicaid and certain drugs or biologicals under Medicare Part B, we pay a rebate to state Medicaid programs for each unit of our covered outpatient drugs dispensed to a Medicaid beneficiary and paid for by the state Medicaid program. Medicaid rebates are based on pricing data that we report on a monthly and quarterly basis to CMS, the federal agency that administers the MDRP and Medicare programs. For the MDRP, these data include the AMP for each drug and, in the case of innovator products, best price. If we become aware that our MDRP price reporting submission for a prior period was incorrect or has changed as a result of recalculation of the pricing data, we must resubmit the corrected data for up to three years after those data originally were due. If we fail to provide information timely or are found to have knowingly submitted false information to the government, we may be subject to civil monetary penalties and other sanctions, including termination from the MDRP, in which case payment would not be available for our covered outpatient drugs under Medicaid or, if applicable, Medicare Part B.

Federal law requires that any company that participates in the MDRP also participate in the 340B program in order for federal funds to be available for the manufacturer’s drugs under Medicaid and Medicare Part B. The 340B program is administered by HRSA and requires us, as a participating manufacturer, to agree to charge statutorily defined covered entities no more than the 340B “ceiling price” for our covered drugs used in an outpatient setting. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. A drug that is designated for a rare disease or condition by the Secretary of Health and Human Services is not subject to the 340B ceiling price requirement with regard to the following types of covered entities: rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the MDRP. In general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. We must report 340B ceiling prices to HRSA on a quarterly basis, and HRSA publishes them to 340B covered entities. HRSA has finalized regulations regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B-eligible drugs. HRSA has also finalized an administrative dispute resolution process through which 340B covered entities may pursue claims against participating manufacturers for overcharges, and through which manufacturers may pursue claims against 340B covered entities for engaging in unlawful diversion or duplicate discounting of 340B drugs. In addition, legislation may be introduced that, if passed, would further expand the

340B program, such as adding further covered entities or requiring participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

In order to be eligible to have drug products paid for with federal funds under Medicaid and Medicare Part B and purchased by certain federal agencies and grantees, we must also participate in the VA/FSS pricing program. Under the VA/FSS program, we must report the Non-FAMP for our covered drugs to the VA and charge certain federal agencies no more than the Federal Ceiling Price, which is calculated based on Non-FAMP using a statutory formula. These four agencies are the VA, the U.S. Department of Defense, the U.S. Coast Guard, and the U.S. Public Health Service (including the Indian Health Service). We must also pay rebates on products purchased by military personnel and dependents through the TRICARE retail pharmacy program. If we fail to provide timely information or are found to have knowingly submitted false information, we may be subject to civil monetary penalties.

Individual states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation that may prevent or limit our ability to take price increases at certain rates or frequencies. Requirements under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and states may impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers who fail to comply with drug price transparency requirements. If we are found to have violated state law requirements, we may become subject to penalties or other enforcement mechanisms, which could have a material adverse effect on our business.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies, and the courts, which can change and evolve over time. Such pricing calculations and reporting, along with any necessary restatements and recalculations, could increase our costs for complying with the laws and regulations governing the MDRP and other governmental programs, and under the MDRP could result in an overage or undercharge in Medicaid rebate liability for past quarters. Price recalculations under the MDRP also may affect the ceiling price at which we are required to offer products under the 340B program. Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. CMS could also terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B, if applicable, for our covered outpatient drugs. We cannot assure you that our submissions will not be found to be incomplete or incorrect.

Enacted and future healthcare legislation may have a material adverse effect on our business and results of operations.

In the United States, EU and other jurisdictions, there have been and we expect there will continue to be a number of legislative and regulatory initiatives and proposed changes to the healthcare system that could affect our operations. For example, in the United States, the Affordable Care Act (the “ACA”) substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjects biologic products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and biologics that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs and biologics, and a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts which, through subsequent legislative amendments, was increased to 70%, off negotiated prices of applicable brand drugs and biologics to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient products to be covered under Medicare Part D.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the Affordable Care Act. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the

Affordable Care Act brought by several states without specifically ruling on the constitutionality of the Affordable Care Act. Prior to the Supreme Court's decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. The Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through July 1, 2022 (with a 1% payment reduction from April 1 to June 30, 2022), unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several types of providers.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug and biologic pricing, reduce the cost of prescription drugs and biologics under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs and biologics. For example, in May 2019, CMS published a final rule to allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2020. In addition, in March 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, the Build Back Better Act, if enacted, would introduce substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, and the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D. If the Build Back Better Act is not enacted, similar or other drug pricing proposals could appear in future legislation. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our products and product candidates, if approved, or additional pricing pressures.

Individual states and municipalities in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure and other transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our products and product candidates, if approved, or put pressure on our product pricing.

In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of

our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved.

In markets outside of the United States and the EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States, the EU or elsewhere. For example, the new presidential administration may change governmental policies and regulations that affect our operations and business, including our clinical trials, regulatory approval, pharmaceutical pricing and reimbursement. If we or any third party we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third party are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Unfavorable global economic or operational conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the COVID-19 pandemic and the ongoing war in Ukraine has impacted and continues to impact the global economy, causing or contributing to global supply chain issues, price fluctuations and other significant economic effects. See "*Risk Factors — General Risk Factors — The COVID-19 pandemic, and measures taken in response to the pandemic, could have an adverse impact that is significant on our business and operations as well as the business or operations of our manufacturers, CROs and other third parties with whom we conduct business or otherwise engage, including the FDA and other regulatory authorities, and has impacted and could continue to impact the global economy, which may have a material adverse effect on our business, operations and financial position*" and "*Risk Factors — General Risk Factors — The ongoing war in Ukraine, and actions taken against Russia as a result of its invasion of Ukraine, has and may continue to have an adverse impact on the global economy, equity capital markets and our clinical operations.*"

These disruptions could adversely affect our ability to manufacture, market and sell our commercialized products, including ARCALYST, and satisfy the required supply for any of our product candidates or successfully complete preclinical and clinical development of our product candidates, which could require us to incur additional costs, and impair our ability to obtain regulatory approval of our product candidates and generate revenue. Doing business internationally involves a number of other risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, employment laws, regulatory requirements, permits and export and import restrictions;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing operations outside of the United States;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;

- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability such as war, including the ongoing war in Ukraine, terrorism, political unrest, outbreak of disease and boycotts;
- curtailment of trade, and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over clinical activities, sales and other functions that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its books and records provisions or its antibribery provisions.

Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our information technology systems, or those of our third party CMOs, CROs or other contractors, consultants and service providers, may fail or suffer cyberattacks or security breaches, which could result in a material disruption of our or such third-party's business or operations and our development programs for our product candidates or loss of other assets, including funds.

Despite the implementation of security measures, our information technology systems and those of our third-party CMOs, CROs and other contractors, consultants and service providers as well as employees that are working outside of our facilities are vulnerable to attack, damage or interruption from viruses and malware (e.g., ransomware), malicious code, theft, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic, we may face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Employees may also fail to comply with our cybersecurity protocols, exposing us to vulnerabilities despite our safeguards. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. In addition, a breach at a CMO, CRO, contractor, consultant, service provider or other third party with which we engage may increase our exposure by allowing criminals to exploit our relationship with such persons. Such security breaches may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our business and operations or those of our third party CMOs, CROs and other contractors, consultants and service providers as well as employees that are working outside of our facilities, the costs associated with the investigation, remediation and potential notification of a breach to counter-parties and data subjects could be material. A breach could result in a material disruption of our or such third-party's business or operations and our development programs of our product candidates' or loss of other assets, including funds. For example, the loss of clinical trial data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or

product candidates, or inappropriate disclosure or theft of confidential or proprietary information, the further development of our product candidates could be delayed. Although we maintain cybersecurity insurance coverage, it may not be adequate to cover all liabilities that we may incur from cyber-attacks or security breaches and is subject to deductibles and coverage limitations.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

We are or in the future may be subject to data privacy and protection laws, regulations, policies and contractual obligations that govern the collection, transmission, storage, processing, and use of personal information or personal data. The regulatory framework for data privacy and security worldwide is continuously evolving and developing and, as a result, interpretation and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, results of operation, and financial condition.

For example, most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended. We do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient support program. As such, we may be subject to state laws requiring notification of affected individuals and state regulatory authorities in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA.

In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Certain states have also adopted comparable privacy and security laws and regulations governing the privacy, processing and protection of personal information. For example, California enacted the California Consumer Privacy Act, or the CCPA, on June 28, 2018, which went into effect on January 1, 2020. The CCPA gives California residents expanded rights to access, correct, and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the California Privacy Rights Act, or CPRA, recently passed in California. The CPRA significantly amends the CCPA and will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Virginia and Colorado have also enacted similar legislation to California increasing complexity of compliance with privacy laws. The majority of the provisions for these laws will go into effect in 2023, and additional compliance investment and potential business process changes may be required.

Furthermore, the Federal Trade Commission, or FTC, and many state Attorneys General continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

Our clinical trial programs outside the United States may implicate international data protection laws, including the General Data Protection Regulation 2016/679, or GDPR, and legislation of EU member states and European Economic Area, or EEA, countries implementing it. The GDPR went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States called the Privacy Shield, but in July 2020 the Court of Justice of the EU, or the CJEU, limited how organizations could lawfully transfer personal data from the EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on use of the standard contractual clauses, or SCCs. While the CJEU upheld the adequacy of the SCCs, it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the SCCs must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. The CJEU went on to state that if a competent supervisory authority believes that the SCCs cannot be complied with in the destination country and the required level of protection cannot be secured by other means, such supervisory authority is under an obligation to suspend or prohibit that transfer. The European Commission issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. The revised SCCs apply only to the transfer of personal data outside of the EEA and not the UK. The UK's Information Commissioner's Office has published new data transfer standard contracts for transfers from the UK under the UK GDPR. This new documentation will be mandatory for relevant data transfers from September 21, 2022; existing standard contractual clauses arrangements must be migrated to the new documentation by March 21, 2024. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate or intend to operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Further, following the withdrawal of the UK from the EU on January 31, 2020, and the expiration of the transition period, from January 1, 2021, companies have had to comply with the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, e.g., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the medium to longer term. The European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews or extends that decision and remains under review by the Commission during this

period. In September 2021, the UK government launched a consultation on its proposals for wide-ranging reform of UK data protection laws following Brexit. There is a risk that any material changes which are made to the UK data protection regime could result in the European Commission reviewing the UK adequacy decision, and the UK losing its adequacy decision if the European Commission deems the UK to no longer provide adequate protection for personal data.

Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information. Moreover, patients about whom we or our collaborators obtain health information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. If we or third-party CMOs, CROs or other contractors or consultants fail to comply with applicable regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our product candidates and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

Securities class action and derivative lawsuits and other legal proceedings are often brought against companies, which could result in substantial costs and divert management's attention.

Securities class action and derivative lawsuits and other legal proceedings are often brought against companies following a decline in the market price of their securities. There can be significant fluctuations in market price for the securities of biopharmaceutical companies, such as us. As a result, we may be more susceptible to these types of lawsuits and legal proceedings than other companies with more stable security prices. In connection with any litigation or other legal proceedings, we could incur substantial costs, and such costs and any related settlements or judgments may not be covered by insurance. We could also suffer an adverse impact to our reputation and a diversion of management's attention and resources, which could have a material adverse effect on our business.

Although we maintain director and officer liability insurance coverage, it may not be adequate to cover all liabilities that we may incur and is subject to deductibles and coverage limitations. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If we are unable to obtain insurance at acceptable cost or otherwise protect against potential class action and derivative lawsuits and other legal proceedings or claims often brought against companies following a decline in the market price of their securities, we will be exposed to significant liabilities, which may materially and adversely affect our business and financial position.

We and our employees and third parties with whom we contract are increasingly utilizing social media tools as a means of communication both internally and externally, and noncompliance with applicable requirements, policies or contracts due to social media use or negative posts or comments could have an adverse effect on our business.

Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our products, product candidates or business may cause us to be found in violation of applicable requirements. In addition, our employees or third parties with whom we contract, such as our CROs or CMOs, may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property or result in public exposure of personal

information of our employees, clinical trial patients, customers and others or information regarding our product candidates or clinical trials. Clinical trial patients may also knowingly or inadvertently make use of social media in ways that may not align with our communication strategies, including with respect to any adverse events they may experience, which may give rise to liability and regulatory risk. Furthermore, negative posts or comments about us or our products or product candidates in social media could seriously damage our reputation, brand image and goodwill. Any of these events could have a material adverse effect on our business, prospects, operating results and financial condition and could adversely affect the price of our Class A common shares.

Our future success depends on our ability to retain key executives and senior management as well as to attract, retain and motivate qualified personnel.

We are highly dependent on the research and development, clinical, medical, regulatory, manufacturing, commercial and business development expertise of members of our executive and senior management teams, as well as the other members of our management, scientific and clinical teams. Although we have entered into employment agreements with our executive officers and certain members of senior management, each of them or we may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives, senior management or other employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Recruiting and retaining qualified scientific, clinical, regulatory, manufacturing and sales and marketing personnel is also critical to our success. The failure to recruit, or the loss of the services of our executive officers, senior management or other key employees could impede the achievement of our research, development and commercialization objectives, including with respect to our sales, marketing and distribution capabilities, infrastructure and organization to commercialize products for which we have obtained marketing approval and maintain proper regulatory oversight functions, any of which would seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers, senior management and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Changes in our senior management may be disruptive to our business, and, if we are unable to manage an orderly transition of responsibilities, our business may be adversely affected. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific and clinical personnel. If we are not able to continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or growth.

Our employees, principal investigators, CROs, consultants and other third-party service providers may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, principal investigators, CROs, consultants and other third-party service providers may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, including

off-label promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation.

It is not always possible to identify and deter misconduct by employees and other third parties. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The increasing focus on environmental sustainability and social initiatives could increase our costs, harm our reputation and adversely impact our financial results.

There has been increasing public focus by investors, patients, environmental activists, the media and governmental and nongovernmental organizations on a variety of environmental, social and other sustainability matters. We may experience pressure to make commitments relating to sustainability matters that affect us, including the design and implementation of specific risk mitigation strategic initiatives relating to sustainability. If we are not effective in addressing environmental, social and other sustainability matters affecting our business, or setting and meeting relevant sustainability goals, our reputation and financial results may suffer. In addition, even if we are effective at addressing such concerns, we may experience increased costs as a result of executing upon our sustainability goals that may not be offset by any benefit to our reputation, which could have an adverse impact on our business and financial condition.

In addition, this emphasis on environmental, social and other sustainability matters has resulted and may result in the adoption of new laws and regulations, including new reporting requirements. If we fail to comply with new laws, regulations or reporting requirements, our reputation and business could be adversely impacted.

Risks Related to Ownership of Our Common Shares

The concentration of ownership of our Class B common shares, which are held primarily by our executive officers and certain other members of our senior management, and the conversion rights of the holders of our Class A1 common shares, which shares are held primarily by entities affiliated with certain of our directors, and Class B1 common shares, all of which shares are held by entities affiliated with certain of our directors means that such persons are, and such entities may in the future be, able to influence certain matters submitted to our shareholders for approval, which may have an adverse effect on the price of our Class A common shares and may result in our Class A common shares being undervalued.

Each Class A common share is entitled to one vote per Class A common share and each Class B common share is entitled to ten votes per Class B common share. Our Class A1 common shares and Class B1 common shares have no voting rights. As a result, all matters submitted to our shareholders are decided by the vote of holders of our Class A common shares and Class B common shares. As a result of the multi-class voting structure of our common shares, our executive officers and certain other members of our senior management collectively control a substantial amount of the voting power of our common shares and therefore are able to control the outcome of certain matters submitted to our shareholders for approval. As of March 31, 2022, the holders of Class A common shares accounted for approximately 65% of our aggregate voting power and the holders of Class B common shares accounted for approximately 35% of our aggregate voting power. Our executive officers and certain other members of our senior management hold Class A common shares and Class B common shares representing approximately 31% of our aggregate voting power as of March 31, 2022 and may have the ability to influence the outcome of certain matters submitted to our shareholders for approval.

However, this percentage may change depending on any conversion of our Class B common shares, Class A1 common shares or Class B1 common shares. Each holder of our Class B common shares has the ability to convert any portion of its Class B common shares into Class B1 common shares or Class A common shares at any time with advance notice to us. Each holder of our Class B1 common shares has the ability to convert any portion of its Class B1 common shares into Class A common shares or Class B common shares at any time with advance notice to us, and each holder of our Class A1 common shares has the ability to convert any portion of its Class A1 common shares into Class A common shares at any time with advance notice to us. Our Class A1 common shares and Class B1 common shares cannot be converted if, immediately prior to or following such conversion, the holder and its affiliates beneficially own, or would beneficially own, more than 4.99% of our issued and outstanding Class A common shares unless such holder provides us with 61-days' prior notice that it intends to increase, decrease or waive such threshold upon conversion. For example, as of March 31, 2022, entities affiliated with certain members of our directors could convert their Class A1 common shares and Class B1 common shares upon 61-days' prior written notice into Class A common shares and Class B common shares, respectively, which in the aggregate would result in such entities holding approximately 78% of our aggregate voting power and having the ability to control the outcome of certain matters submitted to our shareholders for approval. Due to these conversion rights, holders of our Class A1 common shares and our Class B1 common shares could, at any time with appropriate advance notice to us, significantly increase their voting control of us, which could result in their ability to significantly influence or control matters submitted to our shareholders for approval and significantly decrease the voting power of our currently outstanding Class A common shares.

These conversion rights as well as concentrated control that limit certain shareholders' ability to influence corporate matters may have an adverse effect on the price of our Class A common shares. Holders of our Class B common shares collectively control our management and affairs and are able to influence or control the outcome of certain matters submitted to our shareholders for approval, including the election of directors. Due to the conversion rights of the holders of our Class A1 and B1 common shares, entities affiliated with certain of our directors could significantly increase their voting control of us. This concentration of control might adversely affect certain corporate actions that some of our shareholders may view as beneficial, for example, by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

The price of our Class A common shares is likely to continue to be volatile and fluctuate substantially, which could result in substantial losses for holders of our Class A common shares.

Our share price is likely to continue to be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility, including as a result of the COVID-19 pandemic, that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our shareholders may not be able to sell their Class A common shares at or above the price they paid for their shares. The market price for our Class A common shares may be influenced by many factors, including:

- our ability to generate revenue through the successful commercialization of our products and product candidates, if approved;
- the size of the market for our products and product candidates, if approved;
- the results of clinical trials for our product candidates or any delays in the commencement, enrollment and the ultimate completion of clinical trials;
- failures in obtaining approval of our product candidates;

- the results and potential impact of competitive products or technologies;
- our ability to manufacture and successfully produce our products and product candidates;
- actual or anticipated changes in estimates as to financial results, capitalization, development timelines or recommendations by securities analysts;
- the level of expenses related to any of our products and product candidates or clinical development programs;
- variations in our financial results or those of companies that are perceived to be similar to us;
- financing or other corporate transactions, or our inability to obtain additional funding;
- failure to meet or exceed the expectations of the investment community;
- regulatory or legal developments in the United States and other countries;
- the recruitment or departure of key personnel;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or from our entering into collaborations or other strategic transaction agreements;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions, including as a result of the COVID-19 pandemic and measures taken in response to the pandemic;
- changes in voting control of, or sales of our shares by, our executive officers and certain other members of our senior management or entities affiliated with certain of our directors that hold our shares; and
- the other factors described in this “Risk Factors” section.

Additionally, the trading prices of biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. The COVID-19 outbreak continues to rapidly evolve, including through the emergence of new variants of the virus. The extent to which the outbreak may impact our business in the future, including our commercialization of ARCALYST, our preclinical studies and clinical trials, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence. See “*Risk Factors—General Risk Factors – The COVID-19 pandemic, and measures taken in response to the pandemic or the easing of such measures, could have an adverse impact that is significant on our business and operations as well as the business or operations of our manufacturers, CROs and other third parties with whom we conduct business or otherwise engage, including the FDA and other regulatory authorities, and has impacted and could continue to impact the global economy, which may have a material adverse effect on our business, operations and financial position.*”

The ongoing war in Ukraine has also introduced significant market volatility and economic instability, which may materially impact our business, operations and financial position. See “*Risk Factors—General Risk Factors – The ongoing war in Ukraine, and actions taken against Russia as a result of its invasion of Ukraine, has and may continue to have an adverse impact on the global economy, equity capital markets and our clinical operations.”*

If securities or industry analysts cease publishing or publish unfavorable research or reports about us, our business or our market, our share price and trading volume could decline.

The trading market for our Class A common shares is influenced by the research and reports that equity research analysts publish about us and our business. We do not have any control over the analysts or the content and opinions included in their reports. The price of our Class A common shares could decline if one or more equity research analysts downgrades our shares or issues other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our Class A common shares could decrease, which in turn could cause the price of our Class A common shares or its trading volume to decline.

Sales of a number of our Class A common shares in the public market, including Class A common shares issuable upon conversion of our Class B, Class A1 and Class B1 common shares, could cause the share price of our Class A common shares to fall.

A significant number of our Class A common shares are issuable upon conversion of our Class B, Class A1, and Class B1 common shares, subject to certain limitations on conversion. As of March 31, 2022, approximately 1.9 million Class A common shares directly held by our executive officers and directors, inclusive of Class A common shares issuable upon conversion of our Class B, Class A1, and Class B1 common shares, were eligible for resale in the public market to the extent permitted by the provisions of Rule 144 promulgated under the Securities Act of 1933, as amended, or the Securities Act, and such rule, Rule 144. In addition, as of March 31, 2022, there were approximately 10.1 million Class A common shares subject to outstanding share options and RSUs under our equity incentive plans that may become eligible for sale in the public market to the extent permitted by the provisions of applicable vesting schedules and Rule 144 and Rule 701 under the Securities Act.

Over a majority of our common shares are held by our executive officers and other members of our senior management team, together with entities affiliated with certain of our directors. As of March 31, 2022, on an as-converted to Class A common shares basis, these shareholders collectively held approximately 33.9 million of our Class A common shares. If any of these shareholders sell, convert or transfer, or indicate an intention to sell, convert or transfer, a substantial amount of their common shares (after certain restrictions on conversion or resale lapse), the market price of our Class A common shares could decline.

Pursuant to our amended and restated investor rights agreement, or our investors rights agreement, certain shareholders are entitled to certain registration rights with respect our Class A common shares, including Class A common shares issuable upon conversions of our Class B, Class A1, and Class B1 common shares and upon the exercise of certain rights to acquire Class A common shares, or collectively registerable securities, under the Securities Act. As of March 31, 2022, on an as-converted to Class A common shares basis, we have registered approximately 31.8 million Class A common shares held by certain holders affiliated with certain of our directors as well as certain other shareholders pursuant to our investor rights agreement, which are freely tradable without restriction under the Securities Act, to the extent permitted by Rule 144. Further, pursuant to the investors rights agreement (a) the holders affiliated with certain of our directors are entitled to certain registration rights under the Securities Act with respect to registrable securities they may own now or in the future and (b) our executive officers are also entitled to certain registration rights under the Securities Act with respect to registrable securities they may own now or in the future, including, on an as-converted to Class A common shares basis, approximately 1.7 million Class A common shares held by certain of our executive officers as of March 31, 2022. If any of these Class A common shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our Class A common shares could decline.

Future sales or issuances of our common shares or rights to purchase common shares, including under our shelf registration statement or pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our shareholders and could cause our Class A common share price to fall.

We may need additional capital in the future to continue our planned operations. To the extent we raise additional capital by issuing additional Class A common shares, Class B common shares, Class A1 common shares, Class B1 common shares or other equity securities, our shareholders may experience substantial dilution. We may sell

common shares, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time under our shelf registration statement or otherwise. If we sell common shares, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing shareholders, and new investors could gain rights superior to our existing shareholders.

In addition, the consummation or performance of any acquisition, business combination, collaboration or other strategic transaction we may undertake in furtherance of our growth strategy may cause dilution to our existing shareholders if we issue equity securities for all or a portion of the consideration.

We are currently a "smaller reporting company" and the reduced disclosure requirements applicable to "smaller reporting companies" may make our Class A common shares less attractive to investors.

We are currently a "smaller reporting company" as defined under the rules promulgated under the Securities Act. As a smaller reporting company, we may follow reduced disclosure requirements and do not have to make all of the disclosures that public companies that are not smaller reporting companies do.

For so long as we remain a smaller reporting company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not smaller reporting companies. Smaller reporting companies are able to provide simplified executive compensation disclosure and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, supplemental financial information or risk factors.

We may choose to take advantage of some, but not all, of the available exemptions for smaller reporting companies. We cannot predict whether investors will find our Class A common shares less attractive if we rely on these exemptions. If some investors find our Class A common shares less attractive as a result, there may be a less active trading market for our Class A common shares and the share price of our Class A common shares may be more volatile.

We incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses. In addition, the Sarbanes Oxley Act of 2002 and rules subsequently implemented by the SEC and The Nasdaq Global Select Market, or Nasdaq, where our Class A common shares are listed, impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly, which increased, for example, in connection with having been a large accelerated filer in 2021 and no longer qualifying as an emerging growth company. This may require management and other personnel to divert attention from operational and other business matters to devote substantial time to public company reporting requirements.

Pursuant to Section 404, we are required to furnish a report by our management on our internal control over financial reporting. To maintain compliance with Section 404 within the prescribed period, we engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, engage outside consultants and refine and revise a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

We have anti-takeover provisions in our amended and restated bye-laws that may discourage a change of control.

Our amended and restated bye-laws contain provisions that could make it more difficult for a third party to acquire us. These provisions provide for:

- a classified board of directors with staggered three-year terms;
- directors only to be removed for cause;
- an affirmative vote of 66 2/3% of the voting power of our voting shares for certain "business combination" transactions that have not been approved by our board of directors;
- our multi-class common share structure, which provides our holders of Class B common shares with the ability to significantly influence the outcome of matters requiring shareholder approval, even if they own less than a majority of our outstanding Class A common shares;
- restrictions on the time period in which directors may be nominated; and
- our board of directors to determine the powers, preferences and rights of our preferred shares and to issue the preferred shares without shareholder approval.

These anti-takeover defenses could discourage, delay or prevent a transaction involving a change in control of our company and may prevent our shareholders from receiving the benefit from any premium to the market price of our Class A common shares offered by a bidder in a takeover context. Even in the absence of a takeover attempt, the existence of these provisions may adversely affect the prevailing market price of our Class A common shares if the provisions are viewed as discouraging takeover attempts in the future. These provisions could also discourage proxy contests, make it more difficult for our shareholders to elect directors of their choosing and cause us to take corporate actions other than those our shareholders desire.

Because we do not anticipate paying any cash dividends on our shares in the foreseeable future, capital appreciation, if any, will be the sole source of gain for our shareholders.

We have never declared or paid cash dividends on our shares. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. Additionally, the proposal to pay future dividends to shareholders will effectively be at the sole discretion of our board of directors after considering various factors our board of directors deems relevant, including our business prospects, capital requirements, financial performance and new product development. As a result, capital appreciation, if any, of our Class A common shares will be the sole source of gain for our shareholders for the foreseeable future.

Risks Related to Owning Shares in a Bermuda Exempted Company and Certain Tax Risks

We are a Bermuda company and it may be difficult for our shareholders to enforce judgments against us or our directors and executive officers.

We are a Bermuda exempted company. As a result, the rights of holders of our Class A common shares will be governed by Bermuda law and our memorandum of association and amended and restated bye-laws. The rights of shareholders under Bermuda law may differ from the rights of shareholders of companies incorporated in other jurisdictions. It may be difficult for investors to enforce in the United States judgments obtained in U.S. courts against us based on the civil liability provisions of the U.S. securities laws. It is doubtful whether courts in Bermuda will enforce judgments obtained in other jurisdictions, including the United States, against us or our directors or officers under the securities laws of those jurisdictions or entertain actions in Bermuda against us or our directors or officers under the securities laws of other jurisdictions.

Our amended and restated bye-laws designate the Supreme Court of Bermuda as the choice of jurisdiction for disputes that arise concerning the Bermuda Companies Act 1981, as amended, or the Companies Act, or out of or in connection with our amended and restated bye-laws, which could limit our shareholders' ability to choose the judicial forum for disputes with us or our directors or officers.

Our amended and restated bye-laws provide that, unless we consent in writing to the selection of an alternative jurisdiction, any dispute that arises concerning the Companies Act, or out of or in connection with our amended and restated bye-laws, including any question regarding the existence and scope of any bye-law or whether there has been a breach of the Companies Act or the amended and restated bye-laws by any of our officers or directors (whether or not such a claim is brought in the name of a shareholder or in the name of our company) shall be subject to the jurisdiction of the Supreme Court of Bermuda.

Any person or entity purchasing or otherwise acquiring any interest in any of our shares shall be deemed to have notice of and consented to this provision. This choice of jurisdiction provision may limit a shareholder's ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors or officers, which may discourage lawsuits against us and our directors and officers. If a court were to find either choice of jurisdiction provision in our amended and restated bye-laws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could harm our results of operations.

Bermuda law differs from the laws in effect in the United States and may afford less protection to our shareholders.

We are organized under the laws of Bermuda. As a result, our corporate affairs are governed by the Companies Act, which differs in some material respects from laws typically applicable to U.S. corporations and shareholders, including the provisions relating to interested directors, amalgamations, mergers and acquisitions, takeovers, shareholder lawsuits and indemnification of directors. Generally, the duties of directors and officers of a Bermuda company are owed to the company only. Shareholders of Bermuda companies typically do not have rights to act against directors or officers of the company and may only do so in limited circumstances. Shareholder class actions are not available under Bermuda law. The circumstances in which shareholder derivative actions may be available under Bermuda law are substantially more proscribed and less clear than they would be to shareholders of U.S. corporations. The Bermuda courts, however, would ordinarily be expected to permit a shareholder to commence an action in the name of a company to remedy a wrong to the company where the act complained of is alleged to be beyond the corporate power of the company or illegal, or would result in the violation of the company's memorandum of association or bye-laws. Furthermore, consideration would be given by a Bermuda court to acts that are alleged to constitute a fraud against the minority shareholders or, for instance, where an act requires the approval of a greater percentage of the company's shareholders than those who actually approved it.

When the affairs of a company are being conducted in a manner that is oppressive or prejudicial to the interests of some shareholders, one or more shareholders may apply to the Supreme Court of Bermuda, which may make such order as it sees fit, including an order regulating the conduct of the company's affairs in the future or ordering the purchase of the shares of any shareholders by other shareholders or by the company. Additionally, under our amended and restated bye-laws and as permitted by Bermuda law, each shareholder has waived any claim or right of action against our directors or officers for any action taken by directors or officers in the performance of their duties, except for actions involving fraud or dishonesty. In addition, the rights of our shareholders and the fiduciary responsibilities of our directors under Bermuda law are not as clearly established as under statutes or judicial precedent in existence in jurisdictions in the United States, particularly the State of Delaware. Therefore, our shareholders may have more difficulty protecting their interests than would shareholders of a corporation incorporated in a jurisdiction within the United States.

There are regulatory limitations on the ownership and transfer of our common shares.

Common shares may be offered or sold in Bermuda only in compliance with the provisions of the Companies Act and the Bermuda Investment Business Act 2003, as amended, which regulates the sale of securities in Bermuda. In addition, the Bermuda Monetary Authority must approve all issues and transfers of shares of a Bermuda exempted company. However, the Bermuda Monetary Authority has, pursuant to its statement of June 1, 2005, given its general

permission under the Exchange Control Act 1972 and related regulations for the issue and free transfer of our common shares to and among persons who are non-residents of Bermuda for exchange control purposes as long as the shares are listed on an appointed shares exchange, which includes Nasdaq. This general permission would cease to apply if we were to cease to be listed on Nasdaq.

We may become subject to unanticipated tax liabilities.

Although we are incorporated under the laws of Bermuda, we may become subject to income, withholding or other taxes in certain other jurisdictions by reason of our activities and operations, including the movement of assets to and between one or more foreign subsidiaries. It is also possible that taxing authorities in any such jurisdictions could assert that we are subject to greater taxation than we currently anticipate. Any such non-Bermudian tax liability could materially adversely affect our results of operations.

Taxing authorities could reallocate our taxable income among our subsidiaries, which could increase our overall tax liability.

We are incorporated under the laws of Bermuda and currently have subsidiaries in the United States, the United Kingdom, Germany, Switzerland and France. If we succeed in growing our business, we expect to conduct increased operations through our subsidiaries in various tax jurisdictions subject to transfer pricing arrangements between us and such subsidiaries. If two or more affiliated companies are located in different countries, the tax laws or regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arms' length and that appropriate documentation is maintained to support the transfer prices. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable tax authorities.

If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arms' length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

Changes in laws related to tax practices and substance requirements in Bermuda and other jurisdictions could adversely affect our operations.

Our tax position could be adversely impacted by changes in tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the tax authorities in Europe (including the United Kingdom), the United States, Bermuda and other jurisdictions, as well as being affected by certain changes currently proposed by the Organization for Economic Co-operation and Development and their action plan on Base Erosion and Profit Shifting. Such changes may become more likely as a result of recent economic trends in the jurisdictions in which we operate, particularly if such trends continue. If such a situation were to arise, it could adversely impact our tax position and our effective tax rate. Failure to manage the risks associated with such changes, or misinterpretation of the laws providing such changes, could result in costly audits, interest, penalties and reputational damage, which could adversely affect our business, results of operations and our financial condition. Our actual effective tax rate may vary from our expectation and that variance may be material. A number of factors may increase our future effective tax rates, including:

- the jurisdictions in which profits are determined to be earned and taxed;
- the resolution of issues arising from any future tax audits with various tax authorities;
- changes in the valuation of our deferred tax assets and liabilities;

- changes to and increases in expenses not deductible for tax purposes, including transaction costs and impairments of goodwill in connection with acquisitions;
- changes in the taxation of share-based compensation;
- changes in tax laws or the interpretation of such tax laws, and changes in generally accepted accounting principles; and
- challenges to the transfer pricing policies related to our structure.

Pursuant to the Bermuda Economic Substance Act 2018 (as amended) and related Economic Substance Regulations (collectively, "ES Laws"), certain entities in Bermuda engaged in "relevant activities" are required to maintain appropriate physical presence in Bermuda and to satisfy economic substance requirements commencing as of January 1, 2019. The list of "relevant activities" includes carrying on as a business in any one or more of the following categories: banking, insurance, fund management, financing and leasing, headquarters, shipping, distribution and service center, intellectual property and holding entities. Under the ES Laws, any relevant entity must satisfy economic substance requirements locally or face financial penalties, restriction or regulation of its business activities or may be struck off as a registered entity from the Bermuda Register of Companies. Because we are not engaged in any "relevant activities", we believe that we are not obliged to meet the economic substance requirements. We will continue to monitor our status with respect to the ES Laws and whether further action may be required in the future by the Company to comply with the ES Laws.

The United States government may enact significant changes to the taxation of business entities including, among others, an increase in the corporate income tax rate, the imposition of minimum taxes or surtaxes on certain types of income, significant changes to the taxation of income derived from international operations, and an addition of further limitations on the deductibility of business interest. While certain draft legislation has been publicly released, the likelihood of these changes being enacted or implemented is unclear. We are currently unable to predict whether such changes will occur. If such changes are enacted or implemented, we are currently unable to predict the ultimate impact on our business and therefore there can be no assurance our business will not be adversely affected.

We may be treated as a passive foreign investment company ("PFIC") for U.S. federal income tax purposes for the year ended December 31, 2022. If we were to be classified a PFIC, this could result in adverse U.S. federal income tax consequences to U.S. Holders.

We plan to perform an analysis to determine whether the Company or its subsidiaries are expected to be treated as PFICs for the year ended December 31, 2022. A non-U.S. company will generally be considered as a PFIC for any taxable year if (i) at least 75% of its gross income is passive (including interest income), or (ii) at least 50% of the value of its assets (based on an average of the quarterly values of the assets during a taxable year) is attributable to assets that produce or are held for the production of passive income. If we, or our subsidiaries, are classified as a PFIC in any year with respect to which a U.S. Holder (as defined below) owns our Class A common shares, we will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns the Class A common shares, regardless of whether we continue to meet the PFIC test described above, unless we cease to be a PFIC and the U.S. Holder made a "qualified electing fund" election or "mark-to-market" election for (a) the first taxable year the U.S. Holder was treated as owning our shares while we were a PFIC or (b) for the taxable year in which we were a PFIC and the U.S. Holder made a "deemed sale" election or was qualified to and made a "deemed dividend" election. A "U.S. Holder" is a beneficial owner of our Class A common shares that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;

- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or

- a trust that (i) is subject to the supervision of a U.S. court and all substantial decisions of which are subject to the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the U.S. Internal Revenue Code of 1986, as amended (the "Code")), or (ii) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

If we are classified as a PFIC for any taxable year during which a U.S. Holder holds our Class A common shares, certain adverse U.S. federal income tax consequences could apply to such U.S. Holder, including (i) the treatment as ordinary income of any gain realized on a disposition of our shares and distributions on our shares not being qualified dividend income, (ii) the application of a deferred interest charge on the tax on such gain and distributions, and (iii) the obligation to comply with certain reporting requirements.

If a U.S. Holder is treated as owning at least 10% of our shares, by vote or by value, such holder may be subject to adverse U.S. federal income tax consequences.

We believe we will likely be classified as a "controlled foreign corporation" (as such term is defined in the Code) for the taxable year ended December 31, 2022. Even if we were not classified as a controlled foreign corporation, certain of our non-U.S. subsidiaries could be treated as controlled foreign corporations because our group includes one or more U.S. subsidiaries. If a U.S. Holder is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our shares, such U.S. Holder may be treated as a "United States shareholder" (as such term is defined in the Code) with respect to us (if we are classified as a controlled foreign corporation) and each controlled foreign corporation in our group (if any). A United States shareholder of a controlled foreign corporation may be required to annually report and include in its U.S. taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income," or GILTI, and investments in U.S. property by such controlled foreign corporation, regardless of whether such corporation makes any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. Failure to comply with these reporting obligations or income inclusions may subject such shareholder to significant monetary penalties and may prevent the statute of limitations with respect to such shareholder's U.S. federal income tax return for the year for which reporting was due from starting. We cannot provide any assurances that we will assist investors in determining whether such investor is treated as a United States shareholder with respect to us or any of our non-U.S. subsidiaries. Further, we cannot provide any assurances that we will furnish to any United States shareholders information that may be necessary to comply with the reporting and tax paying obligations discussed above. U.S. Holders should consult their tax advisors regarding the potential application of these rules to any investment in our Class A common shares.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.1#	Non-Employee Director Compensation Program					*
10.2†+	Collaboration and License Agreement (Rilonacept), by and between Kiniksa Pharmaceuticals (UK), Ltd. and Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd., dated as of February 21, 2022					*
10.3†+	Collaboration and License Agreement (Mavrilimumab), by and between Kiniksa Pharmaceuticals (UK), Ltd. and Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd., dated as of February 21, 2022					*
10.4#	Amended and Restated Employment Agreement, effective as of January 3, 2022, by and between Eben Tesari and Kiniksa Pharmaceuticals Corp.	8-K	001-38492	10.1	01/03/2022	
31.1	Rule 13a-14(a) / 15d-14(a) Certification of Chief Executive Officer					*
31.2	Rule 13a-14(a) / 15d-14(a) Certification of Chief Financial Officer					*
32.1	Section 1350 Certification of Chief Executive Officer					**
32.2	Section 1350 Certification of Chief Financial Officer					**
101.INS	XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document					***
101.SCH	Inline XBRL Taxonomy Extension Schema Document					***
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					***
101.DEF	Inline XBRL Extension Definition Linkbase Document					***
101.LAB	Inline XBRL Taxonomy Label Linkbase Document					***

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					***
104	Cover page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101) - The cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document					***

* Filed herewith
** Furnished herewith
*** Submitted electronically herewith
Indicates management contract or compensatory plan
† Portions of the exhibit have been redacted in compliance with Regulation S-K Item 601(a)(6)
+ Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

KINIKSA PHARMACEUTICALS, LTD.

Date: May 5, 2022

By: /s/ Mark Ragosa
Mark Ragosa
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

KINIKSA PHARMACEUTICALS, LTD.

NON-EMPLOYEE DIRECTOR COMPENSATION PROGRAM

Non-employee members of the board of directors (the "***Board***") of Kiniksa Pharmaceuticals, Ltd. (the "***Company***") shall receive cash and equity compensation as set forth in this Non-Employee Director Compensation Program (as amended, this "***Program***"). The cash and equity compensation described in this Program shall be paid or be made, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, a "***Non-Employee Director***") who is entitled to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Program shall remain in effect until it is revised or rescinded by further action of the Board. This Program may be amended, modified or terminated by the Board at any time in its sole discretion. The terms and conditions of this Program shall supersede any prior cash and/or equity compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors. No Employee Director shall have any rights hereunder.

I. CASH COMPENSATION

A. Annual Retainers. Each Non-Employee Director shall receive an annual retainer of $40,000 for service on the Board.

B. Additional Annual Retainers. In addition, each Non-Employee Director shall receive the following annual retainers:

1. *Chairperson of the Board or Lead Independent Director*. A Non-Employee Director serving as Chairperson of the Board or Lead Independent Director shall receive an additional annual retainer of $30,000 for such service.

2. *Audit Committee*. A Non-Employee Director serving as Chairperson of the Audit Committee shall receive an additional annual retainer of $19,000 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Audit Committee shall receive an additional annual retainer of $9,000 for such service.

3. *Compensation Committee*. A Non-Employee Director serving as Chairperson of the Compensation Committee shall receive an additional annual retainer of $13,400 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Compensation Committee shall receive an additional annual retainer of $6,300 for such service.

4. *Nominating and Corporate Governance Committee*. A Non-Employee Director serving as Chairperson of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of $9,300 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of $5,000 for such service.

5. *Science and Research Committee*. A Non-Employee Director serving as Chairperson of the Science and Research Committee shall receive an additional annual

retainer of $13,400 for such service. A Non-Employee Director serving as a member other than the Chairperson of the Science and Research Committee shall receive an additional annual retainer of $6,300 for such service.

C. Payment of Retainers. The annual retainers described in Sections I(A) and I(B) shall be earned on a quarterly basis based on a calendar quarter and shall be paid in cash by the Company in arrears not later than the fifteenth day following the end of each calendar quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described in Section I(B), for an entire calendar quarter, the retainer paid to such Non-Employee Director shall be prorated for the portion of such calendar quarter actually served as a Non-Employee Director, or in such position, as applicable.

II. EQUITY COMPENSATION

Non-Employee Directors shall be granted the equity awards described below. The awards described below shall be granted under and shall be subject to the terms and provisions of the Company's 2018 Incentive Award Plan or any other applicable Company equity incentive plan then-maintained by the Company (the "***Equity Plan***") and shall be granted subject to award agreements in substantially the form previously approved by the Board. All applicable terms of the Equity Plan apply to this Program as if fully set forth herein, and all grants of share options hereby are subject in all respects to the terms of the Equity Plan and the applicable award agreement.

A. Initial Awards. Each Non-Employee Director who is initially elected or appointed to the Board shall automatically be granted a mix of (a) an option to purchase the Company's Class A common shares and (b) restricted stock units, representing the right to receive Class A common shares ("***RSUs***"), with a combined value equal to $600,000 divided by the Black-Scholes Value (as defined below), rounded down to the nearest whole share, with such other adjustments as determined by the Board's Compensation Committee, but no more than a total of 80,000 shares, of the Company's Class A common shares on the date of such initial election or appointment. The proportion of share options to RSUs included in such award shall be determined by the Board's Compensation Committee from time-to-time. The awards described in this Section II(A) shall be referred to as "***Initial Awards***." No Non-Employee Director shall be granted more than one Initial Award.

B. Subsequent Awards. A Non-Employee Director who (i) has been serving as a Non-Employee Director on the Board for at least six (6) months as of the date of any annual meeting of the Company's shareholders and (ii) will continue to serve as a Non-Employee Director immediately following such meeting, shall be automatically granted a mix of (a) an option to purchase the Company's Class A common shares and (b) RSUs, with a combined value equal to $300,000 divided by the Black-Scholes Value, rounded down to the nearest whole share, with such other adjustments as determined by the Board's Compensation Committee, but no more than a total of 40,000 shares, of the Company's Class A common shares on the date of such annual meeting. The proportion of share options to RSUs included in such award shall be determined by the Board's Compensation Committee from time-to-time. The awards described in this Section II(B) shall be referred to as "***Subsequent Awards***." For the avoidance of doubt, a Non-Employee Director elected for the first time to the Board at an annual meeting of the Company's shareholders

shall only receive an Initial Award in connection with such election, and shall not receive any Subsequent Award on the date of such meeting as well.

C. Black-Scholes Value. For purposes of this Section II, "***Black-Scholes Value***" means the per share fair value of an option calculated on the basis of the Black-Scholes option pricing model and using as inputs to such model (i) for the value of one Class A common share of the Company, the average closing price of the Company's Class A common shares over each trading day occurring in the 30 calendar days ending on the last day of the month prior to the month in which the grant date of the relevant Initial Award or Subsequent Award occurs and (ii) such other assumptions as are determined by the Company's Chief Accounting Officer on or prior to the grant date of the relevant Initial Award or Subsequent Award.

D. Termination of Employment of Employee Directors. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their employment with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Award pursuant to Section II(A) above, but to the extent that they are otherwise entitled, will receive, after termination of employment with the Company and any parent or subsidiary of the Company, Subsequent Awards as described in Section II(B) above.

E. Terms of Option Awards Granted to Non-Employee Directors

1. *Exercise Price*. The per share exercise price of each option granted to a Non-Employee Director shall equal the Fair Market Value (as defined in the Equity Plan) of a share of the Company's Class A common shares on the date the option is granted.

2. *Vesting*. The share options contained in an Initial Award shall vest and become exercisable as to one-third of the share options subject to the Initial Award on the first anniversary of the date of grant and as to the remainder in twenty-four (24) substantially equal monthly installments thereafter, such that the share options contained in an Initial Award shall be fully vested on the third anniversary of the date of grant, subject to the Non-Employee Director continuing in service as a Non-Employee Director through each such vesting date. The share options contained in a Subsequent Award shall vest and become exercisable in twelve (12) substantially equal monthly installments following the date of grant, subject to the Non-Employee Director continuing in service on the Board as a Non-Employee Director through each such vesting date. Unless the Board otherwise determines, any share options contained in an Initial Award or Subsequent Award which are unvested or unexercisable at the time of a Non-Employee Director's termination of service on the Board as a Non-Employee Director shall be immediately forfeited upon such termination of service and shall not thereafter become vested and exercisable. All of the share options contained in a Non-Employee Director's Initial Awards and Subsequent Awards shall vest in full immediately prior to the occurrence of a Change in Control (as defined in the Equity Plan), to the extent outstanding at such time.

3. *Term*. The maximum term of each share option granted to a Non-Employee Director hereunder shall be ten (10) years from the date the option is granted.

F. Terms of RSU Awards Granted to Non-Employee Directors

1. *Vesting*. The RSUs contained in an Initial Award shall vest as to one-third of the RSUs subject to the Initial Award on each anniversary of the date of grant, such that the RSUs contained in an Initial Award shall be fully vested on the third anniversary of the date of grant, subject to the Non-Employee Director continuing in service as a Non-Employee Director through each such vesting date. The RSUs contained in a Subsequent Award shall vest in their entirety on the first anniversary of the date of grant, subject to the Non-Employee Director continuing in service on the Board as a Non-Employee Director through such vesting date. Unless the Board otherwise determines, any RSUs contained in an Initial Award or Subsequent Award which are unvested at the time of a Non-Employee Director's termination of service on the Board as a Non-Employee Director shall be immediately forfeited upon such termination of service and shall not thereafter become vested. All of the RSUs contained in a Non-Employee Director's Initial Awards and Subsequent Awards shall vest in full immediately prior to the occurrence of a Change in Control (as defined in the Equity Plan), to the extent outstanding at such time.

* * * * *

COLLABORATION AND LICENSE AGREEMENT

by and between

Kiniksa Pharmaceuticals (UK), Ltd.

and

Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd.

Dated as of February 21, 2022

[**] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(a)(6)

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10)(iv). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

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Schedules

COLLABORATION AND LICENSE AGREEMENT

This Collaboration and License Agreement (this "**Agreement**") is made as of February 21, 2022 (the "**Effective Date**") by and between Kiniksa Pharmaceuticals (UK), Ltd., a United Kingdom corporation ("**Kiniksa**"), having a place of business at Third Floor, 23 Old Bond Street, London, United Kingdom, W1S 4PZ, and Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd ("**Partner**"), having a place of business at No. 866 Moganshan Road, GongShu District, Hangzhou City, Zheijiang Province, People's Republic of China. Kiniksa and Partner are referred to in this Agreement individually as a "**Party**" and collectively as the "**Parties**."

Recitals

WHEREAS, Kiniksa, including its Affiliates, is a biopharmaceutical company focused on discovering, acquiring, developing, and commercializing therapeutic medicines for patients suffering from debilitating diseases with significant unmet medical need, including rilonacept;

WHEREAS, Kiniksa Controls certain Know-How and Patent Rights relating to such product;

WHEREAS, Partner is a pharmaceutical company engaged in the research, development, and commercialization of pharmaceutical and biologic products in the greater China region; and

WHEREAS, Partner wishes to obtain from Kiniksa an exclusive license to perform Clinical Development of, perform Medical Affairs for, and Commercialize the Licensed Product in the Territory, and Kiniksa is willing to grant such a license to Partner, as such terms are defined herein and all in accordance with the terms and conditions set forth herein.

AGREEMENT

NOW, **THEREFORE**, the Parties hereby agree as follows:

ARTICLE 1
DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms will have the respective meanings set forth below, whether used in the singular or plural:

1.1 "**Accounting Standards**" means GAAP or IFRS (as applicable to a Party).

1.2 "**Acquired Party**" has the meaning set forth in Section 2.8.3 (Business Combinations).

1.3 "**Affiliate**" means, with respect to a Person, any other Person that controls, is controlled by, or is under common control with such Person. For the purpose of this definition only, "control" (including, with correlative meaning, the terms "controlled by" and "under the common control") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of any Person, whether by the ownership of more than 50% of the voting security of such Person, by contract or otherwise. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than 50%, and that in such case such lower percentage will be substituted in the preceding sentence; *provided* that such foreign investor has the power to direct the management and policies of such entity. Notwithstanding the foregoing, neither Baker Brothers Advisors nor any other financial investor (excluding a financial investor that is the

investment entity of a pharmaceutical or biotechnology company), nor any funds affiliated with Baker Brothers Advisors or entities controlled by Baker Brothers Advisors or any other financial advisor (excluding a financial investor that is the investment entity of a pharmaceutical or biotechnology company) will be considered an Affiliate of Kiniksa.

1.4 "**Agreement**" has the meaning set forth in the Preamble.

1.5 "**Alliance Manager**" has the meaning set forth in Section 3.1 (Alliance Managers).

1.6 "**Annual Inventory Report**" has the meaning set forth in Section 10.3.5(b) (Annual Inventory Reports).

1.7 "**Anti-Corruption Laws**" means all local or other laws prohibiting or regulating public or private-sector corruption, bribery, kickbacks, speed or facilitation payments, ethical business conduct, money laundering, embezzlement, political contributions, gifts, gratuities, expenses, entertainment, hospitalities, agency relationships, commissions, lobbying, books and records, and financial controls, including the United States Foreign Corrupt Practices Act, the U.S. Travel Act, the UK Bribery Act 2010, and other anti-corruption laws, in each case, as amended.

1.8 "**Applicable Law**" means collectively all laws, rules, regulations, ordinances, decrees, judicial and administrative orders (and any license, franchise, permit, or similar right granted under any of the foregoing), and any policies and other requirements of any applicable Governmental Authority that govern or otherwise apply to a Party, including all Anti-Corruption Laws.

1.9 "**Approved Labeling**" means, with respect to the Licensed Product: (a) the Regulatory Authority-approved full prescribing information for the Licensed Product; and (b) the Regulatory Authority-approved labels and other written, printed, or graphic materials on any container, wrapper, or any package insert that is used with or for the Licensed Product.

1.10 "**Assigned Collaboration Know-How**" means any Collaboration Know-How developed or invented by Representatives of Partner or its Affiliates or its or their licensees (other than Kiniksa), Sublicensees, or Subcontractors, or any Persons contractually required to assign or license such Collaboration Know-How to Partner or any Affiliate of Partner, whether alone or jointly with others (including jointly with Kiniksa), that (a) [***] (b) [***] or (c) [***]

1.11 "**Assigned Collaboration Patent Rights**" means all Collaboration Patent Rights that Cover Assigned Collaboration Know-How.

1.12 "**Assigned Collaboration Technology**" means the Assigned Collaboration Know-How and the Assigned Collaboration Patent Rights.

1.13 "**Biosimilar Competition**" means, with respect to a Biosimilar Product in a country or region in the Territory and particular Calendar Quarter following the Biosimilar Launch Quarter for such Biosimilar Product in such country or region, the decrease in the Net Sales in such country or region for the Licensed Product during the applicable Calendar Quarter, as compared to the average quarterly Net Sales of the Licensed Product in such country or region during the four Calendar Quarters immediately preceding such Biosimilar Launch Quarter.

1.14 "**Biosimilar Launch Quarter**" means, with respect to a Biosimilar Product to the Licensed Product in a country or region in the Territory, the Calendar Quarter in which the First Commercial Sale of the applicable Biosimilar Product in such country or region occurred following the receipt of all necessary

Regulatory Approvals from the applicable Regulatory Authorities in such country or region to market and sell such Biosimilar Product as a therapeutic product for one or more Indication included in the Approved Labeling for the Licensed Product in such country or region.

1.15 "**Biosimilar Product**" means, with respect to the Licensed Product in a particular country or region, after receipt of Regulatory Approval of the Licensed Product in such country or region, any other therapeutic drug product designated for human use that [***].

1.16 "**Breach Notification**" has the meaning set forth in Section 15.2.2 (Termination for Material Breach).

1.17 "**Business Day**" means a day other than a Saturday, Sunday, or a day on which banking institutions in Boston, Massachusetts, Beijing, China, or Hong Kong are required by Applicable Law to remain closed.

1.18 "**Calendar Quarter**" means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30, and December 31.

1.19 "**Calendar Year**" means each 12-month period commencing on January 1.

1.20 "**Change of Control**" means, with respect to a Party, that: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of such Party, or if the percentage ownership of such Third Party in the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing more than 50% of the total voting power of all of the then outstanding voting securities of such Party; (b) any merger, consolidation, recapitalization, or reorganization of such Party is consummated that would result in shareholders or equity holders of such Party immediately prior to such transaction owning 50% or less of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; (c) the shareholders or equity holders of such Party approve any plan of complete liquidation of such Party, or an agreement for the sale or disposition by such Party of all or substantially all of such Party's assets, in each case, through one or more related transactions, other than to an Affiliate or pursuant to one or more related transactions that would result in shareholders or equity holders of such Party immediately prior to such transaction owning more than 50% of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; or (d) the sale or transfer to any Third Party, in one or more related transactions, of all or substantially all of such Party's consolidated assets taken as a whole.

1.21 "**Clinical Development**" has the meaning set forth in Section 1.47 (Development).

1.22 "**Clinical Supply Agreement**" has the meaning set forth in Section 7.1.1 (Development Supply).

1.23 "**Clinical Trial**" means any clinical trial in humans that is conducted in accordance with cGCP and is designed to generate data (a) under an IND, (b) to address a commitment or requirement under a Regulatory Approval or Reimbursement Approval (as applicable), or (c) to support an expansion of an Indication.

1.24 "**Collaboration Know-How**" means any Know-How developed or invented during the Term by Representatives of a Party or its Affiliates or its or their licensees, Sublicensees, or Subcontractors, or any Persons contractually required to assign or license such Know-How to a Party or any Affiliate of a Party, whether alone or jointly with Representatives of the other Party or its Affiliates or its or their

licensees, Sublicensees, or Subcontractors, or any Persons contractually required to assign or license such Know-How to the other Party or any Affiliate of the other Party, in each case, in the performance of activities under this Agreement.

1.25 "**Collaboration Patent Right**" means any Patent Right that (a) has a priority date after the Effective Date and (b) Covers any invention included in the Collaboration Know-How.

1.26 "**Collaboration Technology**" means Collaboration Know-How and Collaboration Patent Rights.

1.27 "**Commercial Supply Agreement**" has the meaning set forth in Section 7.1.2 (Commercial Supply).

1.28 "**Commercialization**" means with respect to any product, any and all activities directed to the marketing, promotion, distribution, pricing, reimbursement, import, export, offering for sale, and sale of such product and interacting with Regulatory Authorities following receipt of Regulatory Approval in the applicable country or region for such product regarding the foregoing, including seeking and maintaining any required Reimbursement Approval, but excluding any activities directed to Manufacturing, Development, or Medical Affairs. "**Commercialize**," "**Commercializing**," and "**Commercialized**" will be construed accordingly.

1.29 "**Commercialization Plan**" means, with respect to the Licensed Product, the written high-level strategic and tactical plans for the Commercialization activities for the Licensed Product to be conducted in the Territory, and budget associated with such activities, that will be prepared and updated by or on behalf of Partner as provided in Section 9.2 (Commercialization Plan), and will include for the Licensed Product in each country or region in the Territory: (a) the general strategies for promoting, marketing, and distributing the Licensed Product, including anticipated major advertising, public relations, and patient advocacy or education programs, (b) pre-launch Commercialization activities and the expected date of First Commercial Sale, (c) the nature of promotional activities anticipated, (d) non-binding summary-level market and sales forecasts for the Licensed Product, (e) non-binding projection of Net Sales for the Licensed Product, (f) plans regarding distribution and supply chain management, (g) reimbursement and pricing information and strategies, including information regarding reimbursement and patient support programs, (h) market access strategy, and (i) competitive positioning.

1.30 "**Commercially Reasonable Efforts**" means, with respect to the Exploitation of the Licensed Product by Partner, [***]. Notwithstanding the foregoing, in a determination of an expenditure of Commercially Reasonable Efforts, Partner may not take into account payments made or required to be made to Kiniksa (or received by Kiniksa) under this Agreement or other payments made or required to be made under this Agreement (that is, Partner may not apply lesser resources or efforts in support of the Licensed Product because it must make any payments hereunder).

1.31 "**Competitive Activities**" has the meaning set forth in Section 2.8.1 (Partner Exclusivity).

1.32 "**Competitive Infringement**" has the meaning set forth in Section 14.4.2(a)(ii) (Kiniksa First Right).

1.33 "**Competitive Product**" means any product, other than the Licensed Product, that [***].

1.34 "**Confidential Information**" means, subject to Section 11.3 (Exemptions), (a) Know-How and any technical, scientific, trade, research, manufacturing, business, financial, marketing, product, supplier, intellectual property, and other non-public or proprietary data or information (including

unpublished patent applications) that may be disclosed by one Party or its Affiliates to the other Party or its Affiliates pursuant to this Agreement (including information disclosed prior to the Effective Date pursuant to the Confidentiality Disclosure Agreement), regardless of whether such information is specifically marked or designated as confidential and regardless of whether such information is in written, oral, electronic, or other form, and (b) the terms of this Agreement.

1.35 "**Confidentiality Disclosure Agreement**" means the Confidentiality Disclosure Agreement by and between the Parties dated March 8, 2021 (as amended from time to time).

1.36 "**Continuing Know-How Transfer**" has the meaning set forth in Section 4.2 (Continuing Know-How Transfer).

1.37 "**Control**" or "**Controlled**" means the possession by a Party (whether by ownership, license, or otherwise other than pursuant to this Agreement) of, (a) with respect to any tangible Know-How, the legal authority or right to physical possession of such tangible Know-How, with the right to provide such tangible Know-How to the other Party on the terms set forth herein, (b) with respect to Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How, or other intellectual property rights, the legal authority or right to grant a license, sublicense, access, or right to use (as applicable) to the other Party under such Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How, or other intellectual property rights on the terms set forth herein, in each case ((a) and (b)), without breaching or otherwise violating the terms of any arrangement or agreement with a Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right to use, license, or sublicense and without being required to make any payment to any Third Party or incurring any payment obligations under any such arrangement or agreement, other than payment obligations pursuant to Third Party IP Agreements in accordance with Section 2.7.3 (Third Party In-Licenses) or if Kiniksa determines, in its sole discretion, that Partner need not be responsible for any costs associated with the grant of a sublicense thereunder, and (c) with respect to any product, the legal authority or right to grant an exclusive license or sublicense under Patent Rights that Cover such product or Know-How that relates to such product. Notwithstanding the foregoing, a Party and its Affiliates will not be deemed to "**Control**" any of the foregoing (a) – (c) that, (i) prior to the consummation of a Change of Control of such Party, is owned or in-licensed by a Third Party that becomes an Affiliate of such acquired Party (or that merges or consolidates with such Party) after the Effective Date as a result of such Change of Control and (ii) was not, at the time of such Change of Control already Controlled by such Party undergoing such Change of Control.

1.38 "**Controlling Party**" has the meaning set forth in Section 14.4.2(a)(v) (Step-In Rights).

1.39 "**Cover**" means, with respect to a particular subject matter at issue and a relevant Patent Right, that the manufacture, use, sale, offer for sale, or importation of such subject matter would fall within the scope of one or more claims in such Patent Right.

1.40 "**CPI**" means (a) with respect to Kiniksa, the Consumer Price Index-Urban Wage Earners and Clerical Workers, U.S. City Average, All Items 1982-84=100, published by the United States Department of Labor, Bureau of Labor Statistics (or its successor equivalent index), in the United States and (b) with respect to Partner, the consumer price index for Beijing as published by The National Bureau of Statistics of China.

1.41 "**CREATE Act**" has the meaning set forth in Section 14.2 (CREATE Act).

1.42 "**CRO**" means a contract research organization.

1.43 "**CSO**" means a contract sales organization.

1.44 "**Debarred/Excluded**" means any Person becoming debarred or suspended under 21 U.S.C. §335(a) or (b), the subject of a conviction described in Section 306 of the FD&C Act, excluded, or having previously been excluded, from a federal or governmental health care program, debarred from federal contracting, convicted of or pled *nolo contendere* to any felony, or to any federal or state legal violation (including misdemeanors) relating to prescription drug products or fraud, the subject to OFAC sanctions or on the OFAC list of specially designated nationals, or the subject of any similar sanction of any Governmental Authority in the Territory.

1.45 "**Deficient Site**" has the meaning set forth in Section 5.8.2 (Deficient Sublicensees or Sites and Replacement).

1.46 "**Deficient Sublicensee**" has the meaning set forth in Section 5.8.2 (Deficient Sublicensees or Sites and Replacement).

1.47 "**Development**" means, with respect to any product, any and all internal and external research, development and regulatory activities regarding such product, including (a) research, process development, non-clinical testing, toxicology, non-clinical activities, GLP toxicology and other preclinical studies (the conduct of those development activities described in the foregoing clause (a), "**Pre-Clinical Development**") and (b) Clinical Trials, preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct Clinical Trials and to obtain, support, or maintain Regulatory Approval of such product (such as post-marketing approval studies and observational studies for an indication, if required by any Regulatory Authority in any country in the Territory to support or maintain Regulatory Approval for a product in such indication in such country) (the conduct of Clinical Trials and the conduct of those regulatory activities described in the foregoing clause (b), to the extent related to the conduct of Clinical Trials, "**Clinical Development**") but, in each case of (a) and (b), excluding any activities directed to Manufacturing, Medical Affairs, or Commercialization. Development will include research, development, and regulatory activities for additional presentations or indications for a product after receipt of Regulatory Approval of such product, including Clinical Trials commenced following receipt of Regulatory Approval or any Clinical Trial to be conducted after receipt of Regulatory Approval that was mandated by the applicable Regulatory Authority as a condition of such Regulatory Approval with respect to an approved indication (such as post-marketing approval studies and observational studies, if required by any Regulatory Authority in any country in the Territory to support or maintain Regulatory Approval for a product in such country). "**Develop**," "**Developing**," and "**Developed**" will be construed accordingly.

1.48 "**Development Milestone Event**" has the meaning set forth in Section 10.2.1 (Development Milestone Events and Payments).

1.49 "**Development Milestone Payment**" has the meaning set forth in Section 10.2.1 (Development Milestone Events and Payments).

1.50 "**Disclosing Party**" has the meaning set forth in Section 11.1.1 (Duty of Confidence).

1.51 "**Dispute**" has the meaning set forth in Section 16.1 (Dispute Resolution; General).

1.52 "**Dollar**" means the U.S. dollar, and "$" will be interpreted accordingly.

1.53 "**Effective Date**" has the meaning set forth in the Preamble.

1.54 "**Ex-Territory Infringement**" has the meaning set forth in Section 14.4.1 (Patent Enforcement; Notice).

1.55 "**Examined Party**" has the meaning set forth in Section 10.11 (Financial Records and Audits).

1.56 "**Executive Officers**" has the meaning set forth in Section 3.5.3 (Decisions of the JSC).

1.57 "**Existing Product Trademarks**" means those trademarks Controlled by Kiniksa and used in connection with the Commercialization of the Licensed Product as of the Effective Date. The Existing Product Trademarks as of the Effective Date are set forth on Schedule 1.57.

1.58 "**Exploit**" means to make, have made, use, import, export, offer to sell, sell, Develop, Manufacture, perform Medical Affairs activities for, Commercialize, or otherwise exploit. "**Exploitation**" will be construed accordingly.

1.59 "**FD&C Act**" means the United States Federal Food, Drug and Cosmetic Act, as amended from time to time, together with any rules, regulations, and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.60 "**FDA**" means the United States Food and Drug Administration or any successor entity thereto having essentially the same function.

1.61 "**Field**" means all human diagnostic, prophylactic, and therapeutic uses, subject to any restrictions or limitations in any Third Party IP Agreement.

1.62 "**First Commercial Sale**" means, with respect to the Licensed Product or Biosimilar Product (as applicable) in any country or region, the first sale of the Licensed Product or Biosimilar Product (as applicable) to a Third Party for distribution, use, or consumption in such country or region after receipt of Regulatory Approval for the Licensed Product in such country or region. First Commercial Sale excludes any sale or other distribution of the Licensed Product for use in a Clinical Trial or other Development activity or for compassionate or named-patient use, in each case, sold at or below cost of goods sold.

1.63 "**Force Majeure**" has the meaning set forth in Section 17.4 (Force Majeure).

1.64 "**FTE**" means the equivalent of the work of one duly qualified employee of a Party full time for one year (consisting of a total of [***] hours per year) carrying out Development, Manufacturing, Medical Affairs activities, or other scientific or technical work under this Agreement. Overtime and work on weekends, holidays, and the like, in each case, will not be counted with any multiplier (*e.g.*, time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution. The portion of an FTE billable by a Party for one individual during a given accounting period will be determined by dividing the number of hours worked directly by such individual on the work to be conducted under this Agreement during such accounting period and the number of FTE hours applicable for such accounting period based on [***] working hours per Calendar Year.

1.65 "**FTE Rate**" means the amount for an FTE per Calendar Year, which for the Calendar Year ending on December 31, 2022 will be (a) with respect to Kiniksa, $[***] per FTE; and (b) with respect to Partner, $[***] per FTE, in each case, pro-rated for the period beginning on the Effective Date and ending on December 31, 2022. Beginning on January 1, 2023 and on January 1 of each subsequent Calendar Year during the Term, each FTE Rate is subject to annual adjustment by the percentage increase or decrease in

the applicable CPI comparing the levels of the applicable CPI as of December 31 of the two most recently completed Calendar Years.

1.66 "**Fully Burdened Manufacturing Cost**" means, with respect to the Licensed Product, in each case, supplied by or on behalf of Kiniksa or its Affiliates hereunder:

(a) if and to the extent the Licensed Product (or any precursor or intermediate thereof), as applicable, is Manufactured by a Third Party, the amounts paid by Kiniksa or its Affiliate to such Third Party for the Licensed Product as invoiced to, or otherwise paid by, Kiniksa or its Affiliate [***]to be calculated using methodology that is in accordance with GAAP and consistently applied by Kiniksa or its Affiliate throughout its operations (but for clarity, not the capital expenditures themselves); *and*

(b) if and to the extent the Licensed Product (or any precursor or intermediate thereof), as applicable, is Manufactured by Kiniksa or its Affiliate, [***] Such fully burdened costs will be calculated in accordance with applicable Accounting Standards, consistently applied.

1.67 "**GAAP**" means United States generally accepted accounting principles, consistently applied.

1.68 "**GCP**" or "**cGCP**" means all applicable current good clinical practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Trials, including, as applicable (a) as set forth in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonized Tripartite Guideline for Good Clinical Practice E6 (the "**GCP Guideline**") and any other guidelines for good clinical practice for trials on medicinal products in the Territory, (b) the Declaration of Helsinki (2013) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards), and 312 (Investigational New Drug Application), as may be amended from time to time, and (d) the equivalent Applicable Law in each country or region in the Territory, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

1.69 "**Global Brand Elements**" has the meaning set forth in Section 14.9.1 (Global Brand Elements).

1.70 "**Global Brand Strategy**" has the meaning set forth in Section 9.2 (Commercialization Plan).

1.71 "**Global Clinical Trial**" means a Clinical Trial for the Licensed Product the data from which is intended to be used to obtain or support Regulatory Approval both inside and outside of the Territory.

1.72 "**Global Development Plan**" has the meaning set forth in Section 5.3 (Global Development Plan).

1.73 "**GLP**" or "**cGLP**" means all applicable good laboratory practice standards, including, as applicable, as set forth in the then-current good laboratory practice standards promulgated or endorsed by the U.S. Food and Drug Administration, as defined in 21 C.F.R. Part 58, and the equivalent Applicable Law in each country or region in the Territory, each as may be amended and applicable from time to time.

1.74 "**Governmental Authority**" means any federal, national, state, provincial, or local government, or political subdivision thereof, or any multinational organization or any authority, agency, regulatory body, or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, or any court or tribunal (or any department, bureau or division of any of the foregoing, or any governmental arbitrator or arbitral body). Governmental Authorities include all Regulatory Authorities.

1.75 "**ICC Rules**" has the meaning set forth in Section 16.5 (Arbitration).

1.76 "**IDL**" has the meaning set forth in Section 1.112 (Marketing Authorization Application).

1.77 "**IFRS**" means International Financial Reporting Standards, consistently applied.

1.78 "**IND**" means an Investigational New Drug application required pursuant to 21 C.F.R. Part 312 required to commence human clinical trials in the U.S. or, to the extent required in any country or region in the Territory, any equivalent application in such country or region, and including all supplements or amendments that may be filed with respect to the foregoing.

1.79 "**Indemnified Party**" has the meaning set forth in Section 13.3 (Indemnification Procedure).

1.80 "**Indemnifying Party**" has the meaning set forth in Section 13.3 (Indemnification Procedure).

1.81 "**Indication**" means a separate and distinct disease, disorder, or medical condition that the Licensed Product is intended to treat, prevent, cure, or ameliorate in the indication section of the Approved Labeling for the Licensed Product, or that is the subject of a Clinical Trial and where it is intended that the data and results of such Clinical Trial (if successful) will be used to support a Regulatory Submission and Regulatory Approval that is intended to result in distinct labeling in the indication section of the Approved Labeling relevant to usage of the Licensed Product in such disease, disorder, or medical condition that is separate and distinct from another disease, disorder, or medical condition.

1.82 "**Initial Know-How Transfer**" has the meaning set forth in Section 4.1 (Initial Know-How Transfer).

1.83 "**Initiate**" means, with respect to a Clinical Trial, the first patient, first visit in such Clinical Trial.

1.84 "**Invoiced Sales**" has the meaning set forth in Section 1.120 (Net Sales).

1.85 "**JDC**" has the meaning set forth in Section 3.3.1 (Formation and Purpose of the JDC).

1.86 "**Joint Collaboration Know-How**" means all Collaboration Know-How, other than Assigned Collaboration Know-How, developed or invented jointly by Representatives of a Party or its Affiliates or its or their licensees, Sublicensees, or Subcontractors, or any Persons contractually required to assign or license such Collaboration Know-How to such Party or any Affiliate of such Party, on the one hand, and Representatives of the other Party or its Affiliates or its or their licensees, Sublicensees, or Subcontractors, or any Persons contractually required to assign or license such Collaboration Know-How to such Party or any Affiliate of such Party, on the other hand.

1.87 "**Joint Collaboration Patent Rights**" means all Collaboration Patent Rights that Cover Joint Collaboration Know-How.

1.88 "**Joint Collaboration Technology**" means the Joint Collaboration Know-How and the Joint Collaboration Patent Rights.

1.89 "**JSC**" has the meaning set forth in Section 3.2.1 (Formation and Purpose of JSC).

1.90 "**JSC Chairperson**" has the meaning set forth in Section 3.2.1 (Formation and Purpose of JSC).

1.91 "**Key Country**" has the meaning set forth in Section 6.2.3 (Review of Regulatory Submissions).

1.92 "**Kiniksa**" has the meaning set forth in the Preamble.

1.93 "**Kiniksa Collaboration Know-How**" means any Collaboration Know-How developed or invented solely by Representatives of Kiniksa or its Affiliates or its or their licensees (other than Partner), Sublicensees (other than Partner), or Subcontractors, or any Persons contractually required to assign or license such Collaboration Know-How to Kiniksa or any Affiliate of Kiniksa.

1.94 "**Kiniksa Collaboration Patent Rights**" means any Patent Rights that Cover any Kiniksa Collaboration Know-How.

1.95 "**Kiniksa Collaboration Technology**" means the Kiniksa Collaboration Know-How and the Kiniksa Collaboration Patent Rights.

1.96 "**Kiniksa Identified Rights**" has the meaning set forth in Section 2.7.1 (Kiniksa Identified Rights).

1.97 "**Kiniksa Indemnitee(s)**" has the meaning set forth in Section 13.1 (Indemnification; By Partner).

1.98 "**Kiniksa Know-How**" means any Know-How that is Controlled by Kiniksa or any of its Affiliates as of the Effective Date or during the Term (including Kiniksa Collaboration Know-How and Kiniksa's interest in the Joint Collaboration Know-How), and [***] to perform Clinical Development, Pre-Clinical Development (solely to the extent permitted in accordance with Section 5.2.2 (Pre-Clinical Development)), or Medical Affairs with respect to, or Commercialize the Licensed Product in the Territory in the Field, but expressly excluding Kiniksa Manufacturing Know-How.

1.99 "**Kiniksa Manufacturing Know-How**" means any Know-How that is Controlled by Kiniksa or any of its Affiliates as of the Effective Date or during the Term (including Kiniksa Collaboration Know-How), and is necessary for the Manufacturing of the Licensed Product in the Territory in the Field.

1.100 "**Kiniksa Manufacturing Patent Rights**" means any Patent Rights that are Controlled by Kiniksa or any of its Affiliates as of the Effective Date or during the Term (including Kiniksa Collaboration Patent Rights), and are necessary for the Manufacturing of the Licensed Product in the Territory in the Field.

1.101 "**Kiniksa Manufacturing Technology**" means all Kiniksa Manufacturing Know-How and Kiniksa Manufacturing Patent Rights.

1.102 "**Kiniksa P&L Process and Specifications**" has the meaning set forth in Section 4.1 (Initial Know-How Transfer).

1.103 "**Kiniksa Patent Right Infringement**" has the meaning set forth in Section 14.4.1 (Patent Enforcement; Notice).

1.104 "**Kiniksa Patent Rights**" means any Patent Right that (a) is Controlled by Kiniksa or any of its Affiliates as of the Effective Date or during the Term (including Kiniksa Collaboration Patent Rights and Joint Collaboration Patent Rights), and (b) is [***] (or, with respect to patent applications, would be [***] if such patent applications were to issue as patents) to perform Clinical Development or Pre-Clinical Development (solely to the extent permitted in accordance with Section 5.2.2 (Pre-Clinical Development)) or Medical Affairs with respect to, or Commercialize, the Licensed Product in the Territory in the Field (including any such Patent Right that Covers a composition of matter (*e.g.*, a drug formulation) of the Licensed Product), but expressly excluding Kiniksa Manufacturing Patent Rights. Schedule 1.104 (Kiniksa Patent Rights) sets forth the Kiniksa Patent Rights that are owned or exclusively licensed by Kiniksa or its Affiliates as of the Effective Date in the Territory.

1.105 "**Kiniksa Technology**" means the Kiniksa Know-How and Kiniksa Patent Rights.

1.106 "**Know-How**" mean any and all proprietary technical, scientific, or other information, data (including physical, chemical, biological, toxicological, pharmacological, clinical and veterinary data), test results, knowledge, know-how, techniques, practices, processes, discoveries, inventions, specifications, strategies, plans, dosage regimens, drug formulations, control assays, product specifications, analytical and quality control data, marketing, pricing, distribution cost and sales data or descriptions, designs (including study designs), trade secrets, Regulatory Submissions, and other technology, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or otherwise protected by trade secret law, in each case, that is not in the public domain or otherwise generally known.

1.107 "**Knowledge**" means the actual knowledge, without any inquiry, investigation, or obligation to conduct any freedom to operate analysis, of (a) with respect to Kiniksa, the Chief Intellectual Property Officer, the Chief Medical Officer, and the Chief Operating Officer, in each case, of Kiniksa or its Affiliates; and (b) with respect to Partner, the Chief Medical Officer, the Chief Business Officer, and the General Counsel.

1.108 "**Licensed Product**" means any product Controlled by Kiniksa or its Affiliates that has rilonacept as its sole active ingredient (a) in the form Commercialized by Kiniksa as of the Effective Date of this Agreement (*i.e.*, the 160 mg dosage form), (b) in any other form that is being Commercialized by Kiniksa in the United States, or (c) to the extent permitted under the Regeneron License Agreement, in any other form as agreed in writing by the Parties.

1.109 "**Listing Patent Rights**" has the meaning set forth in Section 14.6 (Patent Listings).

1.110 "**Losses**" means damages, debts, obligations, and other liabilities, losses, claims, taxes, interest obligations, deficiencies, judgments, assessments, fines, fees, penalties, or expenses (including amounts paid in settlement, interest, court costs, costs of investigators, reasonable fees and expenses of attorneys, accountants, financial advisors, consultants, and other experts, and other expenses of litigation).

1.111 "**Manufacture**" means with respect to any product, any and all activities directed to manufacturing, processing, packaging, labeling, filling, finishing, assembly, quality assurance, quality control, testing, and release, shipping, supply, or storage of such product (or any components or process

steps involving such product), as the case may be, including qualification, validation, and scale-up, preclinical, clinical, and commercial manufacture and analytic development, product characterization, and stability testing, but excluding any activities directed to Development, Medical Affairs, or Commercialization. "**Manufacturing**" and "**Manufactured**" will be construed accordingly.

1.112 "**Marketing Authorization Application**" or "**MAA**" means any new drug application, biologics license application, or other marketing authorization application, in each case, filed with the applicable Regulatory Authority in a country or other regulatory jurisdiction, which application is required to commercially market or sell a pharmaceutical or biologic product in such country or jurisdiction (and any amendments thereto). In the context of imported drugs in the PRC, MAA is also known as the Import Drug License ("**IDL**") application.

1.113 "**Marketing Authorization Holder**" has the meaning set forth in Section 6.2.1 (Obtaining and Maintaining Regulatory Approvals).

1.114 "**Material Adverse Impact**" means, with respect to any matter, that such matter could (a) have a materially adverse impact on the Development or Commercialization of the Licensed Product outside of the Territory (including any concern related to quality, safety, toxicity, or side effects), or (b) be inconsistent with Kiniksa's global regulatory strategy or Global Development Plan for the Licensed Product.

1.115 "**Material Subcontractor**" has the meaning set forth in Section 2.2.3 (Right to Subcontract).

1.116 "**Medical Affairs**" means activities conducted by a Party's medical affairs department (or, if a Party does not have a medical affairs department, the equivalent function thereof), including communications with key opinion leaders and clinical or scientific thought leaders, medical education, symposia, advisory boards (to the extent related to medical affairs or clinical guidance), activities performed in connection with patient registries, and other medical programs and communications, including educational grants, research grants (including those related to investigator-initiated studies), and charitable donations to the extent related to medical affairs and not to other activities that involve the promotion, marketing, sale, or other Commercialization of the Licensed Product and are not conducted by a Party's medical affairs (or equivalent) department. Medical Affairs excludes any activities directed to Manufacturing, Development, or Commercialization.

1.117 "**Medical Affairs Plan**" means, with respect to the Licensed Product, the written high-level strategic and tactical plans for the Medical Affairs activities for the Licensed Product to be conducted in the Territory that will be prepared and updated by Partner as provided in Section 8.1 (Medical Affairs Plan).

1.118 "**Milestone Events**" has the meaning set forth in Section 10.2.3 (Notification of Milestone Events).

1.119 "**Milestone Payments**" has the meaning set forth in Section 10.2.3 (Notification of Milestone Events).

1.120 "**Net Sales**" means with respect to the Licensed Product for any period, the gross amounts invoiced by Partner or its Affiliates to Third Parties or Sublicensees for sales of the Licensed Product in the Territory (the "**Invoiced Sales**") less the following deductions:

(a) [***];

(b) [***];

(c) [***];

(d) [***]; and

(e) [***].

For the avoidance of doubt, (a) in the case of any sale or other disposal of the Licensed Product between or among Partner and its Affiliates for resale, invoiced sales and Net Sales will be calculated only on the amount invoiced on the first arm's length sale thereafter to a Third Party; and (b) Net Sales will not be imputed to transfers of Licensed Product (i) without consideration or for nominal consideration for use in any Clinical Trials reasonably necessary to comply with any Applicable Law or regulation or any request by a Regulatory Authority in the Territory, (ii) for any *bona fide* charitable, compassionate use or indigent patient, or other similar program purpose where the Licensed Product is sold at or below cost of goods sold, or (iii) in commercially reasonable quantities as samples for promotional purposes.

Subject to the above, Net Sales will be calculated in accordance with the standard internal policies and procedures of Partner, its Affiliates or its or their Sublicensees, which must be in accordance with U.S. GAAP or, if applicable, IFRS.

1.121 "**New Development**" has the meaning set forth in Section 5.4 (New Development by Partner).

1.122 "**New Development Activities**" has the meaning set forth in Section 5.4 (New Development by Partner).

1.123 "**New Development Proposal**" has the meaning set forth in Section 5.4 (New Development by Partner).

1.124 "**New Kiniksa In-Licensed Rights**" has the meaning set forth in Section 2.7.3 (Third Party In-Licenses).

1.125 "**New Territory-Specific Development Activities**" has the meaning set forth in Section 5.4 (New Development by Partner).

1.126 "**New Third Party IP Agreement**" has the meaning set forth in Section 2.7.3 (Third Party In-Licenses).

1.127 "**NMPA**" means the National Medical Products Administration of the People's Republic of China, and local counterparts thereto, and any successor agency or authority thereto having substantially the same function.

1.128 "**OFAC**" means the Office of Foreign Assets Control of the United States Department of the Treasury or any successor agency thereto.

1.129 "**Ongoing Global Clinical Trial**" means any Global Clinical Trial for the Licensed Product that is ongoing as of the Effective Date or Initiated within [***] months following the Effective Date.

1.130 "**Partner**" has the meaning set forth in the Preamble.

1.131 "**Partner Collaboration Know-How**" means Collaboration Know-How, other than Assigned Collaboration Know-How, developed or invented solely by Representatives of Partner or its Affiliates or its or their licensees (other than Kiniksa), Sublicensees, or Subcontractors, or any Persons contractually required to assign or license such Collaboration Know-How to Partner or any Affiliate of Partner.

1.132 "**Partner Collaboration Patent Rights**" means any Collaboration Patent Right that Covers Partner Collaboration Know-How.

1.133 "**Partner Collaboration Technology**" means the Partner Collaboration Know-How and Partner Collaboration Patent Rights.

1.134 "**Partner Identified Rights**" has the meaning set forth in Section 2.7.2 (Partner Identified Rights).

1.135 "**Partner Indemnitee(s)**" has the meaning set forth in Section 13.2 (Indemnification; By Kiniksa).

1.136 "**Partner Know-How**" means all Know-How that is Controlled by Partner or any of its Affiliates as of the Effective Date or during the Term, and [***] to Exploit the Licensed Product, including Partner Collaboration Know-How and Partner's interest in the Joint Collaboration Know-How.

1.137 "**Partner Patent Rights**" means all Patent Rights that are Controlled by Partner or any of its Affiliates as of the Effective Date or during the Term, and [***] (or, with respect to patent applications, would be [***] if such patent applications were to issue as patents) to Exploit the Licensed Product, including all Partner Collaboration Patent Rights and Partner's interest in the Joint Collaboration Patent Rights.

1.138 "**Partner Technology**" means Partner Know-How and Partner Patent Rights.

1.139 "**Party**" or "**Parties**" has the meaning set forth in the Preamble.

1.140 "**Patent Challenge**" has the meaning set forth in Section 15.2.3 (Termination for Patent Challenge).

1.141 "**Patent Prosecution**" means activities directed to (a) preparing, filing, and prosecuting applications (of all types) for any Patent Right, (b) maintaining any Patent Right, and (c) deciding whether to abandon or maintain any Patent Right.

1.142 "**Patent Rights**" means any and all (a) patents, patent applications, and utility models in any country or jurisdiction, including provisional applications, priority applications, and international applications, (b) patent applications filed either from such patents or patent applications or from a patent application claiming priority from any of these, including divisionals, provisionals, continuations, and continuations-in-part, (c) patents that have issued or in the future issue from the foregoing patent applications, (d) substitutions, renewals, registrations, confirmations, revalidations, reissues, and re-examinations of the foregoing patents or patent applications, and (e) extensions, restorations, supplemental protection certificates, and the like based on any of the foregoing patents or patent applications.

1.143 "**Patent Term Adjustment**" has the meaning set forth in Section 14.7 (Patent Term Extensions).

1.144 "**Patent Term Extension**" has the meaning set forth in Section 14.7 (Patent Term Extensions).

1.145 "**Paying Party**" has the meaning set forth in Section 10.12.2 (Tax Cooperation).

1.146 "**Person**" means any corporation, limited or general partnership, limited liability company, joint venture, joint stock company, trust, unincorporated association, governmental body, authority, bureau, or agency, or any other entity or body, or an individual.

1.147 "**Phase III Clinical Trial**" means a clinical trial in humans in a manner that is generally consistent with 21 C.F.R. § 312.21(c), as amended (or its successor regulation), or, with respect to any other country or region, the equivalent of such a clinical trial in such other country or region.

1.148 "**Pivotal Clinical Trial**" means any (a) Phase III Clinical Trial, or (b) other Clinical Trial of a pharmaceutical or biologic product on a sufficient number of patients, the results of which, together with prior data and information concerning such product, are sufficient without any additional Clinical Trial, to meet the evidentiary standard for demonstrating the safety, purity, efficacy, and potency of such active substance of such product established by a Regulatory Authority in any particular jurisdiction and that is intended to support the filing of an MAA with a Regulatory Authority in such jurisdiction. Notwithstanding any provision to the contrary set forth in this Agreement, treatment of patients as part of an expanded access program, compassionate sales or use program (including named patient program or single patient program), or an indigent program, in each case, will not be included in determining whether or not a Clinical Trial is a Pivotal Clinical Trial.

1.149 "**PRC**" means the People's Republic of China, which, for purposes of this Agreement, does not include Hong Kong Special Administrative Region, Macau Special Administrative Region, or Taiwan.

1.150 "**Preapproved Subcontractor**" means any Subcontractor to be engaged by Partner to perform its obligations or exercise its rights under this Agreement as further described in Section 2.2.3 (Right to Subcontract) and identified as a Subcontractor in a Territory Development Plan or Global Development Plan that is approved by the JSC.

1.151 "**Pre-Clinical Development Plan**" has the meaning set forth in Section 5.2.2 (Territory Pre-Clinical Development).

1.152 "**Product Marks**" has the meaning set forth in Section 14.9.2 (Product Marks in the Territory).

1.153 "**Public Official**" means (a) any officer, employee or representative of any regional, federal, state, provincial, county or municipal government or government department, agency or other division; (b) any officer, employee or representative of any commercial enterprise that is owned or controlled by a government, including any state-owned or controlled veterinary, laboratory or medical facility; (c) any officer, employee or representative of any public international organization, such as the International Monetary Fund, the United Nations or the World Bank; and (d) any person acting in an official capacity for any government or government entity, enterprise, or organization identified above.

1.154 "**Publication**" has the meaning set forth in Section 11.5 (Publications).

1.155 "**Quarterly Inventory Report**" has the meaning set forth in Section 10.3.5(a) (Quarterly Inventory Report).

1.156 "**Receiving Party**" has the meaning set forth in Section 11.1.1 (Duty of Confidence).

1.157 "**Recipient**" has the meaning set forth in Section 10.12.2 (Tax Cooperation).

1.158 "**Regeneron License Agreement**" means that certain License Agreement by and between Regeneron Pharmaceuticals, Inc. and Kiniksa Pharmaceuticals, Ltd. effective as of September 25, 2017, as amended by Amendment No. 1 effective as of October 29, 2020, as assigned from Kiniksa Pharmaceuticals, Ltd. to Kiniksa Pharmaceuticals (UK), Ltd. as of January 7, 2021, and as amended by Amendment No. 2 effective as of April 14, 2021, as the same may be amended in accordance with the terms of this Agreement.

1.159 "**Regulatory Approval**" means, with respect to a particular country or other regulatory jurisdiction, any approval of an MAA or other approval, product, or establishment license, registration, or authorization of any Regulatory Authority necessary for the commercial marketing or sale of a pharmaceutical or biologic product in such country or other regulatory jurisdiction, excluding, in each case, Reimbursement Approval.

1.160 "**Regulatory Authority**" means any applicable Governmental Authority with jurisdiction or authority over the Development, Manufacture, Commercialization, or other Exploitation (including Regulatory Approval or Reimbursement Approval) of pharmaceutical or biologic products in a particular country or other regulatory jurisdiction, including the NMPA, and any corresponding national or regional regulatory authorities.

1.161 "**Regulatory Exclusivity**" means any exclusive marketing rights or data protection or other exclusivity rights conferred by any Regulatory Authority with respect to a pharmaceutical or biologic product in a particular country or other regulatory jurisdiction, but in all cases excluding Patent Rights.

1.162 "**Regulatory Submissions**" means any filing, application, or submission with any Regulatory Authority in support of Developing, Manufacturing, or Commercializing a pharmaceutical or biologic product (including to obtain, support, or maintain Regulatory Approval from that Regulatory Authority) and any proposed Approved Labeling, and all correspondence or communication with or from the relevant Regulatory Authority, as well as minutes of any substantive meetings, telephone conferences, or discussions with the relevant Regulatory Authority. Regulatory Submissions include all INDs, MAAs, and other applications for Regulatory Approval and their equivalents.

1.163 "**Reimbursement Approval**" means an approval, agreement, determination, or other decision by the applicable Governmental Authority that establishes prices charged to end-users for pharmaceutical or biologic products at which a particular pharmaceutical or biologic product will be reimbursed by the Regulatory Authorities or other applicable Governmental Authorities in the Territory.

1.164 "**Replacement Site**" has the meaning set forth in Section 5.8.2 (Deficient Sublicensees or Sites and Replacement).

1.165 "**Representative**" means any employee, officer, contractor, consultant, or agent of a Party.

1.166 "**Required Pre-Clinical Development**" has the meaning set forth in Section 5.2.2 (Territory Pre-Clinical Development).

1.167 "**Review Period**" has the meaning set forth in Section 11.5 (Publications).

1.168 "**Royalty Patent Rights**" means the Kiniksa Patent Rights and the Kiniksa Manufacturing Patent Rights.

1.169 "**Royalty Payments**" has the meaning set forth in Section 10.3.1 (Royalty Rates).

1.170 "**Royalty Report**" has the meaning set forth in Section 10.3.4 (Royalty Reports and Payments).

1.171 "**Royalty Term**" has the meaning set forth in Section 10.3.2 (Royalty Term).

1.172 "**Safety Agreement**" has the meaning set forth in Section 6.6.1 (Adverse Events Reporting; Safety Agreements).

1.173 "**Sales Milestone Events**" has the meaning set forth in Section 10.2.2 (Sales Milestone Events and Payments).

1.174 "**Sales Milestone Payments**" has the meaning set forth in Section 10.2.2 (Sales Milestone Events and Payments).

1.175 "**Selected Territory GCT Countries**" has the meaning set forth in Section 5.3 (Global Development Plan).

1.176 "**Status Quo Item**" has the meaning set forth in Section 3.6.2(a) (No Change; Status Quo).

1.177 "**Subcontractor**" means (a) a Third Party contractor engaged by a Party to perform certain obligations or exercise certain rights of such Party under this Agreement on a fee-for-service basis (including CROs, and CSOs), or (b) a Third Party Distributor. A Subcontractor of Partner may be deemed a Sublicensee for purposes of this Agreement if such Subcontractor requires a sublicense under the rights granted to Partner in Section 2.1 (License Grants to Partner) to perform the applicable activities for which they were engaged.

1.178 "**Sublicensee**" means any Person (a) with respect to Partner, to whom Partner grants a sublicense of, or other authorization or permission granted under, the rights granted to Partner in Section 2.1 (License Grants to Partner), including any Subcontractor (to the extent such Subcontractor requires a sublicense under the rights granted to Partner in Section 2.1 (License Grants to Partner) to perform the applicable activities for which they were engaged), and (b) with respect to Kiniksa, to whom Kiniksa grants a sublicense of, or other authorization or permission granted under, the rights granted to Kiniksa in Section 2.3 (License Grant to Kiniksa).

1.179 "**Subsidiary**" means, with respect to a Party, any Person that is controlled by such Party. For the purpose of this definition only, "control" (including, with correlative meaning, the terms "controlled by" and "under the common control") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of any Person, whether by the ownership of more than 50% of the voting security of such Person, by contract or otherwise. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than 50%, and that in such case such lower percentage will be substituted in the preceding sentence; *provided* that such foreign investor has the power to direct the management and policies of such entity.

1.180 "**Tax**" or "**Taxes**" means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including any interest thereon), including value add, sales, excise or similar taxes ("**VAT**").

1.181 "**Technology Transfer**" has the meaning set forth in Section 4.2 (Continuing Know-How Transfer).

1.182 "**Term**" has the meaning set forth in Section 15.1 (Term).

1.183 "**Territory**" means, subject to Section 15.2.4 (Termination in [***]), Asia Pacific Region (the People's Republic of China, Hong Kong SAR, Macao SAR, Taiwan Region, South Korea, Indonesia, Singapore, The Philippines, Thailand, Australia, Bangladesh, Bhutan, Brunei, Burma, Cambodia, India, Laos, Malaysia, Maldives, Mongolia, Nepal, New Zealand, Sri Lanka, and Vietnam).

1.184 "**Territory Development**" has the meaning set forth in Section 5.1 (Development Diligence and Responsibilities).

1.185 "**Territory Development Plan**" has the meaning set forth in Section 5.2.1 (Territory Clinical Development).

1.186 "**Territory Sponsor**" means, with respect to a Territory-Specific Clinical Trial or a Global Clinical Trial for the Licensed Product to be conducted at sites in the Territory, the Party that holds the IND from the applicable Regulatory Authority in the Territory for such Clinical Trial in its name.

1.187 "**Territory-Specific Clinical Trial**" means a Clinical Trial for the Licensed Product, the data from which at the time of commencement of such Clinical Trial is intended to be used to obtain Regulatory Approval in the Territory but not to obtain Regulatory Approval outside of the Territory.

1.188 "**Third Party**" means any Person other than a Party or an Affiliate of a Party.

1.189 "**Third Party Claims**" means collectively, any and all Third Party demands, claims, actions, suits, and proceedings (whether criminal or civil, in contract, tort, or otherwise).

1.190 "**Third Party Distributor**" means any Third Party that purchases Licensed Product from Partner or its Affiliates or Sublicensees, takes title to the Licensed Product, and distributes the Licensed Product directly to customers, but does not Develop, Manufacture, or otherwise Commercialize the Licensed Product and does not make any upfront, milestone, royalty, profit-share, or other payment to Partner or its Affiliates or Sublicensees, other than payment for the purchase of Licensed Product for resale.

1.191 "**Third Party IP Agreements**" has the meaning set forth in Section 2.7.3 (Third Party In-Licenses).

1.192 "**United States**" or "**U.S.**" means the United States of America and its territories and possessions.

1.193 "**Valid Claim**" means, with respect to a particular country or region, (a) a claim of an issued and unexpired patent (as may be extended through supplementary protection certificate or patent term extension or the like) that, in such country or region, has not been revoked, held invalid, or unenforceable by a patent office or other Governmental Authority of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period) and that has not been disclaimed, denied, or admitted to be invalid or unenforceable through reissue, re-examination, or disclaimer or otherwise; or (b) a pending claim of an unissued, pending patent application in such country or region that has not been pending for more than [***] years since the date of the first response on the merits received from the relevant patent office regarding such application, *provided* that such [***] year period will be tolled for the duration of any adverse proceeding (*e.g.*, Third Party

oppositions or any appeal of an adverse determination against the Valid Claim) with respect to the patent application at issue.

1.194 "**VAT**" has the meaning set forth in Section 1.180 (Tax).

ARTICLE 2
LICENSES

2.1 License Grants to Partner.

2.1.1 **In the Territory**. Subject to the terms of this Agreement (including Kiniksa's retained rights set forth in Section 2.4 (No Implied Licenses; Retained Rights)), Kiniksa hereby grants to Partner (i) an exclusive, royalty-bearing license, with the right to grant sublicenses solely in accordance with Section 2.2 (Sublicensing and Subcontractors), under its interest in the Kiniksa Technology to perform Clinical Development and Medical Affairs with respect to and Commercialize the Licensed Product in the Field in the Territory and (ii) a non-exclusive license, with the right to grant sublicenses solely in accordance with Section 2.2 (Sublicensing and Subcontractors), under its interest in the Kiniksa Technology to perform Required Pre-Clinical Development in the Field in the Territory solely to the extent permitted under and in accordance with Section 5.2.2 (Territory Pre-Clinical Development), in each case of (i) and (ii), in accordance with the terms of this Agreement. In addition, subject to the terms of this Agreement (including Kiniksa's retained rights set forth in Section 2.4 (No Implied Licenses; Retained Rights)), Kiniksa hereby grants to Partner a non-exclusive, royalty-bearing license, with the right to grant sublicenses solely in accordance with Section 2.2 (Sublicensing and Subcontractors), under its interest in the Kiniksa Technology solely to package and label the Licensed Product in the Territory solely for sale and use of the Licensed Product in the Territory.

2.1.2 **Trademark License Grant**. Subject to the terms of this Agreement (including Kiniksa's retained rights set forth in Section 2.4 (No Implied Licenses; Retained Rights)), Kiniksa hereby grants to Partner (a) an exclusive sublicense under its interest in the Product Marks and the Global Brand Elements to perform Pre-Clinical Development of to the extent permitted under and in accordance with Section 5.2.2 (Pre-Clinical Development), Clinical Development of, and Commercialize, the Licensed Product in the Field in the Territory, and (b) a non-exclusive sublicense under its interest in the Product Marks and Global Brand Elements solely to package and label the Licensed Product in the Field in the Territory solely for sale and use of the Licensed Product in the Territory.

2.1.3 **Third Party Rights**. In addition to the other terms and conditions of this Agreement, the licenses granted hereunder are subject to the terms of (a) all New Third Party IP Agreements (and amendments thereto) as further described in, and solely to the extent such New Third Party IP Agreements (and amendments thereto) are entered into in accordance with, Section 2.6.2 (Third Party IP Agreement Amendments) and Section 2.7.3 (Third Party In-Licenses) and (b) the Regeneron License Agreement.

2.2 Sublicensing and Subcontractors.

2.2.1 **Right to Sublicense**. Subject to the terms of this Agreement, Partner will have the right to grant sublicenses of the rights granted under Section 2.1 (License Grants to Partner):

(a) to (i) Preapproved Subcontractors (to the extent such Preapproved Subcontractors require a sublicense under the rights granted to Partner in Section 2.1 (License Grants to Partner) to perform the applicable activities for which they were engaged) and, (ii) subject to Kiniksa's prior written consent, not to be unreasonably withheld, conditioned, or delayed, to other Subcontractors (to the extent such other Subcontractors require a sublicense under the rights granted to Partner in Section 2.1 (License Grants to Partner) to perform the applicable activities for which they were engaged);

(b) subject to Kiniksa's prior written approval, not to be unreasonably withheld, conditioned, or delayed, to (i) Partner's Subsidiaries or (ii) other Third Parties that are not Subcontractors;

in each case ((a) and (b)), for the sole purpose of performing Partner's obligations and exercising Partner's rights with respect to the Clinical Development, Pre-Clinical Development (solely to the extent permitted under and in accordance with Section 5.2.2 (Territory Pre-Clinical Development)), the performance of Medical Affairs activities with respect to, or Commercialization of the Licensed Product in accordance with this Agreement. [***]. Each Sublicensee will hold its rights contingent on the rights licensed to Partner under the terms of this Agreement and may not grant any further sublicenses of its rights to any Third Party. Any termination of the licenses granted to Partner under Section 2.1 (License Grants to Partner) as a result of a termination of this Agreement will cause the Sublicensees to automatically lose the same rights under any sublicense.

2.2.2 **Terms of Sublicenses to Third Parties**. Partner will provide prior written notice to Kiniksa identifying its intention to grant a sublicense under Section 2.2.1 (Right to Sublicense) to any Third Party that is not a Preapproved Subcontractor (including a Subcontractor that requires a sublicense under the rights granted to Partner in Section 2.1 (License Grants to Partner) to perform the applicable activities for which they were engaged or another proposed Sublicensee), the purpose of such sublicense, and the identity of the Third Party to whom Partner intends to grant such sublicense, and, to the extent required pursuant to the terms of any Third Party IP Agreement, the substantially final version of the agreement between Partner and any such Third Party in English for Kiniksa to review and determine whether to approve. Each sublicense to a Third Party (including any Preapproved Subcontractor or other Subcontractor, in each case, that requires a sublicense under the rights granted to Partner in Section 2.1 (License Grants to Partner) to perform the applicable activities for which they were engaged) will be granted under a written agreement that is consistent with and subject to the terms of this Agreement, to the extent required pursuant to the terms of any Third Party IP Agreement, that has been approved in writing by Kiniksa, and that:

(a) contains the requirements set forth under Section 2.2.4 (Terms of Sublicenses and Subcontracts with Third Parties);

(b) requires each such Sublicensee to comply with the terms of this Agreement that are applicable to such Sublicensee (including the Milestone Event and Royalty Payment reporting obligations set forth under Section 10.2 (Milestone Payments) and Section 10.3 (Royalty Payments to Kiniksa), the record keeping and audit requirements set forth under Section 5.8 (Clinical Trial Audit Rights), Section

10.11 (Financial Records and Audits), and the intellectual property provisions set forth in Article 14 (Intellectual Property));

(c) requires that each such Sublicensee performs the activities that they are sublicensed or engaged to perform (as applicable) in accordance with the terms of all Third Party IP Agreements, cGLP and cGCP, as applicable, and otherwise in compliance with Applicable Law;

(d) includes Kiniksa as an intended third party beneficiary under the sublicense with the right to enforce the applicable terms of such sublicense;

(e) precludes the granting of further sublicenses without the prior written consent of Kiniksa, not to be unreasonably withheld, conditioned, or delayed;

(f) prohibits such Third Party from engaging in, independently or for or with any other Third Party, any Exploitation of any Competitive Product in the Territory; and

(g) is subject in all respects to any applicable Third Party IP Agreement under which Kiniksa is granted any right that will be sublicensed under such proposed sublicense.

2.2.3 **Right to Subcontract**. Partner will not propose the engagement of any Subcontractor that is Debarred/Excluded. The Preapproved Subcontractors will be set forth in the Territory Development Plan or Global Development Plan, or any amendment thereto approved by the JSC. Subject to the applicable terms of this Agreement (including the terms of Section 2.2.4 (Terms of Sublicenses and Subcontracts with Third Parties) and, if such Preapproved Subcontractor is granted a sublicense under the rights granted to Partner in Section 2.1 (License Grants to Partner), the terms of Section 2.2.2 (Terms of Sublicenses to Third Parties)), Partner may engage any Preapproved Subcontractor to perform Partner's obligations and exercise Partner's rights under this Agreement. In addition, if Partner wishes to engage a Subcontractor that does not require a sublicense, is not already a Preapproved Subcontractor, and is (a) a CRO, (b) to be engaged to package and label the Licensed Product in the Territory, or (c) a CSO engaged to operate in [***]% or more of the relevant market in any country or region of the Territory for which Partner is seeking such CSO's assistance (any such Subcontractor described in the preceding clauses (a) or (b), a "**Material Subcontractor**") to perform its obligations or exercise its rights under this Agreement related to the Clinical Development, packaging and labeling, Pre-Clinical Development (solely to the extent permitted in accordance with Section 5.2.2 (Pre-Clinical Development)), performance of Medical Affairs with respect to, or Commercialization of the Licensed Product, then at least [***] days before engaging any such Subcontractor, Partner will provide to the JSC, for review and discussion, written notice identifying Partner's intention to engage such Subcontractor, the purpose of engaging such Subcontractor, and the identity of such Subcontractor. The Parties agree that Partner's engagement of Material Subcontractors that do not require a sublicense do not require the approval of the JSC, and if the JSC does not provide to Partner comments with respect to the engagement of any such proposed Material Subcontractors prior to the end of such [***] day period, then Partner may so engage such Material Subcontractors.

2.2.4 **Terms of Sublicenses and Subcontracts with Third Parties**. In addition to the requirements set forth in Section 2.2.2 (Terms of Sublicenses to Third Parties) with respect

to any grant of rights to a Sublicensee, any sublicense agreement with a Third Party and any agreement pursuant to which Partner engages any Subcontractor (including any Preapproved Subcontractor) must be consistent with, and subject to, the terms of this Agreement and contain (a) an assignment back to Partner of all Collaboration Know-How and Collaboration Patent Rights developed, invented, or filed (as applicable) by or on behalf of the Sublicensee or Subcontractor, as applicable (including all Assigned Collaboration Technology, Partner Collaboration Technology, and Joint Collaboration Technology), (b) a sublicensable (through multiple tiers) license back to Partner of all other Know-How and Patent Rights developed, invented, or filed (as applicable) by or on behalf of the Sublicensee or Subcontractor, as applicable, that are [***] to Exploit the Licensed Product (such that Partner Controls such Know-How and Patent Rights for the purposes of this Agreement), and (c) confidentiality and non-use provisions that are at least as stringent as those set forth in Article 11 (Confidentiality; Publication).

2.2.5 **Notice of Sublicenses**. Partner will provide Kiniksa with a true and complete copy of each agreement between Partner and any Sublicensee no later than [***] days after the execution thereof, *provided* that, to the extent permitted under any Third Party IP Agreement, Partner may redact any financial terms contained therein that are not necessary for Kiniksa to determine the scope of the rights granted under such sublicense. If any such agreement between Partner and any Sublicensee is not in English, then Partner will also provide to Kiniksa an English translation thereof, at Partner's expense, no later than [***] days following the execution thereof.

2.2.6 **Partner Audits of Sublicensees and Subcontractors**. Partner will provide Kiniksa with copies of any quality oversight or audit reports from audits that Partner (or its agent) has conducted on any Sublicensees or other Material Subcontractors engaged by Partner to perform its obligations or exercise its rights under this Agreement to the extent such reports are relevant to such Sublicensees' or other Subcontractors' performance of such obligations or exercise of such rights no later than [***] Business Days after receiving or preparing, as applicable, any such report. Partner will provide to Kiniksa all quality oversight or audit reports from audits that Partner (or its agent) conducts, and, if any such report is not in English, a summary in English of any such report. Solely to the extent that Kiniksa is required to submit such quality oversight or audit reports to a Regulatory Authority, Partner will reimburse Kiniksa for any translation expenses reasonably incurred by Kiniksa to obtain English translation thereof by translators selected by Kiniksa.

2.2.7 **Responsibility for Sublicensees and Subcontractors**. Notwithstanding any sublicense or subcontracting, Partner will remain primarily liable to Kiniksa for the performance of all of its obligations under, and Partner's and its Sublicensees' and other Subcontractors' compliance with all provisions of, this Agreement. Partner will be fully responsible and liable for any breach of the terms of this Agreement by any of its Sublicensees or other Subcontractors to the same extent as if Partner itself has committed any such breach, and Partner will promptly terminate the sublicense or subcontract, as applicable, with any Sublicensee or other Subcontractor if such Sublicensee or Subcontractor is in material breach of this Agreement and does not cure such breach in a timely manner in accordance with the terms of this Agreement.

2.3 License Grant to Kiniksa. Subject to the terms of this Agreement (including Partner's retained rights set forth in Section 2.4 (No Implied Licenses; Retained Rights)), Partner hereby grants to Kiniksa a non-exclusive, royalty-free, fully paid-up, worldwide, transferable (in accordance with

Section 17.1 (Assignment)) license, with the right to grant sublicenses through multiple tiers (a) under the Partner Technology (i) to Manufacture the Licensed Product both inside and outside of the Territory solely for purposes of: (A) use in Commercialization of the Licensed Product outside the Territory, (B) Development of the Licensed Product inside the Territory solely for purposes of performing Kiniksa's obligations and exercising Kiniksa's rights, in each case, under this Agreement, and (C) Development of the Licensed Product outside of the Territory, (ii) to Develop the Licensed Product in the Territory, including to perform Global Clinical Trials and other Development activities for the Licensed Product under the Global Development Plan for purposes of Exploiting the Licensed Product outside the Territory, and (iii) to Exploit Licensed Product outside the Territory, and (b) under the Partner Collaboration Technology to Exploit the Licensed Product, which license under the Partner Collaboration Technology will be irrevocable and perpetual.

2.4 No Implied Licenses; Retained Rights. Nothing in this Agreement will be interpreted to grant a Party any rights under any intellectual property rights owned or Controlled by the other Party, including Kiniksa Technology, Joint Collaboration Technology, or Partner Technology, in each case, that are not expressly granted herein, whether by implication, estoppel, or otherwise. Any rights not expressly granted to Kiniksa by Partner under this Agreement are hereby retained by Partner. Any rights not expressly granted to Partner by Kiniksa under this Agreement are hereby retained by Kiniksa. Notwithstanding any provision to the contrary set forth in this Agreement, Kiniksa may, and hereby retains (on behalf of itself and its licensees, other than Partner and its Sublicensees), (a) the exclusive right under the Kiniksa Technology to conduct Development that is not Clinical Development involving the Licensed Product worldwide, other than Partner's performance of Pre-Clinical Development in the Field in the Territory to the extent permitted by Kiniksa in accordance with Section 5.2.2 (Territory Pre-Clinical Development), and (b) in the event that Partner does not participate in any Global Clinical Trial, the non-exclusive right to Clinically Develop Licensed Product in the Territory solely in connection with the performance of such Global Clinical Trial.

2.5 Restrictions. Partner will not practice the Kiniksa Technology other than as expressly licensed and permitted under this Agreement or otherwise agreed by the Parties in writing. In addition, notwithstanding any provision to the contrary set forth in this Agreement, except as expressly permitted under Section 2.1 (License Grants to Partner) or Section 7.2 (Packaging and Labeling), Partner will not, and will cause its Affiliates not to, Manufacture the Licensed Product (or any component thereof). Kiniksa will not practice the Partner Technology other than as expressly licensed and permitted under this Agreement or otherwise agreed by the Parties in writing.

2.6 Third Party IP Agreements.

2.6.1 **Compliance**. Partner stipulates and agrees that the rights and licenses granted to Partner under this Agreement are subject to the applicable terms of the Third Party IP Agreements with respect to the Kiniksa Technology that is being sublicensed thereunder, and Kiniksa will not be required to take any action or inaction that would cause Kiniksa to be in breach of any Third Party IP Agreement or to grant any rights to Partner hereunder that are in violation of, or inconsistent with, any Third Party IP Agreement. Partner will abide by the applicable terms of the Third Party IP Agreements.

2.6.2 **Third Party IP Agreement Amendments**. During the Term, at least [***] Business Days prior to entering into any amendment to the Regeneron License Agreement or any New Third Party IP Agreement that would conflict with, or adversely affect, the sublicenses

granted to Partner under this Agreement pursuant to the Regeneron License Agreement or such New Third Party IP Agreement, or would otherwise impose any incremental obligation on Partner, Kiniksa will promptly furnish Partner with a copy of such proposed amendment, from which copy Kiniksa may only redact information that is not necessary for Partner to determine the scope of the rights sublicensed to Partner pursuant to the Regeneron License Agreement or such New Third Party IP Agreement or for Partner to determine whether such amendment will relieve or modify Kiniksa's performance of its obligations under this Agreement. Partner will provide to Kiniksa for Kiniksa's reasonable consideration any comments regarding such proposed amendment no later than [***] Business Days after its receipt thereof, and Kiniksa will use reasonable efforts to incorporate Partner's reasonable comments to the extent timely received and applicable to preserving Partner's rights, and Kiniksa's obligations, under this Agreement. Kiniksa will not, without Partner's prior written consent, terminate the Regeneron License Agreement or any New Third Party IP Agreement. In addition, Kiniksa will not, without Partner's prior written consent, enter into any amendment to the Regeneron License Agreement or any New Third Party IP Agreement, in each case, (a) other than in accordance with the terms of this Section 2.6.2 (Third Party IP Agreement Amendments) or (b) to the extent that doing so would conflict with, or materially and adversely affect, the licenses granted to Partner under Section 2.1 (License Grants to Partner) or Partner's other rights under this Agreement. Kiniksa further acknowledges and agrees that Partner is not obligated to comply with, or incur liability under, those terms of any amendment to the Regeneron License Agreement or any New Third Party IP Agreement that Kiniksa fails to provide to Partner for its review and comment prior to the execution thereof in accordance with this Section 2.6.2 (Third Party IP Agreement Amendments). Further, Kiniksa will not be relieved from performing its obligations under this Agreement under or as a result of any amendment to the Regeneron License Agreement or any New Third Party IP Agreement that Kiniksa fails to provide to Partner for its review and comment prior to the execution thereof in accordance with this Section 2.6.2 (Third Party IP Agreement Amendments).

2.7 Third Party In-Licenses.

2.7.1 **Kiniksa Identified Rights**. Kiniksa will remain solely responsible for the payment of all royalties, license fees, milestone payments, and other payment obligations under the Regeneron License Agreement. If, after the Effective Date during the Term, Kiniksa or its Affiliate intends to obtain Control of any Know-How or Patent Rights from a Third Party (whether by acquisition or license) that may be necessary to perform Pre-Clinical Development of (to the extent permitted in accordance with Section 5.2.2 (Territory Pre-Clinical Development)), Clinical Development of or Medical Affairs for, or to Commercialize the Licensed Product in the Field in the Territory (other than through a Change of Control of Kiniksa or any of its Affiliates or as a result of the acquisition by Kiniksa or any of its Affiliates of a Third Party by merger, acquisition, or similar transaction or series of related transactions) and for which Kiniksa intends Partner to share amounts due in consideration of a grant under such Know-How and Patent Rights (such Know-How and Patent Rights, "**Kiniksa Identified Rights**"), then Kiniksa will notify Partner in writing of such Kiniksa Identified Rights and Section 2.7.3 (Third Party In-Licenses) will apply.

2.7.2 **Partner Identified Rights**. If Partner determines that a license under any Know-How or Patent Rights controlled by a Third Party is necessary to perform Pre-Clinical Development of (to the extent permitted in accordance with Section 5.2.2 (Territory Pre-Clinical

Development)), Clinical Development of or Medical Affairs for, or to Commercialize, the Licensed Product in the Field in the Territory (or any country or region therein) ("**Partner Identified Rights**"), then Partner will so notify Kiniksa. Kiniksa will have the first right to acquire rights to any such Partner Identified Rights from such Third Party (whether by acquisition or license), and if Kiniksa intends to acquire such rights, then Kiniksa will notify Partner of such intention no later than [***] days after Kiniksa's receipt of such written notice from Partner, and the terms of Section 2.7.3 (Third Party In-Licenses) will apply. If Kiniksa notifies Partner of its intention not to so acquire such rights within such [***] day period, or otherwise fails within [***] days after the date of Partner's written request to acquire rights under such Partner Identified Rights, then, in each case, Partner will have the right to acquire rights under such Partner Identified Rights from such Third Party (a) solely for the Territory (or any country or region therein), (b) unless such Third Party is only offering rights for the Territory together with rights outside the Territory, in which case, Partner may acquire all Partner Identified Rights being offered, and in each case ((a) and (b)), Partner will use reasonable efforts to ensure that all such Partner Identified Rights are fully sublicensable (through multiple tiers) to Kiniksa to the extent of the licenses granted to Kiniksa hereunder. If thereafter Partner so acquires such rights, then such Know-How or Patent Rights will be included in the Partner Know-How or Partner Patent Rights, as applicable. Upon execution of any agreement pursuant to which Partner acquires any Partner Identified Rights outside of the Territory, Partner will notify Kiniksa in writing and will provide a copy of such agreement to Kiniksa, *provided* that Partner may redact information that is not necessary for Kiniksa to determine the scope of the rights that would be sublicensed to Kiniksa thereunder. If Kiniksa elects to accept a sublicense from Partner under those Partner Identified Rights so acquired by Partner, then Kiniksa will reimburse Partner for (i) [***]% of any payments under such Third Party IP Agreement that solely pertain to, or arise solely as a result of, the Exploitation of the Licensed Product outside the Territory (for example, royalty payments that are solely attributable to sales of Licensed Product outside the Territory or milestone payments payable upon achievement of events solely outside the Territory).

2.7.3 **Third Party In-Licenses**. Prior to Kiniksa's or its Affiliate's execution of an agreement with a Third Party to acquire or license any Kiniksa Identified Rights or Partner Identified Rights that would be licensed to Partner hereunder if Controlled by Kiniksa or its Affiliates (together, "**New Kiniksa In-Licensed Rights**" and any such agreement, a "**New Third Party IP Agreement**," and together with the Regeneron License Agreement, the "**Third Party IP Agreements**"), Kiniksa will provide Partner with a copy of the proposed New Third Party IP Agreement from which copy Kiniksa may only redact information that is not necessary for Partner to determine the scope of the rights sublicensed to Partner or for Partner to determine whether such New Third Party IP Agreement will relieve or modify Kiniksa's performance of its obligations under this Agreement and Partner will have an opportunity to review and comment on the terms of the proposed New Third Party IP Agreement that are applicable to the Territory, the performance of Kiniksa's obligations under this Agreement, and other material terms thereof, including any payments that Kiniksa or its Affiliates would be obligated to pay in connection with the grant, maintenance, or exercise of a license or sublicense thereunder (as applicable) to Partner. To the extent Kiniksa is able to exclude the Territory from the territory of such proposed New Third Party IP Agreement, Partner will have the right to decline to take a sublicense under such proposed New Third Party IP Agreement. If Partner does not decline a sublicense under such proposed New Third Party IP Agreement or if Kiniksa is not able to exclude the Territory from the territory of such proposed New Third Party IP Agreement,

then Kiniksa will take into consideration Partner's reasonable comments with respect to such New Third Party IP Agreement and Kiniksa will use reasonable efforts to ensure that such New Third Party IP Agreement includes the right to grant a sublicense to Partner in the Field in the Territory under the applicable New Kiniksa In-Licensed Rights such that Kiniksa or its Affiliate Controls such rights as Kiniksa Know-How or Kiniksa Patent Rights (as applicable). Upon execution of such New Third Party IP Agreement, Kiniksa will notify Partner in writing and will provide a copy of the New Third Party IP Agreement to Partner, *provided* that Kiniksa may only redact information that is not necessary for Partner to determine the scope of the rights sublicensed to Partner or for Partner to determine whether such New Third Party IP Agreement will relieve or modify Kiniksa's performance of its obligations under this Agreement. Kiniksa further acknowledges and agrees that Partner is not obligated to comply with, or incur liability under, any terms of any New Third Party IP Agreement that Kiniksa fails to provide to Partner for its review and comment prior to the execution thereof in accordance with this Section 2.7.3 (Third Party In-Licenses). Further, Kiniksa will not be relieved from performing its obligations under this Agreement under or as a result of any New Third Party IP Agreement that Kiniksa fails to provide to Partner for its review and comment prior to the execution thereof in accordance with this Section 2.7.3 (Third Party In-Licenses). Each New Third Party IP Agreement will be subject to the requirements of Section 2.6.2 (Third Party IP Agreement Amendments) with respect to amendments of such New Third Party IP Agreements. The terms of this Section 2.7.3 (Third Party In-Licenses) and the payment terms under Section 2.7.4 (Responsibility for Costs) will not apply to any agreement pursuant to which Kiniksa is granted rights under Know-How or Patent Rights that are [***] to Exploit the Licensed Product in the Field in the Territory if Kiniksa determines that Partner need not be responsible for any costs thereunder pursuant to Section 2.7.4 (Responsibility for Costs) (but such agreement will be subject to Section 2.6.1 (Compliance) and Section 2.6.2 (Third Party IP Agreement Amendments)); *provided*, *however*, that (a) Partner is not obligated to comply with, or incur liability under, any terms of any New Third Party IP Agreement that Kiniksa fails to provide to Partner for its review and comment prior to the execution thereof in accordance with this Section 2.7.3 (Third Party In-Licenses) and (b) Kiniksa will not be relieved from performing its obligations under this Agreement under or as a result of any such New Third Party IP Agreement that Kiniksa fails to provide to Partner for its review and comment prior to the execution thereof in accordance with this Section 2.7.3 (Third Party In-Licenses). In addition, if any agreement pursuant to which Kiniksa obtains rights to any Kiniksa Identified Rights does not include the Territory (because Partner declines a sublicense under the applicable Kiniksa Identified Rights and Kiniksa is able to obtain rights under such Kiniksa Identified Rights that exclude the Territory), then the payment terms under Section 2.7.4 (Responsibility for Costs) will not apply to such agreement, such agreement will not be a New Third Party IP Agreement for purposes of this Agreement, and the Know-How and Patent Rights licensed to Kiniksa pursuant to such Agreement will not be deemed "Controlled" by Kiniksa for purposes of this Agreement.

2.7.4 **Responsibility for Costs**. Following Kiniksa's or its Affiliate's execution of the applicable New Third Party IP Agreement, to the extent Kiniksa Controls such rights, (a) such New Kiniksa In-Licensed Rights will be included in the Kiniksa Know-How or Kiniksa Patent Rights (as applicable) and licensed or sublicensed (as applicable) to Partner under the licenses granted in Section 2.1 (License Grants to Partner), subject to the terms of this Agreement and the applicable Third Party IP Agreement, and (b) Partner will reimburse Kiniksa for (i) [***]% of any payments under such Third Party IP Agreement that solely pertain to, or arise solely as a result of, the Exploitation of the Licensed Product

in the Territory (for example, royalty payments that are solely attributable to sales of Licensed Product in the Territory or milestone payments payable upon achievement of events solely in the Territory), with the understanding that any milestone payments that pertain to, or arise solely as a result of, the Exploitation of the Licensed Product in the Territory will not represent more than [***]% of the total milestone payments due under such Third Party IP Agreement, and (ii) [***]% of any upfront payments, milestone payments, or similar payments payable in consideration for any New Kiniksa In-Licensed Rights that pertain to, or arise as a result of, the Exploitation of the Licensed Product both inside and outside of the Territory or that are non-Territory specific (for example, an upfront payment to access technology or worldwide sales milestones).

2.8 Exclusivity Covenants.

2.8.1 **Partner Exclusivity**. Unless otherwise agreed in writing by the Parties or as expressly provided by the terms of this Agreement, during the Term, Partner will not, and will ensure that its Subsidiaries do not, conduct, license, participate in, or fund, directly or indirectly, independently or for or with any Third Party, the Exploitation of any Competitive Product in the Territory (or license or otherwise grant rights or authorize any Third Party to do any of the foregoing) (collectively, the "**Competitive Activities**").

2.8.2 **Kiniksa Exclusivity**. Unless otherwise agreed in writing by the Parties or as expressly provided by the terms of this Agreement, during the Term, Kiniksa will not, and will ensure that its Affiliates do not, conduct, license, participate in, or fund, directly or indirectly, independently or for or with any Third Party, any Competitive Activities.

2.8.3 **Business Combinations**. Neither Party nor its Subsidiaries will be in breach of the restrictions set forth in this Section 2.8 (Exclusivity Covenants) if such Party or any of its Affiliates undergoes a Change of Control with a Third Party (together with such Third Party and its Affiliates following the closing of the applicable Change of Control transaction, the "**Acquired Party**") that (either directly or through an Affiliate, or in collaboration with any Third Party) (a) is performing any Competitive Activities at the closing of the Change of Control transaction or (b) commences any Competitive Activities after the closing of the Change of Control transaction; and such Acquired Party may perform such Competitive Activities in the Territory, as long as (i) no Kiniksa Technology or Partner Technology is used directly or indirectly by or on behalf of such Acquired Party or its Affiliates in connection with the performance of any Competitive Activities, and (ii) such Acquired Party institutes commercially reasonable technical and administrative safeguards to ensure the requirements set forth in the foregoing clause (i) are met, including by creating "firewalls" between the personnel performing any Competitive Activities and the personnel teams charged with Exploiting the Licensed Product or having access to data from activities performed under this Agreement or Confidential Information of the Parties.

2.8.4 **Acquisition of a Competitive Product**. Neither Party nor its Subsidiaries (with respect to Partner) or its Affiliates (with respect to Kiniksa) will be in breach of the restrictions set forth in this Section 2.8 (Exclusivity Covenants) if such Party or any of its Subsidiaries (with respect to Partner) or its Affiliates (with respect to Kiniksa) acquires a Competitive Product that is being Exploited in the Territory through an acquisition of, or a merger with, the whole or substantially the whole of a business or assets of another Person, so long as such Party (or its Affiliate) (a) enters into a definitive agreement with a Third Party to divest (whether by exclusive out-license or otherwise) such Competitive Product

throughout the Territory within [***] months after the closing of such acquisition or merger or (b) terminates the further Exploitation of such Competitive Product throughout the Territory within [***] days after the closing of such acquisition or merger, and, until the completion of such divestiture or termination, (i) no Kiniksa Technology or Partner Technology is used by or on behalf of such Party or its Affiliates in connection with any subsequent Exploitation of such Competitive Products in the Territory, and (ii) such Party and its Affiliates institute commercially reasonable technical and administrative safeguards to ensure the requirements set forth in the foregoing clause (i) are met, including by creating "firewalls" between the personnel Exploiting such Competitive Products and the personnel teams charged with Exploiting the Licensed Product or having access to data from activities performed under this Agreement or Confidential Information of the Parties.

ARTICLE 3
GOVERNANCE

3.1 **Alliance Managers**. Each Party will appoint an individual to act as its alliance manager under this Agreement as soon as practicable after the Effective Date (each an "**Alliance Manager**"). The Alliance Managers will: (a) serve as the primary points of contact between the Parties for the purpose of providing the other Party with information on the progress of a Party's activities under this Agreement; (b) be responsible for facilitating the flow of information and otherwise promoting communication, coordination, and collaboration between the Parties, all of which communications between the Parties will be in English; (c) facilitate the prompt resolution of any disputes; and (d) attend JSC or JDC meetings, in each case, as a non-voting member. An Alliance Manager may also bring any matter to the attention of the JSC or JDC if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party will use reasonable efforts to keep an appropriate level of continuity but may replace its Alliance Manager at any time upon written notice to the other Party.

3.2 **Joint Steering Committee**.

3.2.1 **Formation and Purpose of JSC**. No later than [***] days after the Effective Date, the Parties will establish a joint steering committee (the "**JSC**") to coordinate and oversee the Exploitation of the Licensed Product in the Territory. The JSC will be composed of an equal number of representatives from each Party and a minimum of three representatives of each Party who are fluent in English and who have the appropriate and direct knowledge and expertise and requisite decision-making authority. Any such representative who serves on the JSC or any committee under this Agreement may also serve on one or more other committees under this Agreement. Each Party may replace any of its representatives on the JSC and appoint a person to fill the vacancy arising from each such replacement. A Party that replaces a representative will notify the other Party at least [***] days prior to the next scheduled meeting of the JSC. Both Parties will use reasonable efforts to keep an appropriate level of continuity in representation. Representatives may be represented at any meeting by another person designated by the absent representative. A representative of Kiniksa will chair the JSC ("**JSC Chairperson**") until the first anniversary of the Effective Date. Thereafter, a Partner representative will become the JSC Chairperson for the next [***] months of the Term and then the role of JSC Chairperson will rotate between the Parties every [***] months during the Term. Each Party's representatives on the JSC will inform and coordinate within their respective organization to enable each Party to fulfill its obligations as agreed upon between the Parties under this Agreement, including within the time frames set forth hereunder.

3.2.2 **Meeting Agendas**. Each Party will disclose to the other Party the proposed agenda items along with appropriate information at least [***] Business Days in advance of each meeting of the JSC; *provided* that under exigent circumstances requiring JSC input, a Party may provide its agenda items to the other Party within a shorter period of time in advance of a meeting, or may propose that there not be a specific agenda for a particular meeting, so long as such other Party consents to such later addition of such agenda items or the absence of a specific agenda for such JSC meeting.

3.2.3 **Meetings**. The JSC will hold meetings at such times as it elects to do so, but will meet no less frequently than quarterly, unless otherwise agreed by the Parties. All meetings will be conducted in English. The JSC may meet in person or by means of teleconference, Internet conference, videoconference, or other similar communication method; *provided* that, if practicable or permissible in light of travel restrictions due to the COVID-19 pandemic or any other reason, at least one meeting each Calendar Year will be conducted in person at a location selected alternatively by Kiniksa and Partner or such other location as the Parties may agree. Each Party will be responsible for all of its own costs and expenses of participating in any JSC meeting. The Alliance Managers will jointly prepare and circulate minutes for each JSC meeting within [***] Business Days after each such meeting and will ensure that such minutes are reviewed and approved by their respective companies within [***] days thereafter.

3.2.4 **JSC Roles and Responsibilities**. The responsibilities of the JSC will be to:

(a) provide a forum for the discussion of the Parties' activities under this Agreement;

(b) review and discuss matters that Kiniksa believes may have a Material Adverse Impact on the Licensed Product;

(c) review and discuss Partner's engagement of Subcontractors that are not Preapproved Subcontractors, as described in Section 2.2.3 (Right to Subcontract);

(d) establish and oversee the JDC and settle any disputes that arise within the JDC, as described in Section 3.5.2 (Resolution of JDC Disputes);

(e) oversee the implementation of, and the coordination between the Parties of activities to be performed under, the Clinical Supply Agreement, the Commercial Supply Agreement, the Safety Agreements, and any other written agreement between the Parties with respect to the subject matter hereof;

(f) review, discuss, and determine whether to approve any updates to the Territory Development Plan for the Licensed Product, in each case, as described in Section 5.2.1 (Territory Clinical Development);

(g) [***];

(h) review, discuss, and determine whether to approve any material updates to, the Global Development Plan for the Licensed Product with respect to activities to be conducted by Partner in the Territory, including Partner's participation in the conduct of any Global Clinical Trial, each as described in Section 5.3 (Global Development Plan);

(i) review and discuss if Partner will be the Territory Sponsor for Global Clinical Trials to be conducted under the Global Development Plan (as set forth therein), as described in Section 5.3 (Global Development Plan); *provided* that Partner will have the right, following such review and discussion, to make such determination;

(j) review, discuss, and determine whether to add any countries in the Territory as Selected Territory GCT Countries for a given Global Clinical Trial to be conducted under the Global Development Plan, as described in Section 5.3 (Global Development Plan);

(k) determine the total number of patients to be enrolled in the Territory for a given Global Clinical Trial, as contemplated in the applicable protocol for such Global Clinical Trial, as described in Section 5.3 (Global Development Plan);

(l) review, discuss, and determine whether to approve any New Development Proposal, and review, discuss, and determine whether to approve any New Territory-Specific Development Activities, in each case, as described in Section 5.4 (New Development by Partner);

(m) discuss the status, progress, and results of the Parties' respective Development activities, as described in Section 5.10 (Development Reports);

(n) review, discuss, and determine whether to approve the regulatory strategy for receipt of Regulatory Approval in each country or region in the Territory, as described in Section 6.1 (Regulatory Strategy);

(o) review and discuss Partner's plan for undertaking additional regulatory activities for the Licensed Product delegated by Kiniksa or the JSC to Partner, as described in Section 6.2.1 (Obtaining and Maintaining Regulatory Approvals);

(p) review, discuss, and determine whether to approve any Regulatory Submissions that are in the name of Kiniksa, as described in Section 6.2.2 (Review of Regulatory Submissions);

(q) review, discuss, and determine whether to approve Medical Affairs Plans for the Territory and any updates thereto for the Licensed Product, as described in Section 8.1 (Medical Affairs Plan);

(r) review, discuss, and determine whether to approve the Commercialization Plan for the Territory and any updates thereto for the Licensed Product, as described in Section 9.2 (Commercialization Plan);

(s) review, discuss, and determine whether to approve any brand strategy for the Licensed Product that is specific to the Territory (or any country or region therein) and that is inconsistent with the Global Brand Strategy for the Licensed Product, as described in Section 9.2 (Commercialization Plan);

(t) review, discuss, and determine whether to approve the use of any Product Mark for the Licensed Product in the Territory that deviates from Kiniksa's Global Brand Elements, as described in Section 14.9.2 (Product Marks in the Territory); and

(u) perform such other functions as expressly set forth in this Agreement or allocated to the JSC by the Parties' written agreement.

3.3 Joint Development Committee.

3.3.1 **Formation and Purpose of the JDC**. Promptly, but no later than [***] days after the Parties establish the JSC, the JSC will establish a Joint Development Committee ("**JDC**") to monitor, coordinate, and facilitate cooperation and information exchange of the Development of the Licensed Product in the Field in the Territory, which will be a subcommittee of the JSC and will have the responsibilities set forth in this Article 3 (Governance). The JDC will dissolve upon completion of all Development activities with respect to the Licensed Product in the Territory. The JDC will hold meetings at such times as it elects to do so, but will meet no less frequently than quarterly, unless otherwise agreed by the Parties. All meetings will be conducted in English. The JDC may meet in person or by means of teleconference, Internet conference, videoconference, or other similar communication method. Each Party will be responsible for all of its own costs and expenses of participating in any JDC meeting.

3.3.2 **Membership of the JDC**. Each Party will designate up to three representatives with appropriate knowledge and expertise to serve as members of the JDC. The JDC will be co-chaired by one of the representatives of each Party. Each Party may replace its JDC representatives and co-chairpersons at any time upon written notice to the other Party. The Alliance Manager of each Party (or his or her designee) will attend each meeting of the JDC as a non-voting participant.

3.3.3 **JDC Roles and Responsibilities**. The responsibilities of the JDC will be to:

(a) serve as a forum of information exchange and coordinate for Continuing Know-How Transfer as described in Section 4.2 (Continuing Know-How Transfer);

(b) review, discuss, and submit to the JSC to further review, discuss, and determine whether to approve any updates to the Territory Development Plan, as described in Section 5.2.1 (Territory Clinical Development);

(c) review, discuss, and submit to the JSC to further review, discuss, and determine whether to approve each Territory Pre-Clinical Development Plan, as described in Section 5.2.2 (Territory Pre-Clinical Development);

(d) review, discuss, and submit to the JSC to further review, discuss, and determine whether to approve any updates to the Global Development Plan that include activities to be conducted by Partner in the Territory, including by participating in the conduct of any Global Clinical Trial, as described in Section 5.3 (Global Development Plan);

(e) update the Territory Development Plan to reflect the JSC's decision regarding the conduct of Territory-specific New Development Activities, as described in Section 5.4 (New Development by Partner);

(f) discuss and develop the regulatory strategy for receipt of approval from the NMPA with respect to the conduct of the applicable Clinical Trials in the Territory, and

submit the same to the JSC to further review, discuss, and determine whether to approve, as described in Section 6.1 (Regulatory Strategy);

(g) review, discuss, and submit to the JSC to further review, discuss, and determine whether to approve Regulatory Submissions in each country or region in the Territory for the Licensed Product, as described in Section 6.2.2 (Review of Regulatory Submissions); and

(h) develop, review, and discuss an initial draft of the Medical Affairs Plans for the Licensed Product in the Territory and propose any update thereto, and submit the same to the JSC to further review, discuss, and determine whether to approve, as described in Section 8.1 (Medical Affairs Plan).

3.4 Non-Member Attendance. Each Party may from time to time invite a reasonable number of participants, in addition to its representatives (which may include legal counsel), to attend a meeting of the JSC and the JDC (in a non-voting capacity), if such participants have expertise that is relevant to the planned agenda for such JSC or JDC meeting; *provided* that if either Party intends to have any Third Party (including any consultant) attend such a meeting, then such Party will provide prior written notice to the other Party reasonably in advance of such meeting and will ensure that such Third Party is bound by obligations of confidentiality and non-use at least as stringent as those set forth in Article 11 (Confidentiality; Publication). Notwithstanding any provision to the contrary set forth in this Agreement, if the other Party objects in good faith to the participation of such Third Party in such meeting due to a *bona fide* concern regarding competitively sensitive information that is reasonably likely to be discussed at such meeting *(i.e.*, a consultant that also provides services to a Third Party with a Competitive Product), then such Third Party will not be permitted to participate in such meeting (or the portion thereof during which such competitively sensitive information is reasonably likely to be discussed).

3.5 Decision-Making.

3.5.1 **General Process**. The JSC and the JDC will have only the powers expressly assigned to it in this Article 3 (Governance) and elsewhere in this Agreement and will not have the authority to: (a) modify or amend the terms of this Agreement; or (b) waive either Party's compliance with the terms of this Agreement. All decisions of the JSC and the JDC will be made by unanimous vote, with each Party's representatives having one vote (*i.e.*, one vote per Party). No action taken at any meeting of the JSC or the JDC will be effective unless there is a quorum at such meeting, and at all such meetings, a quorum will be reached if two voting representatives of each Party are present or participating in such meeting and no Party will unreasonably fail to cause a quorum of its representatives to attend any meeting of the JSC and JDC. Except as otherwise expressly set forth in this Agreement, the phrases "determine," "designate," "confirm," "approve," or "determine whether to approve" by the JSC or the JDC and similar phrases used in this Agreement will mean approval in accordance with this Section 3.5 (Decision-Making), including the escalation and tie-breaking provisions herein. For the avoidance of doubt, matters that are specified in Section 3.2.4 (JSC Roles and Responsibilities) and Section 3.3.3 (JDC Roles and Responsibilities) to be reviewed and discussed (as opposed to reviewed, discussed, and approved) do not require any agreement or decision by either Party and are not subject to the voting and decision-making procedures set forth in this Section 3.5 (Decision-Making) or in Section 3.6 (Resolution of JSC Disputes).

3.5.2 **Resolution of JDC Disputes**. The JSC will use good faith efforts to resolve all disputes that arise within the JDC within [***] days after any such matter is brought to the JSC for resolution.

3.5.3 **Decisions of the JSC**. The JSC will use good faith efforts, in compliance with this Section 3.5.3 (Decisions of the JSC), to promptly resolve any such matter for which it has authority. If, after the use of good faith efforts, the JSC is unable to resolve any such matter referred to it by the JDC or any matter that is within the scope of the JSC's authority or any other disagreement between the Parties that may be referred to the JSC, in each case, within a period of [***] days, then a Party may refer such matter for resolution in accordance with 3.6.1 (Referral to Executive Officers) to the Chief Executive Officer of Kiniksa (or an executive officer of Kiniksa designated by the Chief Executive Officer of Kiniksa who has the power and authority to resolve such matter) and the Chief Executive Officer of Partner (or an executive officer of Partner designated by the Chief Executive Officer of Partner who has the power and authority to resolve such matter) (collectively, the "**Executive Officers**").

3.6 Resolution of JSC Disputes.

3.6.1 **Referral to Executive Officers**. If a Party makes an election under Section 3.5.3 (Decisions of the JSC) to refer a matter on which the JSC cannot reach a consensus decision for resolution by the Executive Officers, then the JSC will submit in writing the respective positions of the Parties to their respective Executive Officers. The Executive Officers will use good faith efforts to resolve any such matter so referred to them as soon as practicable, and any final decision that the Executive Officers agree to in writing will be conclusive and binding on the Parties.

3.6.2 **Final Decision-Making Authority**. If the Executive Officers are unable to reach agreement on any such matter referred to them within [***] days after such matter is so referred (or such longer period as the Executive Officers may agree upon), then:

(a) **No Change; Status Quo**. Neither Party will have final decision-making authority over (i) [***], or (ii) [***] (each, a "**Status Quo Item**"), and all such matters must be decided by unanimous agreement in order to take any action or adopt any change from the then-current status quo.

(b) **Partner Final Decision-Making Authority**. Partner will have final decision-making authority over matters that are not Status Quo Items and that are (i) [***], (ii) [***], and (iii) [***].

(c) **Kiniksa Final Decision-Making Authority**. Kiniksa will have final decision-making authority with respect to all matters related to (i) [***], (ii) [***], (iii) [***], (iv) [***], and (vi) [***].

3.6.3 **Limitations on Decision-Making**. Notwithstanding any provision to the contrary set forth in this Agreement, without the other Party's prior written consent, neither Party (in the exercise of a Party's final decision-making authority), the JSC the JDC, nor a Party's Executive Officer, in each case, may make a decision that could reasonably be expected to (a) require the other Party to take any action that such other Party reasonably believes would (i) require such other Party to violate any Applicable Law, the requirements of any Regulatory Authority, or any agreement with any Third Party entered into by such other

Party (including any Third Party IP Agreement) or (ii) require such other Party to infringe or misappropriate any intellectual property rights of any Third Party or (b) conflict with, amend, interpret, modify, or waive compliance under this Agreement, the Clinical Supply Agreement, the Commercial Supply Agreement, the Safety Agreement, or any other agreement between the Parties related to the subject matter set forth herein.

3.7 **Discontinuation of JSC**. The JSC will continue to exist until the first to occur of (a) the Parties agreeing to disband the JSC, or (b) Kiniksa providing written notice to Partner of its intention to disband and no longer participate in the JSC. Once the JSC is disbanded, the JSC will have no further obligations under this Agreement and, thereafter, the Alliance Managers will be the points of contact for the exchange of information between the Parties under this Agreement and any references in this Agreement to performance of the obligations of each Party's representatives to the JSC, the exercise of each Party's representatives rights as members of the JSC, and to the decisions of the JSC, in each case, will automatically become references to the performance of each Party's obligations, exercise of rights, and decisions by and between the Parties in writing, subject to the other terms of this Agreement and consistent with the terms of Section 3.6 (Resolution of JSC Disputes**)**.

ARTICLE 4
TECHNOLOGY TRANSFERS

4.1 **Initial Know-How Transfer**. Within a reasonable period of time after the Effective Date as agreed by the Parties (but in no event more than [***] days after the Effective Date unless otherwise agreed by the Parties), Kiniksa will provide and transfer to Partner copies of Kiniksa Know-How that exists on the Effective Date to the extent not previously provided to Partner and is [***] for Partner's performance of Clinical Development or Medical Affairs, or Commercialization of Licensed Product in the Territory in accordance with this Agreement, which Kiniksa Know-How will include information regarding the characterization of Licensed Product, other than CMC process characterization and process and specifications relating to the packaging and labeling of Licensed Product ("**Kiniksa P&L Process and Specifications**"), U.S. INDs with respect to Licensed Product, clinical studies data and results related to Licensed Product, and existing IND-enabling Data (the "**Initial Know-How Transfer**"). Kiniksa or its Affiliate may make such Kiniksa Know-How available in the form it is currently constituted or such other reasonable form as Kiniksa reasonably determines.

4.2 **Continuing Know-How Transfer**. Following the Initial Know-How Transfer for the Licensed Product, Kiniksa will provide to the JDC in advance of the last JDC meeting each Calendar Quarter or more frequently as agreed by the Parties, a summary of any additional Kiniksa Know-How that is [***] for Partner's performance of Clinical Development, Pre-Clinical Development (to the extent permitted in accordance with Section 5.2.2 (Territory Pre-Clinical Development)), Medical Affairs, or Commercialization of the Licensed Product in the Field in the Territory in accordance with this Agreement, in each case, developed by or that comes into the Control of Kiniksa or its Affiliates since the previous quarterly disclosure. Upon Partner's reasonable request during the Term (and no later than [***] days after any such reasonable request), Kiniksa will make available to Partner all such Kiniksa Know-How in Kiniksa's or its Affiliates' possession and not previously provided to Partner hereunder (the "**Continuing Know-How Transfer**," and together with the Initial Know-How Transfer, the "**Technology Transfer**").

4.3 **Technology Transfer Costs**. Kiniksa will provide consultation and assistance with qualified personnel in connection with the Technology Transfer for the Licensed Product as reasonably requested by Partner and as reasonably necessary to accomplish each of the Initial Know-How

Transfer and Continuing Know-How Transfer in accordance with the terms of this Agreement. Except for the internal costs associated with the first [***] FTE hours incurred by Kiniksa in connection with the Initial Know-How Transfer, Partner will reimburse Kiniksa for (a) internal costs (at the FTE Rate) of such consultation and assistance for the Licensed Product and (b) all out-of-pocket costs, in each case ((a) and (b)), reasonably incurred by or on behalf of Kiniksa in connection with such assistance for the Initial Know-How Transfer and the Continuing Know-How Transfer within [***] days after receiving Kiniksa's invoice therefor.

ARTICLE 5
DEVELOPMENT PROGRAM

5.1 Development Diligence and Responsibilities. Subject to the terms of this Agreement, Partner will be responsible for and will use Commercially Reasonable Efforts to Clinically Develop and seek, obtain, and maintain Regulatory Approval for the Licensed Product in each Indication included in the Territory Development Plan in each country or region in the Territory ("**Territory Development**"). Without limiting the generality of the foregoing, Partner will use Commercially Reasonable Efforts (a) to perform the activities set forth in, and perform Territory Development of the Licensed Product in accordance with, the Territory Development Plan for the Licensed Product and achieve the objectives set forth therein, and (b) solely to the extent Partner has agreed, following review and discussion by the JSC, to serve as the Territory Sponsor for a given Global Clinical Trial under the Global Development Plan, conduct the tasks assigned to Partner in the Global Development Plan in accordance with Section 5.3 (Global Development Plan).

5.2 Territory Development Plan.

5.2.1 **Territory Clinical Development.** Except for the activities assigned to Partner under a Global Development Plan for the Licensed Product pursuant to Section 5.3 (Global Development Plan), all Clinical Development of the Licensed Product in the Territory by or on behalf of Partner will be conducted pursuant to a written development plan agreed by the JDC and approved by the JSC (as updated from time to time in accordance with this Section 5.2.1 (Territory Clinical Development) and Section 3.2 (Joint Steering Committee), the "**Territory Development Plan**"), and Partner will be primarily responsible for all Clinical Trials for the Licensed Product that are conducted only at clinical trial sites in the Territory. The initial Territory Development Plan for the Licensed Product is set forth on Schedule 5.2 (Territory Development Plan) attached hereto. The Territory Development Plan and all updates thereto will contain in reasonable detail (a) [***], (b) [***], (c) [***], and (d) [***]. In addition, at least annually during the Term or more frequently as may be necessary to include any New Territory-Specific Development Activities, the JDC will propose updates to each Territory Development Plan and submit such proposed updated Territory Development Plan to the JSC. The JSC will review, discuss, and determine whether to approve any and all such updates to the Territory Development Plan. Once approved by the JSC, each update to the Territory Development Plan will become effective and supersede the then-current Territory Development Plan. Notwithstanding any provision to the contrary set forth in this Agreement, including Partner's final decision-making authority under Section 3.6.2(b) (Partner Final Decision-Making Authority), the Territory Development Plan and all updates thereto must be consistent with the Global Development Plan for the Licensed Product, except as provided in Section 5.4 (New Development by Partner). In the event of any conflict or inconsistency between the Territory Development Plan and the Global Development Plan, the Global Development Plan will control and take precedence.

5.2.2 **Territory Pre-Clinical Development**. In connection with the Clinical Development of the Licensed Product pursuant to a given Territory Development Plan, Partner may identify on a country-by-country or region-by-region basis, certain Pre-Clinical Development that is required in order to obtain Regulatory Approval of the Licensed Product in such country or region ("**Required Pre-Clinical Development**"). [***]. If the JSC approves a Pre-Clinical Development Plan, then Kiniksa will have [***] days following the date of such approval by the JSC to determine whether it will either perform or permit Partner to perform such Required Pre-Clinical Development in accordance with the Pre-Clinical Development Plan. If Kiniksa elects to perform such Required Pre-Clinical Development, then Kiniksa will (a) provide to Partner a budget for such Pre-Clinical Development, to be included under the Pre-Clinical Development Plan, (b) use reasonable efforts to perform the Required Pre-Clinical Development in accordance with the applicable Pre-Clinical Development Plan (including the budget therein), and (c) deliver all results therefrom to Partner in accordance with Section 4.2 (Continuing Know-How Transfer) or as otherwise specified in the Pre-Clinical Development Plan. Partner will reimburse Kiniksa for its documented costs and expenses incurred performing such Required Pre-Clinical Development. If Kiniksa elects not to perform the Required Pre-Clinical Development as set forth in the applicable Pre-Clinical Development Plan, or fails to notify Partner of its decision within such [***] day time period, then (i) Partner will have the right to perform, at its cost and expense, the Required Pre-Clinical Development in accordance with the applicable Pre-Clinical Development Plan, and (ii) only in such case, will Partner have the right to practice under the non-exclusive license under the Kiniksa Technology granted pursuant to Section 2.1 (Licenses Granted to Partner) solely with respect to the performance of the Pre-Clinical Development in accordance with the applicable Pre-Clinical Development Plan.

5.3 Global Development Plan. The Parties' global Development of the Licensed Product inside and outside of the Territory will be conducted pursuant to a written plan (as updated from time to time in accordance with this Section 5.3 (Global Development Plan), the "**Global Development Plan**"). The initial Global Development Plan for the Licensed Product is set forth on Schedule 5.3 (Global Development Plan) attached hereto. Other than any Clinical Development for the Licensed Product to be performed by Partner under the Global Development Plan (if Partner either requests or is requested to serve as Territory Sponsor, and agrees, following review and discussion by the JSC, to serve as the Territory Sponsor for such trials in accordance with this Agreement), Kiniksa will have the right to conduct all Development activities for the Licensed Product, including all non-clinical and preclinical studies for the Licensed Product worldwide, pursuant to the Global Development Plan (and solely pursuant to the Global Development Plan as it relates to the Territory) and will have the exclusive right to conduct Development activities for the Licensed Product outside the Territory. In addition to Partner's exclusive right to conduct Territory Development activities for the Licensed Product included in the Territory Development Plan, Partner will have the right to request (or to consent, if Kiniksa so requests of Partner), in each case, following review and discussion by the JSC, and permitted under Applicable Law (and subject to Partner agreeing to bear its share of costs for such Global Clinical Trial in accordance with Section 5.7.2 (Global Development Costs)), to support the global Development of the Licensed Product by serving as Territory Sponsor for and otherwise participating in the conduct of certain Global Clinical Trials, including, to the extent practicable, any Ongoing Global Clinical Trial, and other Clinical Development activities in the Territory as set forth in, and in accordance with, the Global Development Plan. Following any determination that Partner will serve as Territory Sponsor for a given Global Clinical Trial:

(a) the JSC will discuss and determine whether to add any additional countries or regions in the Territory to those countries and regions in the Territory first proposed by Kiniksa in the Global Development Plan as countries in which such Global Clinical Trial will be conducted (the countries in the Territory in which the Global Clinical Trial will be conducted, the "**Selected Territory GCT Countries**") and, unless Applicable Law prevents the conduct of such Global Clinical Trial in the PRC, the Selected Territory GCT Countries will include the PRC,

(b) if the PRC is a Selected Territory GCT Country, then the protocol for such Global Clinical Trial will contemplate the enrollment of a sufficient number of patients in the PRC to support the submission of an MAA for the Licensed Product in the applicable Indication in the PRC, and

(c) unless otherwise agreed by the JSC, the Global Development Plan will not require Partner to enroll more than [***]% of the total number of patients contemplated in the applicable protocol for such Global Clinical Trial (and nothing set forth herein will require Kiniksa to otherwise increase the total number of patients contemplated in the applicable protocol for such Global Clinical Trial).

Kiniksa will not approach any other Third Party to serve as the Territory Sponsor for any Global Clinical Trial in the Territory without first offering such opportunity to Partner. The Global Development Plan and each update thereto will include: (i) an outline of all major Development activities for the Licensed Product to be conducted worldwide by Kiniksa, and (ii) for those Global Clinical Trials in which Partner agrees to participate and serve as Territory Sponsor in accordance with the terms set forth in this Agreement, details and estimated timelines of the Clinical Development activities to be conducted in the Selected Territory GCT Countries and assigned to Partner to support Global Clinical Trials or other global Development for the Licensed Product, which activities will, unless otherwise agreed to by Partner, be designed to support the filing of the Marketing Authorization Applications within the Territory for the Licensed Product. From time to time, Kiniksa may make and implement updates to the then-current Global Development Plan for the Licensed Product, including to contemplate the conduct of the Development of the Licensed Product for a New Development. Solely to the extent such amendments (A) are material (in cost, time, and scope), and (B) include activities to be conducted by Partner in the Territory, Kiniksa or the JDC (as applicable) will submit such proposed updates to the JSC to review, discuss, and determine whether to approve.

5.4 **New Development by Partner**. Notwithstanding Partner's final decision-making authority with respect to Development activities for the Licensed Product that are Territory-specific as set forth in Section 3.6.2(b) (Partner Final Decision-Making Authority), if Partner proposes to perform any Clinical Trials for or otherwise Develop (a) a new formulation of the Licensed Product, (b) any new combination regimen or fixed dose combination for the Licensed Product and another agent, or (c) the Licensed Product in a new Indication, in each case ((a), (b), and (c)) that is not already the subject of the Global Development Plan or Territory Development Plan ("**New Development**") for the Territory, then Partner will present to the JSC to review, discuss, and determine whether to approve a proposal to add such Development activities for such New Development to the Territory Development Plan for the Licensed Product, including the countries or regions in the Territory in which such activities would be conducted (a "**New Development Proposal**"). Each New Development Proposal will describe in reasonable detail the applicable Clinical Trials that Partner desires to conduct with respect to such New Development, including a synopsis of the trial or

activities, the proposed enrollment criteria, the number of patients to be included, the endpoints to be measured, and the statistical design and powering (the "**New Development Activities**"), as well as a proposed timeline and budget and an analysis of the business opportunity and revenue potential anticipated to result from such New Development Activities. The JSC will review, discuss, and determine whether to approve a New Development Proposal within [***] days after receipt thereof from Partner. Upon such an approval, (a) the New Development Activities set forth in such New Development Proposal will be "**New Territory-Specific Development Activities**" for purposes of this Agreement, and (b) the JDC will update the Territory Development Plan for the Licensed Product to include such New Territory-Specific Development Activities for those countries or regions in the Territory agreed by the JSC, including the proposed timelines, in each case, for such New Development Activities set forth in such New Development Proposal (as may be amended by the JSC upon such approval). Any New Territory-Specific Development Activities included in a Territory Development Plan pursuant to this 5.4 (New Development by Partner) will be Development activities for all purposes under this Agreement.

5.5 New Development by Kiniksa. If Kiniksa proposes any Global Clinical Trials for the Licensed Product for any New Development, then:

5.5.1 **Right to Develop**. Subject to the terms of Section 5.3 (Global Development Plan), if Partner (either itself or through its Affiliate) does not elect to serve as the Territory Sponsor or regulatory agent for any such Global Clinical Trials for such New Development in all countries or regions in the Territory in which Kiniksa proposes to perform such Global Clinical Trials pursuant to Section 5.3(a) (Global Development Plan), then:

(a) Partner will not be obligated to implement such Global Clinical Trials in any such country or region in the Territory or perform any activities in connection therewith, and

(b) notwithstanding any provision to the contrary set forth in this Agreement (including the terms of Section 2.1 (License Grants to Partner)), unless Partner subsequently elects to (and does) reimburse Kiniksa for the costs and expenses of such Global Clinical Trials for the Licensed Product in accordance with Section 5.5.3(b) (Reimbursement at a Premium), Partner will not have any rights with respect to any data or results generated in such Global Clinical Trials for such New Development, including pursuant to Section 5.11 (Data Exchange and Use) or Section 6.5 (Right of Reference) except as necessary for Partner to comply with Applicable Law or safety reporting requirements to applicable Regulatory Authorities in the Territory, and (c) Kiniksa will have the right to conduct such Global Clinical Trials for the Licensed Product for such New Development globally (including in the Territory), at Kiniksa's cost and expense. Notwithstanding any provision to the contrary set forth in this Agreement, if Partner agrees to act as Territory Sponsor or regulatory agent throughout the Selected Territory GCT Countries for a given Global Clinical Trial, but is prevented by Applicable Law from participating in such Global Clinical Trial for such New Development in the PRC and instead conducts a Pivotal Clinical Trial within the PRC with respect to such New Development for the submission of a MAA for the PRC with respect to such New Development, then (i) the foregoing restriction on access to data or results generated in such Global Clinical Trials for such New Development, including pursuant to Section 5.11 (Data Exchange and Use), and (ii) the obligation to reimburse a percentage of the costs and expenses of

such Global Clinical Trial in order to obtain access to such data and results, pursuant to Section 5.5.3 (Partner Sharing of Development Costs and Data Access), will not apply and such data and results will be included within Partner's right of reference pursuant to Section 6.5 (Right of Reference).

5.5.2 **Partner Assistance**. If Partner (either itself or through its Affiliate) elects to serve as the Territory Sponsor or regulatory agent in the Territory for, and enroll and treat patients in, any such Global Clinical Trials for a New Development, then such Partner activities will be added to the Global Development Plan and submitted to the JSC for approval in accordance with Section 5.3 (Global Development Plan).

5.5.3 **Partner Sharing of Development Costs and Data Access**.

(a) **Ongoing Reimbursement**. If Partner (either itself or through its Affiliate) elects to serve as the Territory Sponsor or regulatory agent in all Selected Territory GCT Countries, for a New Development, then Partner will be granted rights with respect to any and all data or results generated in such Global Clinical Trials for the Licensed Product pursuant to Section 5.11 (Data Exchange and Use) and under Section 6.5 (Right of Reference), if, prior to the Initiation of such Global Clinical Trial for the Licensed Product (or, as of the Effective Date with respect to any Ongoing Global Clinical Trials), Partner agrees in writing to bear [***]% of the documented costs and expenses that are incurred by or on behalf of the Parties to conduct such Global Clinical Trial in the Selected Territory GCT Countries (including for all clinical sites in the Selected Territory GCT Countries and enrollment of the patients in the Selected Territory GCT Countries, as set forth in the Global Development Plan), any other Development costs or expenses associated therewith, and the Fully Burdened Manufacturing Cost of the Licensed Product used in the Selected Territory GCT Countries in such Global Clinical Trial.

(b) **Reimbursement at a Premium**. If Partner (either itself or through its Affiliate) either:

(i) elects to serve as the Territory Sponsor or regulatory agent in all Selected Territory GCT Countries, but does not bear [***]% of the costs and expenses incurred by or on behalf of the Parties in the conduct of such Global Clinical Trial in all such Selected Territory GCT Countries, any other Development costs or expenses associated therewith, and the Fully Burdened Manufacturing Cost of the Licensed Product used for such Global Clinical Trial as set forth above in Section 5.5.3(a) (Ongoing Reimbursement) or

(ii) does not elect to serve as the Territory Sponsor or regulatory agent in all Selected Territory GCT Countries for any such Global Clinical Trials and to bear [***]% of the costs and expenses incurred by or on behalf of the Parties in the conduct of such Global Clinical Trials in all such Selected Territory GCT Countries, any other Development costs or expenses associated therewith, and the Fully Burdened Manufacturing Cost of the Licensed Product used for such Global Clinical Trial as set forth above in Section 5.5.3(a) (Ongoing Reimbursement),

then, in each case ((i) and (ii)), if Partner wishes to be granted rights with respect to any data or results generated in such Global Clinical Trial for the Licensed Product for such New Development for the Territory, including pursuant to Section 5.11 (Data Exchange and Use) or Section 6.5 (Right of Reference), then unless otherwise agreed by the Parties, upon the receipt of the first Regulatory Approval for the Licensed Product for such New Development in the U.S. or any country or region in the Territory, Partner must:

(A) reimburse Kiniksa, in case (ii), for [***]% of all costs and expenses incurred by or on behalf of Kiniksa in the conduct of such Global Clinical Trial for the Licensed Product, including the Fully Burdened Manufacturing Cost of the Licensed Product used for such Global Clinical Trial, and reimburse Kiniksa, in case (i), for [***]% of all costs and expenses of such Global Clinical Trial solely in the Selected Territory GCT Countries for the Licensed Product and any other Development costs or expenses associated therewith, including the Fully Burdened Manufacturing Cost of the Licensed Product used for such Global Clinical Trial and other Development activities for the Selected Territory GCT Countries, which costs and expenses are incurred by or on behalf of Kiniksa as a result of Partner's failure to bear such costs in accordance with Section 5.5.3(a) (Ongoing Reimbursement), *plus*, in each case ((i) and (ii)), a [***]% mark-up with respect to all such costs and expenses, and

(B) pay to Kiniksa any Development Milestone Payment that would have been payable with respect to such Global Clinical Trial pursuant to Section 10.2.1 (Development Milestone Events and Payments) had Partner participated in such Global Clinical Trial.

(c) Notwithstanding any provision to the contrary in this Section 5.5.3 (Partner Sharing of Development Costs and Data Access), if Partner has elected to serve as the Territory Sponsor for a given Global Clinical Trial, but Partner is prevented from selecting certain country(ies) in the Territory as Selected Territory GCT Countries in one or more Indications pursuant to Section 3.6.2(b)(iii)(A) or Section 3.6.2(b)(iii)(B) (Partner Final Decision-Making Authority), then, if Partner is required to perform a Territory-Specific Clinical Trial in order to obtain Regulatory Approval of the Licensed Product and does perform such Territory-Specific Clinical Trial in such country(ies) in such Indications, Partner will be granted rights with respect to any and all data or results generated in such Global Clinical Trials for the Licensed Product in such indications pursuant to Section 5.11 (Data Exchange and Use) and under Section 6.5 (Right of Reference) and will not be obligated to pay to Kiniksa the amounts due under this Section 5.5.3 (Partner Sharing of Development Costs and Data Access) with respect to such indications.

5.6 Standard of Conduct.

5.6.1 **General Obligations**. Partner will perform, and will cause its Affiliates, Sublicensees, and Subcontractors to perform, all Development activities for the Licensed Product in a timely and professional manner, and in compliance with the Territory Development Plan, Global Development Plan, or Pre-Clinical Development Plan, as applicable, and all Applicable

Law, including as applicable cGLP and cGCP. In addition, each Party will conduct its obligations with respect to any Global Clinical Trial under a Global Development Plan. Pre-Clinical Development Plan, or (with respect to Partner) Territory-Specific Clinical Trial under a Territory Development Plan (as applicable) in strict adherence with the study design set forth in the applicable protocol therefor and as set forth in such Global Development Plan or such Territory Development Plan, each as may be amended from time to time, and will comply with each statistical analysis plan implemented by the other Party (as applicable) in connection therewith.

5.6.2 **Global Development**. Kiniksa agrees that if Kiniksa or its Affiliates fail to perform one or more Global Clinical Trials as set forth in any Global Development Plan in accordance with the study design set forth in the protocol(s) therefor, then, to the extent that, as a direct result of such failure, Partner is unable to complete its obligations under the Global Development Plan (if Partner is participating as Territory Sponsor) or any Territory Development Plan, Partner will not be in breach of its diligence obligations under Section 5.1 (Development Diligence and Responsibilities) with respect to such failure to perform its obligations under the Global Development Plan or Territory Development Plan, as applicable, as a result of Kiniksa's failure to perform.

5.7 Responsibility for Development Costs.

5.7.1 **Territory-Specific Development Costs**. Except as otherwise set forth in this Agreement, and otherwise subject to Section 5.3 (Global Development Plan) and Section 5.5 (New Development by Kiniksa), Partner will be solely responsible for all costs and expenses incurred by or on behalf of Partner in connection with the Territory Development of the Licensed Product, including the performance of Territory Development activities for the Licensed Product under each Territory Development Plan, including all local studies necessary for Regulatory Approval of the Licensed Product in the Territory. In addition, Partner will be responsible for all costs arising from any compassionate use or open protocols arising from the Territory Development of the Licensed Product to the extent required by applicable Regulatory Authority in any country or region in the Territory.

5.7.2 **Global Development Costs**. Except as provided in this Section 5.7.2 (Global Development Costs), Kiniksa will be solely responsible for all costs and expenses incurred in connection with the Development of Licensed Product pursuant to the Global Development Plan and for the purpose of obtaining Regulatory Approvals and Reimbursement Approvals outside the Territory. Notwithstanding the foregoing, except as otherwise set forth in this Agreement, and only if Partner elects to serve as the Territory Sponsor in accordance with Section 5.3 (Global Development Plan) and Section 5.5 (New Development by Kiniksa), Partner will be responsible for and will pay (a) for all costs and expenses incurred in the furtherance of the conduct of any Global Clinical Trial in the Selected Territory GCT Countries and any other Clinical Development activities in the Selected Territory GCT Countries, to the extent assigned to Partner under the Global Development Plan, and (b) all other costs and expenses incurred by or on behalf of Partner in connection with the performance of any Clinical Development activities in the Selected Territory GCT Countries assigned to Partner under any Global Development Plan. Kiniksa will invoice Partner quarterly for the foregoing costs incurred by or on behalf of Kiniksa in such Calendar Quarter, and Partner will pay the undisputed invoiced amounts within [***] days after the date of any such invoice.

5.8 Clinical Trial Audit Rights.

5.8.1 **Conduct of Audits**. Upon at least [***] days' prior notice by Kiniksa and no more frequently than [***] in each Calendar Year, at Kiniksa's cost and expense, Kiniksa or its representatives may conduct an audit of Partner, its Affiliates, or any Sublicensees, Subcontractors, and all Clinical Trial sites engaged by Partner or its Affiliates or Sublicensees to perform Partner's obligations under the Global Development Plan or Territory Development Plan, in each case, to determine whether the applicable Global Clinical Trials and Territory-Specific Clinical Trials are being conducted in compliance with the terms of the Third Party IP Agreements, this Agreement, the Global Development Plan (if Partner is serving as the Territory Sponsor) or Territory Development Plan, cGLP, cGCP, and Applicable Law and meet Kiniksa's Global Clinical Trial standards provided by Kiniksa from time to time during the Term (which standards will be made known to Partner or included in the Global Development Plan or Territory Development Plan as applicable). Notwithstanding any provision to the contrary set forth in this Agreement, there will be no limit on the number of "for cause" audits that Kiniksa may conduct of Partner, its Affiliates, or any Sublicensees, Subcontractors, and all Clinical Trial sites engaged by Partner or its Affiliates or Sublicensees to perform Partner's obligations under the Global Development Plan or Territory Development Plan, and Kiniksa will use reasonable efforts to notify Partner in writing of any "for cause" audit at least [***] Business Days in advance thereof. After preparing or receiving an audit report, Kiniksa will provide Partner with a written summary of Kiniksa's findings of any material deficiencies from such standards or other areas of remediation that Kiniksa identifies during any such audit. Partner will remediate any such undisputed deficiencies no later than [***] days after Partner's receipt of such report, at Partner's cost and expense or, if such remediation is anticipated to take longer than [***] days, then Partner will promptly implement a plan to complete such remediation as soon as practicable. If any material undisputed deficiencies or areas of remediation are identified in the course of such audit, then Partner will reimburse Kiniksa for Kiniksa's costs and expenses relating to the conduct of such audit within [***] days after receiving Kiniksa's invoice therefor. If Partner disputes any of Kiniksa's findings of deficiencies, then either Party may refer the issue to an independent Third Party regulatory compliance consultant expert agreed by both Parties for resolution. The decision of such independent expert will be final and binding and all fees and expenses of such independent expert will be borne by the Party against which the decision is rendered by the independent Third Party expert.

5.8.2 **Deficient Sublicensees or Sites and Replacement**. With respect to any Global Clinical Trial or Territory-Specific Clinical Trial, if any audit of a Clinical Trial site conducted pursuant to Section 5.8.1 (Conduct of Audits) identifies any non-compliance by such Clinical Trial site with the Third Party IP Agreements, this Agreement, the Global Development Plan (only if Partner has elected to serve as the Territory Sponsor) or Territory Development Plan, cGLP, cGCP, Applicable Law, or Kiniksa's Global Clinical Trial standards provided by Kiniksa in accordance with Section 5.8.1 (Conduct of Audits) (each, a "**Deficient Site**") that may reasonably cause a Regulatory Authority to reject or otherwise deem deficient the Clinical Trial data from Partner's conduct of any such Global Clinical Trial or Territory-Specific Clinical Trial (as applicable) at such Deficient Site, then subject to Partner's right to remediate under Section 5.8.1 (Conduct of Audits), if Partner is unable to successfully remediate the situation in a timely manner and reasonably eliminate the condition causing the Clinical Trial site to be a Deficient Site, then Partner will promptly remove such Deficient Site from the applicable Global Clinical Trial or

Territory-Specific Clinical Trial and replace such Deficient Site with a new Clinical Trial site (a "**Replacement Site**") within the Territory at Partner's sole cost and expense (unless not permitted by Applicable Law or for ethical reasons). Any such Replacement Site will be compliant in all respects with Applicable Law and Kiniksa's Global Clinical Trial standards provided by Kiniksa from time to time during the Term. In addition, if any audit of any Sublicensee conducted pursuant to Section 5.8.1 (Conduct of Audits) identifies that any Sublicensee (including any contract research organizations or other subcontractors engaged to perform activities under the Global Development Plan or Territory Development Plan) is not performing its activities in accordance with the terms of the Third Party IP Agreements, this Agreement, the Global Development Plan or Territory Development Plan, cGLP, or cGCP, as applicable, and Applicable Law or do not meet Kiniksa's Global Clinical Trial standards provided by Kiniksa in accordance with Section 5.8.1 (Conduct of Audits), or that any deficiencies identified as a result of any such audit related to any such Sublicensee's performance may cause a Regulatory Authority to reject or otherwise deem deficient the Clinical Trial data from Partner's conduct of any such Global Clinical Trial or Territory-Specific Clinical Trial (as applicable) (each, a "**Deficient Sublicensee**"), then Partner will promptly (a) require such Deficient Sublicensee to remediate such deficiencies in a timely manner or (b) remove such Deficient Sublicensee from performing further activities under the Global Development Plan or Territory Development Plan and replace such Deficient Sublicensee with a new Sublicensee engaged in accordance with Section 2.2 (Sublicensing and Subcontractors) to perform the applicable Development activities at Partner's sole cost and expense unless such deficiencies can be promptly remedied to Kiniksa's reasonable satisfaction in a timely manner. If the Deficient Sublicensee is unable to mitigate the deficiencies in a timely manner or Partner is unable to mitigate the deficiencies or replace any Deficient Site with a Replacement Site or Deficient Sublicensee with a replacement Sublicensee (as applicable), as applicable, or, in Kiniksa's reasonable discretion, the Deficient Sublicensee or Partner, as applicable, is unable to mitigate the deficiencies or replace any Deficient Site or Deficient Sublicensee, as applicable, in a timely manner so as not to jeopardize the Parties' ability to meet the timelines for Regulatory Submissions set forth in the Territory Development Plan, then, in each case, Kiniksa may (i) replace such Deficient Site with one or more Replacement Sites outside of the Territory, or (ii) with respect to a Deficient Sublicensee, perform itself or have performed by any Third Party engaged by Kiniksa in its sole discretion, the applicable Development activities, and in each case ((i) and (ii)), Partner will be responsible for all costs and expenses incurred by or on behalf of Kiniksa in connection with the engagement of any such Replacement Site or replacement Sublicensee. Kiniksa will invoice Partner quarterly for the foregoing costs incurred by or on behalf of Kiniksa in such Calendar Quarter, and Partner will pay the amount invoiced within [***] days after the date of any such invoice.

5.8.3 **Partner Audits**. Partner will provide Kiniksa with copies of all quality oversight or audit reports prepared in connection with any audit that Partner or its Affiliates or Sublicensees conduct of any Sublicensee, Subcontractor, or Clinical Trial site that Partner or its Affiliates or Sublicensees have engaged or are evaluating to potentially engage to fulfill Partner's obligations under a Global Development Plan or a Territory Development Plan no later than [***] days after receiving or preparing any such report (as applicable), and Kiniksa may provide any such reports to any counterparty to any Third Party IP Agreement if required by the terms of any such Third Party IP Agreement. If Kiniksa believes in good faith that it is required to submit any such quality oversight or audit report to any Regulatory Authority outside of the Territory in connection with obtaining, supporting, or

maintaining one or more Regulatory Approvals for the Licensed Product or for other communications with Regulatory Authorities for the Licensed Product outside of the Territory, then upon Kiniksa's request, Partner will provide a copy of any such quality oversight or audit report to Kiniksa and Partner will reimburse Kiniksa for any translation expenses reasonably incurred by Kiniksa to obtain translation thereof by translators selected by Kiniksa.

5.9 Development Records. Partner will, and will cause its Affiliates, Sublicensees, and Subcontractors to, maintain reasonably complete, current, and accurate records of all Development activities conducted by or on behalf of Partner, and its Affiliates, Sublicensees, and Subcontractors, respectively, pursuant to this Agreement and all data and other information resulting from such activities consistent with its usual practices, in validated computer systems that are compliant with 21 C.F.R. §11 and in accordance with Applicable Law of both the United States and the Territory. Partner will maintain all such records for a period of [***] years after the end of the Term. Such records will fully and properly reflect all work done and results achieved in the performance of the Development activities for the Licensed Product in good scientific manner appropriate for regulatory and patent purposes and may record only activities performed under this Agreement and not include or be comingled with records of activities not conducted under this Agreement. Partner will document all non-clinical and preclinical studies and Clinical Trials in formal written study reports in accordance with cGLP and cGCP, as applicable, and in compliance with Applicable Law. Upon Kiniksa's reasonable request, not more frequently than once each Calendar Quarter during which Partner or its Affiliates, Sublicensees, or Subcontractors are performing or having performed Development activities for the Licensed Product, Partner will, and will cause its Affiliates, Sublicensees, and Subcontractors to, allow Kiniksa to access, review, and copy such records (including access to relevant databases). Kiniksa and its Affiliates, licensees, licensors, and Sublicensees will have the right to use the data and results generated by or on behalf of Partner and its Affiliates, Sublicensees, and Subcontractors hereunder to Exploit the Licensed Product outside of the Territory and to perform Development activities under a Global Development Plan. Partner will transmit all records or other documents to Kiniksa electronically under this Agreement over secure systems that include adequate encryption safeguards to prevent unauthorized access and maintain data security.

5.10 Development Reports. No later than the end of each Calendar Quarter during which Partner is performing, or having performed, Development activities for the Licensed Product, and solely to the extent Partner has not already made a report to the JDC concerning its Development activities, Partner will provide Kiniksa, at Partner's sole cost and expense, with reasonably detailed written reports summarizing the Development activities performed during the period since the preceding report, the Development activities in process, and the future activities that Partner or its Sublicensees or Subcontractors expect to initiate, including a summary of the data, timelines, and results of such Development activities. Such reports will be in English. Partner will also establish a secure link that includes adequate encryption safeguards to provide solely to Kiniksa electronic access to such information. Without limiting the foregoing, such reports will contain sufficient detail to enable Kiniksa to assess Partner's compliance with its Development diligence obligations set forth in Section 5.1 (Development Diligence and Responsibilities) and progress towards obtaining Regulatory Approval for the Licensed Product, including under the then-current Territory Development Plan. Partner will promptly respond to Kiniksa's reasonable requests from time to time for additional information regarding significant Development activities for the Licensed Product performed by or on behalf of Partner or its Affiliates, Sublicensees, or Subcontractors. The Parties will discuss the status, progress, and results of all Development activities at each JDC and JSC meeting. Such reports will be the Confidential Information of each Party and subject to the

terms of Article 11 (Confidentiality; Publication). In addition, Partner agrees to promptly disclose to Kiniksa all information related to the Development and Commercialization by or on behalf of Partner under this Agreement to the extent that such information may reasonably be expected to have an impact on the Development or Commercialization of the Licensed Product in the Regeneron Retained EEO Field (as defined in the Regeneron License Agreement).

5.11 **Data Exchange and Use**. In addition to its adverse event and safety data reporting obligations set forth in Section 6.6 (Adverse Events Reporting), each Party will promptly provide the other Party, through the JDC, with copies of all data and results and all supporting documentation (*e.g.*, protocols, Investigator's Brochures, case report forms, and analysis plans, all in English language) Controlled by such Party that are generated by or on behalf of such Party or its Affiliates, Sublicensees, or Subcontractors, if applicable, in the Development of the Licensed Product, including all data and results (or on whose behalf such data and results are generated) in the course of conducting such non-clinical or preclinical studies or Clinical Trials for the Licensed Product. Such data, results, and supporting documentation provided by a Party pursuant to this Section 5.11 (Data Exchange and Use) will be the Confidential Information of such Party, and such Party will be the Disclosing Party with respect thereto, in each case, subject to the terms of Article 11 (Confidentiality; Publication). Partner will not have the right to use or reference such data and results provided by Kiniksa or any data that constitutes Assigned Collaboration Know-How, unless and until Partner bears its applicable share of the costs and expenses in accordance with Section 5.5 (New Development by Kiniksa), in which case, Partner will have the exclusive right to use and reference such data and results for the purpose of performing Development activities in accordance with this Agreement (including under any Global Development Plan and Territory Development Plan), and obtaining, supporting, and maintaining Regulatory Approvals and any Reimbursement Approval, as applicable, of the Licensed Product in the Territory without additional consideration. Kiniksa and its designees will have the exclusive right to use and reference such data and results provided by Partner, for the purpose of Developing the Licensed Product, and obtaining, supporting, or maintaining Regulatory Approval or any Reimbursement Approval, as applicable, of the Licensed Product outside the Territory, without additional consideration.

ARTICLE 6
REGULATORY

6.1 **Regulatory Strategy**. The JDC will discuss and develop a regulatory strategy for the Licensed Product in each country or region in the Territory (which, strategy will include the estimated timeline for submission of MAAs for the Licensed Product in each country and region in the Territory) to be included in the Territory Development Plan and will submit the same to the JSC to review, discuss, and determine whether to approve. From time to time the JDC may update the regulatory strategy for the Licensed Product and submit the same to the JSC to review, discuss, and determine whether to approve. Once approved by the JSC, each update to a regulatory strategy for such the Licensed Product will become effective and supersede the then-current regulatory strategy for the Licensed Product. In addition, Partner will notify Kiniksa if any data regarding the Licensed Product generated under this Agreement is submitted to Regulatory Authorities or Governmental Authorities in the Territory in support of the Licensed Product that may reasonably be expected to have a Material Adverse Impact on the Licensed Product.

6.2 **Partner's Responsibilities**.

6.2.1 **Obtaining and Maintaining Regulatory Approvals**. Through its reports submitted to the JDC, Partner will keep Kiniksa informed of regulatory developments related to the Licensed Product in each country and region in the Territory and will promptly notify

Kiniksa in writing of any decision by any Regulatory Authority in the Territory regarding the Licensed Product. Subject to this Section 6.2.1 (Obtaining and Maintaining Regulatory Approvals), for each Indication that is included in the Territory Development Plan or Global Development Plan for the Licensed Product, Partner will be the marketing authorization holder and will be responsible for all regulatory activities leading up to and including obtaining, and thereafter maintaining, Regulatory Approvals and any Reimbursement Approvals in all countries and regions of the Territory, in its own name or in the name of its Affiliate, Sublicensee, or Third Party Distributor. If it is not feasible for Partner to own any such Regulatory Submissions, Regulatory Approvals, or Reimbursement Approvals in its own name according to the relevant Applicable Laws in the Territory, then (a) Kiniksa will hold such Regulatory Submissions, Regulatory Approvals, or Reimbursement Approvals in its own name for the benefit of and on behalf of Partner (in such case, Kiniksa will be the "**Marketing Authorization Holder**", which means the Party in whose name the Regulatory Approvals and Reimbursement Approvals for the Licensed Product in the Territory are held) and will appoint Partner as its legal agent in the Territory; (b) without the prior written consent of Kiniksa, Partner will not conduct any activities or initiate any procedures that would affect the validity or change the information of such Regulatory Submissions, Regulatory Approvals, or Reimbursement Approvals; (c) Kiniksa will reasonably cooperate with Partner and execute such documents and make such submissions on behalf of Partner as may be reasonably necessary or to the extent Kiniksa is required to do so as owner of such Regulatory Submissions, Regulatory Approvals, or Reimbursement Approvals under Applicable Law in the Territory; *provided* that Kiniksa will assume no liability as a result of being the Marketing Authorization Holder or otherwise holding such Regulatory Submissions (unless Kiniksa is grossly negligent or willfully breaches its obligations as the Marketing Authorization Holder), Regulatory Approvals, or Reimbursement Approvals on behalf of Partner; (d) Partner will reimburse Kiniksa for Kiniksa's costs and expenses incurred in its acting as Marketing Authorization Holder within [***] days after the date of any invoice from Kiniksa for any such costs or expenses; and (e) when feasible pursuant to Applicable Law, Kiniksa will conduct activities and execute documents that are necessary for transferring such Regulatory Submissions, Regulatory Approvals, or Reimbursement Approvals to Partner upon Partner's written request.

6.2.2 **Partner Assistance outside the Territory**. Partner will reasonably cooperate to assist Kiniksa in its efforts to prepare and submit any Regulatory Submissions to obtain, support, or maintain Regulatory Approvals for the Licensed Product outside the Territory, including by providing to Kiniksa all data and documentation related to the Licensed Product generated by Partner or its Affiliates (which assistance and data generation must be in accordance with Applicable Law and all requirements and standards of the FDA) as well as any necessary samples and materials. Partner will invoice Kiniksa quarterly for the costs (at the FTE Rate) and expenses incurred by or on behalf of Partner in the performance of such activities during such Calendar Quarter, and Kiniksa will pay the undisputed invoiced amounts within [***] days after the date of any such invoice.

6.2.3 **Review of Regulatory Submissions**. Partner will provide to Kiniksa (through the JDC) for each of [***] (each a "**Key Country**"), and for each other country and region in the Territory upon Kiniksa's request, in each case, for review and comment, drafts of all Regulatory Submissions for which Partner is responsible and all proposed Approved Labeling in the Territory for the Licensed Product, including all INDs and MAAs for the Licensed Product in each Indication in each Key Country and, to the extent requested by

Kiniksa for each other country or region in the Territory, and Partner will incorporate any reasonable comments received from Kiniksa on such drafts. The JDC will review any changes in regulatory strategy and, to the extent requested by Kiniksa, will discuss any Regulatory Submission for which Partner is responsible and all proposed Approved Labeling for the Licensed Product in each Key Country and, to the extent requested by Kiniksa for each other country or region in the Territory. Partner will incorporate any reasonable comments received from Kiniksa on such proposed Approved Labeling. Notwithstanding the foregoing, if any regulatory activities are conducted, or any Regulatory Submissions filed, in each case, in Kiniksa's name, then (a) Kiniksa will have final decision-making authority regarding all such regulatory activities, including the content of Regulatory Submissions for the Licensed Product in the Field in the Territory; *provided* that Kiniksa will reasonably consider any comments Partner may have regarding such regulatory activities; and (b) Partner will, and will ensure that its relevant Affiliates and Sublicensees will, conduct all regulatory activities in compliance with Kiniksa's final decisions. In addition, each Party will notify the other Party of any substantive Regulatory Submissions in the U.S. or in any country or region the Territory and proposed Approved Labeling for the Licensed Product and any comments or other substantive correspondences related thereto submitted to or received from any Regulatory Authority in the U.S. or in any country or region in the Territory and will provide the other Party with copies thereof as soon as reasonably practicable, but in all events within [***] days after submission or receipt thereof (or such longer time period as may be necessary to obtain translations thereof). If any such Regulatory Submission or proposed Approved Labeling, comment, or correspondence is not in English, then Kiniksa may obtain English translation thereof by translators selected by Kiniksa, at Kiniksa's sole cost and expense, unless Kiniksa is the Marketing Authorization Holder or any such Regulatory Submission or proposed Approved Labeling is otherwise in Kiniksa's name, in each of which cases Kiniksa will invoice Partner for translation expenses with respect thereto and Partner will reimburse such undisputed invoiced amounts within [***] days after the date of any such invoice.

6.2.4 **Notice of Meetings**. Partner will provide Kiniksa with notice of any meeting or discussion with any Regulatory Authority in the Territory related to the Licensed Product no later than [***] Business Days after receiving notice thereof or in any event with as much advanced notice as is possible prior to such meeting or discussion if Partner receives notice thereof less than [***] Business Days in advance of the applicable meeting or discussion. Partner (or its designee) will lead any such meeting or discussion and Kiniksa or its designee will have the right, but not the obligation, to attend and participate in any such meeting or discussion unless prohibited or restricted by Applicable Law or Regulatory Authority. Notwithstanding the foregoing, if any such meeting or discussion with a Regulatory Authority concerns the Licensed Product for which Kiniksa is the Marketing Authorization Holder from such Regulatory Authority at such time, then Kiniksa or its designee will have the further right, but not obligation, to lead such meeting or discussion. At Kiniksa's request, Kiniksa may participate in any preparations of Partner or its Affiliates or Sublicensees for any such meeting or discussion. If Kiniksa elects not to attend such meeting or discussion, then Partner will provide to Kiniksa a written summary thereof in English promptly following such meeting or discussion, as well as any minutes prepared by Partner or, to the extent available, formal minutes generated by the Regulatory Authority.

6.2.5 **Partner Responsibility for Costs and Expenses**. Irrespective of which Party is the Marketing Authorization Holder for the Licensed Product in the Territory, Partner will be responsible for all costs and expenses incurred in connection with the performance of all

regulatory activities leading up to and including obtaining and thereafter maintaining Regulatory Approvals and any Reimbursement Approvals, as applicable, for the Licensed Product from Regulatory Authorities in the Territory.

6.3 Communications with Regulatory Authorities. Unless otherwise agreed by the Parties (or unless otherwise set forth in this Agreement or in the applicable Global Development Plan), Partner will not, and will ensure that its Affiliates and its Sublicensees do not, communicate with any Regulatory Authority having jurisdiction outside of the Territory with respect to the Licensed Product, unless so ordered by such Regulatory Authority, in which case, Partner will immediately notify Kiniksa of such order.

6.4 Kiniksa's Responsibilities. Except with respect to the New Development of the Licensed Product for a Global Clinical Trial for which Partner does not agree to bear its share of costs and expenses as set forth under Section 5.5.3 (Partner Sharing of Development Costs and Data Access), Kiniksa will reasonably cooperate with Partner in obtaining any Regulatory Approvals and any Reimbursement Approvals, as applicable, for the Licensed Product in the Territory by providing access to Regulatory Approvals, Regulatory Submissions, other information, documentation, samples, and materials for the Licensed Product, both inside and outside of the Territory, in each case, to the extent (a) Controlled by Kiniksa, (b) not previously provided to Partner, and (c) reasonably necessary for or requested by Partner to obtain Regulatory Approvals. Partner will reimburse Kiniksa's out-of-pocket costs reasonably incurred in connection with providing any such access or further assistance to Partner. Accordingly, Kiniksa will invoice Partner quarterly for the foregoing costs incurred by or on behalf of Kiniksa in such Calendar Quarter, and Partner will pay the undisputed invoiced amounts within [***] days after the date of any such invoice.

6.5 Right of Reference. Except with respect to the New Development of the Licensed Product for a Global Clinical Trial for which Partner does not agree to bear its share of costs and expenses as set forth under Section 5.5.3 (Partner Sharing of Development Costs and Data Access) each Party will grant, and hereby does grant, to the other Party a right of reference to all Regulatory Submissions pertaining to the Licensed Product in the Field submitted by or on behalf of such Party or its Affiliates, which right of reference (a) to Regulatory Submissions submitted by or on behalf of Kiniksa is exclusive to Partner in the Territory, and (b) to Regulatory Submissions submitted by or on behalf of Partner is exclusive to Kiniksa outside of the Territory. Partner may use such right of reference to Kiniksa's Regulatory Submissions solely to seek, obtain, support, and maintain Regulatory Approvals and any Reimbursement Approvals, as applicable, for the Licensed Product in the Field in the Territory. Kiniksa may use such right of reference to Partner's Regulatory Submissions, if any, solely to seek, obtain, support, and maintain Regulatory Approval and any Reimbursement Approvals for the Licensed Product outside of the Territory. Each Party will bear its own costs and expenses associated with providing the other Party with the right of reference pursuant to this Section 6.5 (Right of Reference). Each Party will take such actions as may be reasonably requested by the other Party to give effect to the intent of this Section 6.5 (Right of Reference) and to give the other Party the benefit of the granting Party's Regulatory Submissions in the other Party's territory as provided herein. Such actions may include providing to the other Party copies of correspondence and communications received from the applicable Regulatory Authorities related to such Party's application for Regulatory Approval of the Licensed Product in the Territory (if Partner is the Party seeking Regulatory Approval) and of the Licensed Product outside of the Territory (if Kiniksa is the Party seeking Regulatory Approval).

6.6 Adverse Events Reporting.

6.6.1 **Safety Agreement**. Prior to the commencement of the first Clinical Trial of the Licensed Product conducted by or on behalf of Partner or its Affiliates, the Parties will enter into a written agreement setting forth worldwide safety and pharmacovigilance procedures for the Parties with respect to the Licensed Product (the "**Safety Agreement**"). The Safety Agreement will describe the obligations of both Parties with respect to the coordination of collection, investigation, reporting, and exchange of information between the Parties concerning any adverse event experienced by a subject, and the seriousness thereof, whether or not determined to be attributable to the Licensed Product, including any such information received by either Party from a Third Party (subject to receipt of any required consents from such Third Party) and will be sufficient to permit each Party and its Affiliates, licensees, or Sublicensees (as applicable) to comply with its legal obligations with respect thereto, including each Party's obligations as the owner or holder of Regulatory Submissions, Regulatory Approvals, and Reimbursement Approvals for the Licensed Product in the Territory, as applicable. The Safety Agreement will also detail each Party's responsibilities with respect to recalls and withdrawals of the Licensed Product inside and outside of the Territory. If required by changes in Applicable Law, the Parties will make appropriate updates to the Safety Agreement. Each Party will comply with its respective obligations under the Safety Agreement and cause its Affiliates, licensees, and Sublicensees to comply with such obligations. Each time the JSC approves a new planned Clinical Trials for the Licensed Product, the Parties will update the Safety Agreement to the extent necessary to comply with any applicable requirements set forth under Applicable Law or of any Regulatory Authorities related to adverse event reporting, drug safety, patient safety, pharmacovigilance, and risk management. Notwithstanding any provision to the contrary in this Agreement or the Safety Agreement, each Party and its Affiliates, licensees, and Sublicensees will have the right to disclose information related to the safety of the Licensed Product to the extent that such disclosure is required for such Party to comply with its obligations under Applicable Law or the safety requirements of the applicable Regulatory Authorities. The Parties will cooperate with each other to address any safety-related inquiries or requests for safety assessment by any Regulatory Authority, including providing any necessary data or information in a timely manner. To the extent that there is a conflict between the terms of this Agreement and the terms of the Safety Agreement, the terms of the Safety Agreement will govern with respect to the subject matter set forth therein.

6.6.2 **Safety Databases**. Partner will maintain a safety database in English for Clinical Trials for the Licensed Product conducted in the Territory under a Territory Development Plan, at its sole cost and expense. Partner will be responsible for: (a) reporting to the applicable Regulatory Authorities in the Territory all quality complaints, adverse events, and safety data related to the Licensed Product for all Territory-Specific Clinical Trials or Global Clinical Trials conducted in the Territory; and (b) responding to safety issues and to all requests of Regulatory Authorities related to the Licensed Product in the Territory. Partner will provide Kiniksa (i) real-time access to Partner's safety database for the Licensed Product in the Territory, and (ii) upon Kiniksa's request, query results from Partner's safety database for the Licensed Product. As between the Parties, Kiniksa will maintain a global safety database for Global Clinical Trials for the Licensed Product conducted under each Global Development Plan at Kiniksa's cost and expense.

6.7 **Regulatory Audits**. In addition to its rights to conduct audits pursuant to Section 5.8 (Clinical Trial Audit Rights), upon reasonable notification and no more frequently than [***] in each Calendar Year (unless Kiniksa is the Marketing Authorization Holder for the Licensed Product for

a country or region in the Territory, in which case, there will be no such limitation on the number of inspections or audits that may be conducted in such country or region in a given Calendar Year), Kiniksa or its representatives will be entitled to conduct audits of safety and regulatory systems, procedures, or practices of Partner or its Affiliates or Sublicensees (including Clinical Trial sites) relating to the Licensed Product. Notwithstanding any provision to the contrary set forth in this Agreement, there will be no limit on the number of "for cause" audits that Kiniksa may conduct of safety and regulatory systems, procedures, or practices of Partner or its Affiliates or Sublicensees (including Clinical Trial sites) related to the Licensed Product, and Kiniksa will use reasonable efforts to notify Partner in writing of any "for cause" audit at least [***] Business Days in advance thereof. Kiniksa or its representatives will conduct all such audits in accordance with Applicable Law. With respect to any inspection of Partner or its Affiliates or Sublicensees (including Clinical Trial sites) by any Governmental Authority relating to the Licensed Product, Partner will notify Kiniksa of such inspection (a) no later than [***] Business Days after Partner receives notice of such inspection (or in any event with as much advanced notice as is possible prior to such inspection if Partner receives notice thereof less than [***] Business Days in advance of the applicable inspection) or (b) within [***] Business Days after the completion of any such inspection of which Partner did not receive prior notice. Partner will promptly provide Kiniksa with all available information related to any such inspection (unless prohibited by Applicable Law), and Kiniksa may provide any such reports to any counterparty to any Third Party IP Agreement if required by the terms of such Third Party IP Agreement. Partner will also permit Governmental Authorities outside of the Territory to conduct inspections of Partner or its Affiliates or Sublicensees (including Clinical Trial sites) relating to the Licensed Product, and will ensure that all such Affiliates or Sublicensees permit such inspections. Kiniksa or its designee will have the right, but not the obligation (unless required by Applicable Law or any Governmental Authority), to be present at any such inspection at its sole cost and expense. Following any such regulatory inspection related to the Licensed Product, Partner will provide Kiniksa with (i) an unredacted copy of any findings, notice, or report provided by any Governmental Authority related to such inspection (to the extent related to the Licensed Product) within [***] Business Days of Partner receiving the same, and (ii) a written summary in English of any findings, notice, or report of a Governmental Authority related to such inspection (to the extent related to the Licensed Product) no later than [***] Business Days after receiving the same.

6.8 **Notice of Regulatory Action**. If any Regulatory Authority takes or gives notice of its intent to take any regulatory action with respect to any activity of Partner relating to the Licensed Product, then Partner will notify Kiniksa of such contact, inspection, or notice or action within [***] Business Days after receipt of such notice (or, if action is taken without notice, within [***] Business Days of Partner becoming aware of such action). Partner will have the final decision-making authority with respect to such responses and will incorporate Kiniksa's reasonable comments to any such responses, *provided* that if Kiniksa is then the Marketing Authorization Holder for the Licensed Product, then Kiniksa will have final decision-making authority with respect to such responses. The costs and expenses of any regulatory action in the Territory will be borne by Partner. Each Party will keep the other Party informed, as soon as possible, but no later than 24 hours after notification of any action by, or notification or other information that it receives (directly or indirectly) from, any Regulatory Authority, Third Party, or other Governmental Authority that:

(a) raises any material concerns regarding the safety or efficacy of the Licensed Product;

(b) indicates or suggests a potential investigation or formal inquiry by any Regulatory Authority in connection with the Exploitation of the Licensed Product; or

(c) is reasonably likely to lead to a recall or market withdrawal of the Licensed Product anywhere in the Territory.

ARTICLE 7
MANUFACTURING

7.1 Supply by Kiniksa.

7.1.1 **Development Supply**. Promptly after the Effective Date and in no event later than [***] days prior to the anticipated commencement of the first Clinical Trial to be conducted by Partner in the Territory, the Parties will use reasonable efforts to negotiate in good faith to enter into a clinical supply agreement for the supply to Partner of the Licensed Product (for the Licensed Product, together with the corresponding quality agreement, the "**Clinical Supply Agreement**") pursuant to which Partner will purchase from Kiniksa or its Affiliate all of its requirements of drug product for the Licensed Product as necessary for Partner to fulfill its obligations under this Agreement related to the Clinical Development of the Licensed Product in the Territory, which drug product will be labeled or unlabeled as applicable depending on whether such Licensed Product is to be used in the performance of a Global Clinical Trial or a Territory-Specific Clinical Trial and as to be further specified in the Clinical Supply Agreement. The terms of the Clinical Supply Agreement will include product warranties and terms related to labeling, audit, delivery, acceptance and rejection, limitations of liability, and other customary terms, which, in each case, are consistent with the terms of any agreement between Kiniksa and any Third Party that is Manufacturing the Licensed Product. Pursuant to and in accordance with the Clinical Supply Agreement, Kiniksa will use reasonable efforts to supply unlabeled drug product to Partner pursuant to this Section 7.1.1 (Development Supply) at a transfer price equal to [***]. Upon its receipt of a purchase order from Partner for the Licensed Product under the Clinical Supply Agreement, Kiniksa will invoice Partner for the Licensed Product and, subject to the terms of the Clinical Supply Agreement, Partner will pay the undisputed invoiced amounts within [***] days after the date of the invoice.

7.1.2 **Commercial Supply**. No later than [***] prior to the anticipated First Commercial Sale of the Licensed Product in the Territory, the Parties will use reasonable efforts to negotiate in good faith to agree on the terms of, and enter into, a commercial supply agreement for the Licensed Product (together with the corresponding quality agreement, the "**Commercial Supply Agreement**"), for the supply to Partner of the Licensed Product pursuant to which Partner will purchase from Kiniksa all of its requirements of drug product for the Licensed Product necessary for Partner to fulfill its obligations under this Agreement related to the Commercialization of the Licensed Product in the Territory. The terms of the Commercial Supply Agreement will include product warranties and terms related to labeling, safety stock provisions, failure to supply, audit, shortage allocation, delivery, acceptance and rejection, limitations of liability, and other customary terms, that, in each case, are consistent with the terms of any agreement between Kiniksa and any Third Party Manufacturing the Licensed Product. Pursuant to and in accordance with the Commercial Supply Agreement for the Licensed Product in the Territory, Kiniksa will use reasonable efforts to supply to Partner pursuant to this Section 7.1.2 (Commercial Supply) the Licensed Product at a transfer price equal to [***]. Upon its receipt of a purchase order from Partner for the Licensed Product under the Commercial Supply Agreement, Kiniksa

will invoice Partner for the Licensed Product and, subject to the terms of the Commercial Supply Agreement, Partner will pay the undisputed invoiced amounts within [***] days after the date of the invoice.

7.1.3 **Shipment and Delivery**. Delivery of all Licensed Product supplied by Kiniksa under the Clinical Supply Agreement or Commercial Supply Agreement will take place [***] (Incoterms 2020) at the applicable port of import. Kiniksa will be responsible for obtaining all licenses or other authorizations for the exportation of Licensed Product. Partner will be responsible for obtaining all licenses or other authorizations for the importation of Licensed Product into the Territory, and Kiniksa will use reasonable efforts to provide to Partner any documentation in Kiniksa's Control that is required with respect to the importation of the Licensed Product into the Territory. Partner will also be responsible for all quality control and quality assurance, release, storage, customs clearance, and distribution of the Licensed Product in the Territory, at Partner's cost and expense.

7.2 **Packaging and Labeling**. Partner will package and, to the extent applicable, label all Licensed Product solely for the Territory in accordance with the Kiniksa P&L Process and Specifications and all Applicable Law.

7.3 **Product Tracking in the Territory**. Partner will, and will ensure that its Affiliates and Sublicensees, maintain adequate records to permit the Parties to trace the distribution, sale, and use of all Licensed Product in the Territory. At Kiniksa's request, Partner will provide such records to Kiniksa.

ARTICLE 8
MEDICAL AFFAIRS

8.1 **Medical Affairs Plan**. No later than [***] days prior to the anticipated date of performance of the Medical Affairs activities for the Licensed Product in the Territory, and in no event later than [***] days prior to the anticipated commercial launch of the Licensed Product in the Territory, the JDC will develop, review, and discuss an initial draft of the Medical Affairs Plan for the Licensed Product and provide such initial draft to the JSC to review, discuss, and determine whether to approve. The Medical Affairs Plan will contain a high level summary of the major Medical Affairs activities to be undertaken for the Licensed Product in the Territory and the estimated timelines for performing such activities. Thereafter, from time to time, but at least annually, the JDC will propose updates to the Medical Affairs Plan for the Licensed Product to reflect changes in such plans, including to account for relevant factors that may influence such plan and the Medical Affairs activities set forth therein and provide each such update to the JSC to review, discuss, and determine whether to approve. To the extent relevant to the conduct of Medical Affairs activities for the Licensed Product in the Territory by Partner in accordance with the Medical Affairs Plan, the Parties will discuss, through the JSC, Kiniksa's Medical Affairs activities outside of the Territory, including medical publications, real world study data, symposium, and conference presentations.

8.2 **Medical Affairs Reports**. For each Calendar Quarter in which any Medical Affairs are conducted by or on behalf of Partner or its Affiliates or Sublicensees for the Licensed Product in the Territory no later than the end of such Calendar Quarter, Partner will provide to Kiniksa a report (by means of a slide presentation or otherwise) summarizing the Medical Affairs activities performed by or on behalf of Partner and its Affiliates and Sublicensees in the Territory for the Licensed Product in each country and region in the Territory since the prior report provided by Partner. Such reports will be the Confidential Information of each Party and subject to the terms of Article 11

(Confidentiality; Publication). Partner will provide updates to any such report at each meeting of the JSC and JDC.

8.3 **Coordination of Medical Affairs Activities**. The Parties recognize that each Party may benefit from the coordination of certain Medical Affairs activities for the Licensed Product inside and outside of the Territory. Accordingly, the Parties will coordinate such activities through the JDC where appropriate.

ARTICLE 9
COMMERCIALIZATION

9.1 **Commercialization Diligence Obligations**. Subject to the availability of commercial supply of Licensed Product and receipt of Regulatory Approval for the Licensed Product, Partner will be solely responsible for and will use Commercially Reasonable Efforts to Commercialize Licensed Product in each Indication for which Regulatory Approval is granted in each country or region in the Territory, including to seek and obtain Reimbursement Approval for the Licensed Product in each Indication in each such country or region (to the extent required therein). Partner will conduct all Commercialization of the Licensed Product in the Territory in accordance with the Commercialization Plan for the Licensed Product, at its sole cost and expense, and subject to the terms of this Agreement. Without limiting the foregoing, Partner will use Commercially Reasonable Efforts to achieve First Commercial Sale of the Licensed Product in each country or region in the Territory within [***] months after obtaining Regulatory Approval for the Licensed Product in such country or region, *provided*, that Kiniksa supplies conforming Licensed Product in accordance with the Commercial Supply Agreement.

9.2 **Commercialization Plan.** No later than [***] months prior to the anticipated date of approval of the first filing of the first MAA for the Licensed Product in a country or region in the Territory, Partner will develop an initial draft of the Commercialization Plan for the Licensed Product and provide such initial draft to the JSC to review and discuss such initial draft. The Commercialization Plan for the Licensed Product will contain in reasonable detail the major Commercialization activities to be undertaken (including revenue targets) for the Licensed Product in the Territory and the estimated timelines for achieving such activities. Thereafter, from time to time, but at least annually (and in any event no later than [***] days prior to the anticipated date of the first filing of the first MAA for the Licensed Product in the Territory), Partner will propose updates to the Commercialization Plan for the Licensed Product to reflect changes in such plans, including those in response to changes in the marketplace, relative commercial success of the Licensed Product, and other relevant factors that may influence such plan and the Commercialization activities set forth therein and provide each such update to the JSC to review, discuss, and determine whether to approve. The Commercialization Plan (including each update thereto) must be consistent with Kiniksa's global brand strategy and global key messaging for the Licensed Product (each, a "**Global Brand Strategy**"), as provided to Partner by Kiniksa from time to time during the Term.

9.3 **Commercialization Reports**. Partner will provide to Kiniksa [***] written reports that summarize the Commercialization activities performed by or on behalf of Partner and its Affiliates and Sublicensees in the Territory for the Licensed Product in each country or region in the Territory since the prior report provided by Partner. Each such report will contain reasonably sufficient detail to enable Kiniksa to assess Partner's compliance with its Commercialization diligence obligations set forth in Section 9.1 (Commercialization Diligence Obligations). Such reports will be Confidential Information of each Party and subject to the terms of Article 11 (Confidentiality; Publication). Partner will, or will cause its Affiliates or Sublicensees to, provide updates to any such report at each meeting of the JSC.

9.4 **Coordination of Commercialization Activities**. The Parties recognize that each Party may benefit from the coordination of certain Commercialization activities for the Licensed Product inside and outside of the Territory (other than pricing for the Licensed Product inside and outside of the Territory, the responsibilities for which are set forth in Section 9.5 (Pricing; Reimbursement Approvals)). Accordingly, the Parties will coordinate such activities through the JSC where appropriate.

9.5 **Pricing; Reimbursement Approvals**. Each Party will have the right to determine the price of the Licensed Product sold in its respective territory and neither Party will have the right to direct, control, or approve the pricing of the Licensed Product in the other Party's territory. Partner will keep Kiniksa timely informed on the status of any application for Reimbursement Approval for the Licensed Product in the Territory, including any discussion with any Regulatory Authority with respect thereto.

9.6 **Diversion**. Each Party agrees that it will not, and will ensure that its Affiliates and Sublicensees and Subcontractors will not, either directly or indirectly, promote, market, distribute, import, sell, or have sold the Licensed Product to any Third Party or to any address or Internet Protocol address or the like in the other Party's territory, including via the Internet or mail order. Notwithstanding any provision to the contrary set forth in this Agreement, each Party will have the right to attend conferences and meetings of congresses in the other Party's territory and to promote and market the Licensed Product to Third Party attendees at such conferences and meetings, subject to this Section 9.6 (Diversion). Neither Party will engage, nor permit its Affiliates or Sublicensees to engage, in any advertising or promotional activities relating to the Licensed Product for use directed primarily to customers or other buyers or users of the Licensed Product located in any country or jurisdiction in the other Party's territory or solicit orders from any prospective purchaser located in any country or jurisdiction in the other Party's territory. If a Party or its Affiliates or Sublicensees receive any order for the Licensed Product from a prospective purchaser located in a country or jurisdiction in the other Party's territory, then such Party will immediately refer that order to such other Party and will not accept any such orders. Neither Party will, nor will either Party permit its Affiliates or Sublicensees to, deliver or tender (or cause to be delivered or tendered) the Licensed Product to Third Parties for use in the other Party's territory except in accordance with a Global Development Plan or Territory Development Plan. In addition, Partner and its Affiliates will use reasonable efforts to monitor and prevent exports of the Licensed Product from in the Territory for Commercialization outside the Territory, and will monitor and prevent off-label use outside the Field (but otherwise in the Territory), in each case, using methods commonly used in the industry for such purpose. Partner will promptly inform Kiniksa of any such exports of Licensed Product for Commercialization outside the Territory or off-label use outside the Field (but otherwise in the Territory), and the actions taken to prevent such exports or off-label use. Partner agrees to take reasonable actions requested in writing by Kiniksa that are consistent with Applicable Laws to prevent export of the Licensed Product for Commercialization outside the Territory or for off-label use outside the Field (but otherwise in the Territory).

ARTICLE 10
PAYMENTS

10.1 **Upfront Payment.** No later than [***] days following the Effective Date, Partner will pay to Kiniksa, by wire transfer of immediately available funds, a non-refundable, non-creditable upfront payment of $[***] in U.S. Dollars.

10.2 **Milestone Payments**.

10.2.1 **Development Milestone Events and Payments**. No later than [***] days after the earliest achievement of each development milestone event set forth in Table 10.2.1 below for the Licensed Product, Partner will pay to Kiniksa the corresponding development milestone payment set forth in Table 10.2.1 (the development milestone event set forth Table 10.2.1 below, the "**Development Milestone Event**," and the development milestone payment set forth in Table 10.2.1 below, the "**Development Milestone Payment**").

Table 10.2.1 Development Milestones	
Development Milestone Events	***Development Milestone Payment (in U.S. Dollars)***
Receipt of Regulatory Approval from the NMPA for the Licensed Product in the first Indication	$[***]

10.2.2 **Sales Milestone Events and Payments**. No later than [***] days after the Calendar Quarter in which each sales milestone event set forth below is achieved as set forth in Table 10.2.2 below for the Licensed Product, Partner will pay to Kiniksa the corresponding sales milestone payment set forth in Table 10.2.2 (the sales milestone events set forth in Table 10.2.2, the "**Sales Milestone Events**" and the sales milestone payments set forth in Table 10.2.2, the "**Sales Milestone Payments**"). If in a given Calendar Quarter during the Term more than one Sales Milestone Event is achieved, then Partner will pay to Kiniksa a separate Sales Milestone Payment with respect to each such Sales Milestone Event that is achieved for the first time in such Calendar Quarter.

Table 10.2.2 Sales Milestones		
	Sales Milestone Event	***Sales Milestone Payment (in U.S. Dollars)***
1.	First Calendar Year in which annual Net Sales of the Licensed Product in the Territory equal or exceed $[***] USD	$[***]
3.	First Calendar Year in which annual Net Sales of the Licensed Product in the Territory equal or exceed $[***] USD	$[***]
4.	First Calendar Year in which annual Net Sales of the Licensed Product in the Territory equal or exceed $[***] USD	$[***]

10.2.3 **Notification of Milestone Events**. Partner will promptly notify Kiniksa in writing, but in no event later than (a) [***] days after the achievement of each Development Milestone Event and (b) [***] days after the end of the Calendar Quarter in which each Sales Milestone Event is achieved (together with the Development Milestone Events, the "**Milestone Events**"). However, in no event will a failure by Partner to deliver such notice of achievement of a Milestone Event relieve Partner of its obligation to pay Kiniksa the corresponding Development Milestone Payment or Sales Milestone Payment (collectively, the "**Milestone Payments**").

10.3 Royalty Payments to Kiniksa.

10.3.1 **Royalty Rates**. Subject to the remainder of this Section 10.3 (Royalty Payments to Kiniksa), Partner will pay to Kiniksa royalties in the amount of the marginal royalty rates set forth in Table 10.3.1 below based on the aggregate Net Sales resulting from the sale of the Licensed Product in the Territory during each Calendar Year of the Royalty Term for the Licensed Product in each country. The royalty payments due with respect to Net Sales of the Licensed Product pursuant to this Section 10.3 (Royalty Payments to Kiniksa), collectively the "**Royalty Payments**."

Table 10.3.1 Royalty Payments	
Portion of Aggregate Calendar Year Net Sales of the Licensed Product in the Territory (in U.S. Dollars)	***Royalty Rate***
Greater than $[***] and less than $[***]	[***]%
Greater than or equal to $[***] and less than $[***]	[***]%
Greater than or equal to $[***]	[***]%

For example[***].

10.3.2 **Royalty Term**. Partner will pay to Kiniksa the Royalty Payments on a country-by-country or region-by-region basis, as applicable, until the later of: (a) the [***] anniversary of the date of the First Commercial Sale of the Licensed Product in such country or region in the Territory; (b) the date of expiration of the last-to-expire Valid Claim of a Royalty Patent Right Covering the Licensed Product in such country or region; and (c) the expiration of all Regulatory Exclusivity for the Licensed Product in such country or region ("**Royalty Term**").

10.3.3 **Royalty Reductions**.

(a) **Expiration of Valid Claims**. Subject to Section 10.3.3(e) (Cumulative Reductions Floor), on a country-by-country or region-by-region basis, as applicable, in the Territory, if during the Royalty Term for the Licensed Product in such country or region in the Territory, there is no Valid Claim of a Royalty Patent Right that Covers a composition of matter (including drug formulation), method of use, or method of Manufacturing of the Licensed Product in such country or region, then, commencing the first Calendar Quarter after the date on which this Section 10.3.3(a) (Expiration of Valid Claims) applies and for all Calendar Quarters thereafter during such Royalty Term in which this Section 10.3.3(a) (Expiration of Valid Claims) applies, then the royalty rates for the Licensed Product set forth in Table 10.3.1 in such country or region under Section 10.3 (Royalty Payments to Kiniksa) will be reduced by [***]%; *provided* that if a composition of matter, method of use, or method of Manufacturing of the Licensed Product subsequently becomes Covered by a Valid Claim of a Royalty Patent Right in such country or region prior to the expiration of the Royalty Term for the Licensed Product in such country or region, then the royalty rate of the Licensed Product in such country or region will no longer be subject to the aforementioned

reduction beginning at the commencement of the first Calendar Quarter after the date on which the relevant patent issues.

(b) **Biosimilar Product Reduction**. Subject to Section 10.3.3(e) (Cumulative Reductions Floor), on a country-by-country or region-by-region basis, as applicable, if during any Calendar Quarter, there is Biosimilar Competition for the Licensed Product in such country or region, then the Net Sales of the Licensed Product in such country or region in such Calendar Quarter will be reduced by the applicable percentage set forth in Table 10.3.3(b), in each Calendar Quarter in which the Biosimilar Competition continues during the Royalty Term for the Licensed Product in such country or region. Partner will promptly notify Kiniksa of the occurrence of Biosimilar Competition, which notice will specify the applicable Biosimilar Products, Indication, and country or region in the Territory.

Table 10.3.3(b) – BIOSIMILAR PRODUCT ROYALTY REDUCTION RATES

Percentage Decline in Aggregate Calendar Year Net Sales of the Licensed Product in the Territory Due to Biosimilar Competition	***Net Sales Reduction***
Greater than [***]% but less than [***]%	[***]%
Greater than [***]%	[***]%

(c) **Third Party Patent Rights**. Subject to Section 10.3.3(e) (Cumulative Reductions Floor), on a country-by-country or region-by-region basis, as applicable, during any Calendar Quarter, Partner may credit against the Royalty Payments payable to Kiniksa pursuant to Section 10.3 (Royalty Payments to Kiniksa) with respect to the Licensed Product in such country or region in such Calendar Quarter up to [***]% of any royalty payments for which Partner is responsible (i) under any Third Party IP Agreement pursuant to Section 2.7.4 (Responsibility for Costs), or (ii) under any agreement with a Third Party entered into by Partner pursuant to Section 2.7.2 (Partner Identified Rights), but in each case (i) and (ii) solely to the extent such royalty payments are made in consideration for the acquisition or license of Third Party Patent Rights that (in the opinion of counsel) would be infringed by the sale of the Licensed Product in such country or region.

(d) **Manufacturing Cost Reduction**. Subject to Section 10.3.3(e) (Cumulative Reductions Floor), if the Fully Burdened Manufacturing Cost of the Licensed Product is greater than [***] per vial of [***]mg, then each royalty rate set forth in Table 10.3.1 will be reduced by [***]%.

(e) **Cumulative Reductions Floor**. In no event will the aggregate amount of Royalty Payments due to Kiniksa for the Licensed Product in a country or region in the Territory in any given Calendar Quarter during the Royalty Term for the Licensed Product in such country or region be reduced to less than [***]% of the amount that otherwise would have been due and payable to Kiniksa in such Calendar Quarter for the Licensed Product in such country or region but for the reductions set forth in Section 10.3.3(a) (Expiration of Valid Claims), Section 10.3.3(b) (Biosimilar Product Reduction), Section 10.3.3(c) (Third Party Patent Rights), and Section 10.3.3(d) (Manufacturing Cost Reduction). Partner may carry forward to

subsequent Calendar Quarters any amounts it could not deduct as a result of such floor.

(f) **No Duplicative Royalties**. In no event will the sale of the Licensed Product in a given country in the Territory give rise to more than one Royalty Payment due to Kiniksa, including any instance where the Licensed Product is Covered by more than one Royalty Patent Right in such country.

10.3.4 **Royalty Reports and Payments**. Within [***] days after the end of each Calendar Quarter, Partner will provide Kiniksa with a detailed report that contains the following information for the applicable Calendar Quarter, on a country-by-country or region-by-region basis, as applicable (each, a "**Royalty Report**"): (a) [***], (b) [***], (c) [***], and (d) [***]. If there are no sales of the Licensed Product in a given Calendar Quarter, then the Royalty Report will provide such information. Concurrent with the delivery of the applicable Royalty Report, but in any event within [***] days after each Calendar Quarter, Partner will pay such the amount of the Royalty Payments set forth in the applicable Royalty Report to Kiniksa in Dollars. If requested by Kiniksa, the Parties will seek to resolve any questions or issues related to a Royalty Report within [***] days following receipt by Kiniksa of each Royalty Report. If no Royalty Payments are due in a particular Calendar Quarter, then the applicable Royalty Report will state that no such payments are due.

10.3.5 **Inventory Reports**.

(a) **Quarterly Inventory Reports**. Within [***] days after the end of each Quarter (for the first three Calendar Quarters in a Calendar Year), commencing with the Calendar Quarter in which the First Commercial Sale of the Licensed Product in the Field in the Territory occurs, Partner will deliver electronically to Kiniksa a written inventory report (the "**Quarterly Inventory Report**") setting forth the ending inventory of the Licensed Product balance for that Calendar Quarter. To the extent reasonably practicable, each Quarterly Inventory Report will provide such information broken out by lot numbers, dosage form, and unit size, for units of Licensed Product contained in such report.

(b) **Annual Inventory Reports**. Within [***] days after the end of each Calendar Year, commencing with the Calendar Quarter in which the First Commercial Sale of the Licensed Product in the Field in the Territory occurs, Partner will deliver electronically to Kiniksa a written inventory report (the "**Annual Inventory Report**") reconciling beginning and ending inventory and including (a) the number of units of Licensed Product distributed, but not sold (such as samples, donations, and write-offs) in the Territory during such Calendar Year, (b) the number of units of Licensed Product for the Territory that have been lost, destroyed, expired, or become obsolete or spoiled during such Calendar Year, and (c) the number of units of Licensed Product sold in the Territory during such Calendar Year. To the extent reasonably practicable, each Annual Inventory Report will provide such information broken out by lot numbers, dosage form, and unit size, for units of Licensed Product contained in such report.

10.4 **Payments to Third Parties**. Subject to Section 2.7 (Third Party In-Licenses), each Party will be solely responsible for any payments due to Third Parties under any agreement entered into by such Party prior to or after the Effective Date.

10.5 **Other Amounts Payable**. With respect to any amounts owed under this Agreement by one Party to the other for which no other invoicing and payment procedure is specified hereunder, within [***] days after the end of each Calendar Quarter, each Party will provide an invoice, together with reasonable supporting documentation, to the other Party for such amounts owed in respect of such Calendar Quarter. The owing Party will pay any undisputed amounts within [***] days after the receipt of the invoice, and any disputed amounts owed by a Party will be paid within [***] days after resolution of the dispute.

10.6 **No Refunds**. Except as expressly provided herein, all payments under this Agreement will be irrevocable, non-refundable, and non-creditable.

10.7 **Accounting Standards**. If a Party changes its general accounting principles from the then-current standard (*e.g.*, from GAAP to IFRS) at any time during the Term, then at least [***] days prior to adopting such change in principles, such Party will provide written notice to the other Party of such change.

10.8 **Currency; Exchange Rate**. All payments to be made by Partner to Kiniksa or Kiniksa to Partner under this Agreement will be made in Dollars by electronic funds transfer in immediately available funds to a bank account designated in writing by Kiniksa or Partner, as applicable. Net Sales will be recorded by Partner and its Affiliates and Sublicensees in the currency for the country or region in which the Net Sales occurred. Conversion of Net Sales recorded in local currencies will be converted to Dollars at the exchange rate set forth in Bloomberg or any successor thereto for the last day of the Calendar Quarter in which the applicable payment obligation became due and payable.

10.9 **Blocked Payments**. If by reason of Applicable Law in any country or region, it becomes impossible or illegal for a Party to transfer, or have transferred on its behalf, payments owed the other Party hereunder, then such Party will promptly notify the other Party of the conditions preventing such transfer and such payments will be deposited in local currency in the relevant country or region to the credit of the other Party in a recognized banking institution designated by the other Party or, if none is designated by the other Party within a period of [***] days, in a recognized banking institution selected by the transferring Party, as the case may be, and identified in a written notice given to the other Party. Payments that are blocked as set forth in, but otherwise made in accordance with the terms of, this Section 10.9 (Blocked Payments) will not be deemed a late payment subject to Section 10.10 (Late Payments) and will not be subject to the accrual of interest specified thereunder for so long as such payments are blocked.

10.10 **Late Payments**. Any payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement will bear interest at a rate equal to the lesser of: (a) [***] percentage points above the prime rate as published by *The Wall Street Journal* or any successor thereto on the first day of each Calendar Quarter in which such payments are overdue; or (b) the maximum rate permitted by Applicable Law; in each case, calculated on the number of days such payment is delinquent, compounded monthly.

10.11 **Financial Records and Audits**. Each Party will maintain complete and accurate records in sufficient detail to permit the other Party or its designee to confirm the accuracy of the amount of

Royalty Payments and other amounts payable under this Agreement. Upon at least [***] days' prior written notice, such records will be open during regular business hours for a period of [***] years (or such longer period as may be required under any applicable statute of limitations for applicable Taxes or by Applicable Law) from the creation of individual records for examination by an independent "Big Four" (or equivalent) accounting firm selected by the examining Party and reasonably acceptable to the other Party or its designee for the sole purpose of verifying for the examining Party the accuracy of the financial reports furnished by the other Party (the "**Examined Party**") pursuant to this Agreement or of any payments made, or required to be made, by such Examined Party pursuant to this Agreement; *provided* that such independent accounting firm is subject to written obligations of confidentiality and non-use applicable to each Party's Confidential Information that are at least as stringent as those set forth in Article 11 (Confidentiality; Publication). Such audit will not be (a) performed more frequently than once per [***] during the Term or once during the [***] year period after the expiration or termination of this Agreement, (b) conducted for any Calendar Year more than [***] years after the end of such year, or (c) repeated for any Calendar Year or with respect to the same set of records (unless a material discrepancy with respect to such records is discovered during a prior audit). Such auditor will not disclose the Examined Party's Confidential Information to the examining Party or to any Third Party, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by the Examined Party or the amount of payments by the Examined Party under this Agreement. The Examined Party will pay any amounts shown to be owed to the examining Party but unpaid within [***] days after the accountant's report, *plus* interest (as set forth in Section 10.10 (Late Payments)) from the original due date. The examining Party will bear the full cost of such audit unless such audit reveals an underpayment by the Examined Party of more than [***]% of the amount actually due for the time period being audited, in which case the Examined Party will reimburse the examining Party for the reasonable audit fees for such examination. To the extent that an audit hereunder reveals an overpayment by the Examined Party to the examining Party, the Examined Party may credit such overpayment against amounts due to the examining Party under this Agreement.

10.12 Taxes.

10.12.1 **Taxes on Income; Payments Free of Taxes**. Except as set forth in this Section 10.12 (Taxes) or Section 10.13 (VAT Credits), each Party will be solely responsible for the payment of any and all income Taxes levied on account of all payments it receives under this Agreement. Any and all payments due to Kiniksa from Partner pursuant to this Agreement will be paid without deduction or withholding for any Taxes, except as required by Applicable Law. If any Applicable Law requires the deduction or withholding of any Tax from any such payment, then Partner (or its applicable withholding agent) will be entitled to make such deduction or withholding and Partner will increase the amount of such payment due to Kiniksa under this Agreement upon which such Tax is due as may be necessary so that the net amount Kiniksa receives after making any payments in respect of any such Tax is an amount equal to the sum that it would have received had (i) no such deduction or withholding been required to be made on such amount and (ii) no other Taxes been imposed on any additional amounts payable to Kiniksa. Each Royalty Report will show the amounts of Taxes due and paid by Partner with respect to payments made by Partner to Kiniksa during such Calendar Quarter. The amount of the invoice provided by Kiniksa to Partner must include the withholding income tax amount paid by Partner and the amount actually received by Kiniksa, even if Kiniksa only receives the net amount payable in accordance with this Agreement.

10.12.2 **Tax Cooperation**. The Parties agree to cooperate with one another in accordance with Applicable Law and use reasonable efforts to minimize Tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by each Party to the other Party under this Agreement. To the extent either Party (the "**Paying Party**") is required to deduct and withhold Taxes on any payment to the other Party (the "**Recipient**"), the Paying Party will (a) pay the full amount of such Taxes to the proper Governmental Authority in a timely manner, and (b) promptly transmit to the Recipient an official tax certificate or other evidence of such payment sufficient to enable the Recipient to claim such payment of Taxes on the Recipient's applicable tax returns. The Paying Party will provide the Recipient with advance notice prior to withholding any Taxes from payments payable to the Recipient and will provide the Recipient with a commercially reasonable period of time to claim an exemption or reduction in otherwise applicable Taxes. The Recipient will provide the Paying Party any tax forms that may be reasonably necessary in order for the Paying Party to not withhold Tax or to withhold Tax at a reduced rate under an applicable bilateral income tax treaty, to the extent the Paying Party is legally able to do so. The Recipient will use reasonable efforts to provide any such tax forms to the Paying Party in advance of the due date. Each Party will provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Law, of withholding Taxes or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Paying Party if the Paying Party is the Party bearing such withholding Tax under this Section 10.12 (Taxes). To the extent that Kiniksa recovers any Taxes withheld by Partner or receives Tax credits that would otherwise have reduced the amount by which Partner had to increase the payment to Kiniksa under Section 10.12.1 (Taxes on Income; Payments Free of Taxes) if such withholding recovery or receipt of Tax credit been realized at the time of payment to Kiniksa, then Partner will receive a credit for such amount, which credit Partner may set off against future payments of amounts due to Kiniksa hereunder. In addition, the Parties will cooperate in accordance with Applicable Law to minimize indirect Taxes (such as VAT, sales tax, consumption tax, and other similar Taxes) in connection with this Agreement. In the event of any inconsistency between this Section 10.12 (Taxes) and Section 10.13 (VAT Credits), Section 10.13 (VAT Credits) will take precedence.

10.12.3 **Changes in Domicile**. Notwithstanding any provision to the contrary in this Agreement, if the Paying Party assigns, transfers or otherwise disposes of some or all of its rights and obligations to any Person and if, as a result of such action, the withholding or deduction of Tax required by Applicable Law with respect to payments under this Agreement is increased, then any amount payable to the Recipient under this Agreement will be increased to take into account such withheld Taxes as may be necessary so that, after making all required withholdings (including withholdings on the withheld amounts), the Recipient receives an amount equal to the sum it would have received had no such withholding been made.

10.12.4 **Returns**. All transfer, documentary, sales, use, stamp, registration, and other such Taxes, and any conveyance fees, recording charges, and other fees and charges (including any penalties and interest) incurred in connection with consummation of the transactions contemplated hereby, if any, will be borne and paid by the Paying Party. The Paying Party will prepare and timely file all tax returns required to be filed in respect of any such Taxes. The Parties will reasonably cooperate in accordance with Applicable Law to minimize transfer Taxes in connection with this Agreement.

10.13 VAT Credits. All payments due to Kiniksa from Partner pursuant to this Agreement will be paid without any deduction for any VAT that Partner may be required to collect or pay to any tax authorities in the Territory. Kiniksa will use reasonable efforts to assist Partner to minimize and obtain all available exemptions from such VAT, but if applicable, Partner will pay any such VAT to the proper taxing authorities upon receipt of a valid VAT invoice (where such invoice is required under local VAT laws). If Partner is required to pay or Kiniksa is required to report or pay any such VAT, then Partner will increase the amount of any and all payments under this Agreement upon which such VAT is due as may be necessary so that the net amount Kiniksa receives after making any payments in respect of any such VAT is an amount equal to the sum that it would have received had (i) no such VAT been required to be paid on such amount and (ii) no other Taxes been imposed on any additional amounts payable to Kiniksa. Partner will promptly provide to Kiniksa applicable receipts evidencing payment of such VAT and other documentation reasonably requested by Kiniksa. To the extent that Kiniksa recovers any VAT paid in connection with any payment made by Partner hereunder, then Partner will receive a credit for such refunded or recovered VAT amount, which credit Partner may set off against future payments of amounts due to Kiniksa hereunder.

ARTICLE 11
CONFIDENTIALITY; PUBLICATION

11.1 Duty of Confidence. Subject to the other provisions of this Article 11 (Confidentiality; Publication):

11.1.1 except to the extent expressly authorized by this Agreement, all Confidential Information of a Party (the "**Disclosing Party**") will be maintained in confidence and otherwise safeguarded, and not published or otherwise disclosed, by the other Party (the "**Receiving Party**") and its Affiliates for the Term and for [***] years thereafter;

11.1.2 the Receiving Party will treat all Confidential Information provided by the Disclosing Party at a minimum, with the same degree of care as the Receiving Party uses for its own similar information, but in no event less than a reasonable degree of care;

11.1.3 the Receiving Party may only use any Confidential Information of the Disclosing Party for the purposes of performing its obligations or exercising its rights under this Agreement;

11.1.4 a Receiving Party may disclose Confidential Information of the Disclosing Party to: (a) such Receiving Party's Affiliates, licensees, and Sublicensees; and (b) employees, directors, officers, agents, contractors, consultants, attorneys, accountants, banks, investors, and advisors of the Receiving Party and its Affiliates, licensees, and Sublicensees, in each case ((a) and (b)), to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this Agreement; *provided* that such Persons are bound by legally enforceable obligations of confidentiality and non-use with respect to the Disclosing Party's Confidential Information no less stringent than the confidentiality and non-use obligations set forth in this Agreement. Each Party will remain responsible for any failure by its Affiliates, licensees, and Sublicensees, and its and its Affiliates', licensees', and Sublicensees' respective employees, directors, officers, agents, contractors, consultants, attorneys, accountants, banks, investors, and advisors, in each case, to treat such Confidential Information as required under this Section 11.1 (Duty of Confidence) (as if such Affiliates, licensees, Sublicensees, employees, directors, officers, agents, contractors, consultants, attorneys, accountants, banks, investors, and advisors were Parties directly bound to the requirements of this Section 11.1 (Duty of Confidence)); and

11.1.5 each Party will promptly notify the other Party of any misuse or unauthorized disclosure of the other Party's Confidential Information.

11.2 Confidential Information. The Kiniksa Know-How will be the Confidential Information of Kiniksa notwithstanding the fact that such information may be developed or invented and disclosed to Kiniksa by Partner. The Partner Know-How will be the Confidential Information of Partner. The Joint Collaboration Know-How will be the Confidential Information of both Parties. Except as provided in Section 11.4 (Authorized Disclosures) and Section 11.7 (Publicity; Use of Names), neither Party nor its Affiliates may disclose the existence or the terms of this Agreement.

11.3 Exemptions. Information of a Disclosing Party will not be Confidential Information of such Disclosing Party to the extent that the Receiving Party can demonstrate through competent evidence that such information:

11.3.1 is known by the Receiving Party or any of its Affiliates without an obligation of confidentiality at the time of its receipt from the Disclosing Party, and not through a prior disclosure by or on behalf of the Disclosing Party, as documented by the Receiving Party's business records;

11.3.2 is generally available to the public before its receipt from the Disclosing Party;

11.3.3 became generally available to the public or otherwise part of the public domain after its disclosure by the Disclosing Party and other than through any act or omission of the Receiving Party or any of its Affiliates or disclosees in breach of this Agreement;

11.3.4 is subsequently disclosed to the Receiving Party or any of its Affiliates without obligation of confidentiality by a Third Party who may rightfully do so and is not under a conflicting obligation of confidentiality to the Disclosing Party; or

11.3.5 is developed by the Receiving Party or any of its Affiliates independently and without use of or reference to any Confidential Information received from the Disclosing Party, as documented by the Receiving Party's business records.

No combination of features or disclosures will be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party.

11.4 Authorized Disclosures.

11.4.1 **Permitted Circumstances**. Notwithstanding the obligations set forth in Section 11.1 (Duty of Confidence), a Party may disclose the other Party's Confidential Information (including this Agreement and only the specifically relevant terms herein) to the extent such disclosure is reasonably necessary in the following situations:

(a) disclosure to comply with the terms of any Third Party IP Agreement;

(b) (i) the Patent Prosecution or enforcement of Kiniksa Patent Rights, Kiniksa Manufacturing Patent Rights, or Partner Collaboration Patent Rights, in each case, as contemplated by this Agreement; or (ii) in connection with regulatory filings

and other filings with Governmental Authorities (including Regulatory Authorities), as necessary for the Exploitation of the Licensed Product;

(c) disclosure of this Agreement, its terms, and the status and results of Exploitation of the Licensed Product to actual or *bona fide* potential investors, acquirers, (sub)licensees, lenders, and other financial or commercial partners (including in connection with any royalty monetization transaction), and their respective attorneys, accountants, banks, investors, and advisors, solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, (sub)license, debt transaction, or collaboration; *provided* that, in each such case, on the condition that such Persons are bound by obligations of confidentiality and non-use at least as stringent as those set forth Article 11 (Confidentiality; Publication) or otherwise customary for such type and scope of disclosure any such disclosure is limited to the maximum extent practicable for the particular context in which it is being disclosed;

(d) such disclosure is required to comply with Applicable Law (whether generally or in pursuit of an application for listing of securities) including the United States Securities and Exchange Commission, or equivalent foreign agency or regulatory body, or otherwise required by judicial or administrative process, *provided* that in each such event, as promptly as reasonably practicable and to the extent not prohibited by Applicable Law or judicial or administrative process, such Party will notify the other Party, unless a shorter time period is required by Applicable Law, no later than [***] Business Days in advance of such required disclosure and provide a draft of the disclosure to the other Party reasonably in advance of such filing or disclosure for the other Party's review and comment. The non-disclosing Party will provide any comments as soon as practicable, and the disclosing Party will consider any reasonable, timely comments provided by the non-disclosing Party; *provided* that the disclosing Party may or may not accept such comments in its sole discretion. Confidential Information that is disclosed in order to comply with Applicable Law or by judicial or administrative process pursuant to this Section 11.4.1(d) (Permitted Circumstances), in each case, will remain otherwise subject to the confidentiality and non-use provisions of this Article 11 (Confidentiality; Publication) with respect to the Party disclosing such Confidential Information, and such Party will take all steps reasonably necessary, including seeking of confidential treatment or a protective order for a period of at least [***] years (to the extent permitted by Applicable Law or Governmental Authority), to ensure the continued confidential treatment of such Confidential Information, and each Party will be responsible for its own legal and other external costs in connection with any such filing or disclosure pursuant to this Section 11.4.1(d) (Permitted Circumstances); or

(e) disclosure pursuant to Section 6.8 (Notice of Regulatory Action), Section 11.6 (Publication and Listing of Clinical Trials), and Section 11.7 (Publicity; Use of Name).

11.4.2 **Confidential Treatment**. Notwithstanding any provision to the contrary set forth in this Agreement, in each case of a disclosure to be made pursuant to Section 11.4.1(d) (Permitted Circumstances), where some or all of the terms of this Agreement are to be disclosed, Kiniksa will, to the extent reasonably possible, provide to Partner a redacted version of this

Agreement to be made in connection with any such disclosure and Partner will not disclose or provide any other redacted version hereof, unless such version has been approved in writing by Kiniksa, not to be unreasonably withheld, conditioned, or delayed. Subject to the foregoing, but notwithstanding any other provision to the contrary set forth in this Agreement, if a Party is required or permitted to make a disclosure of the other Party's Confidential Information pursuant to Section 11.4.1 (Permitted Circumstances), then it will, to the extent not prohibited by Applicable Law or judicial or administrative process, except where impracticable, give reasonable advance notice to the other Party of such proposed disclosure and use reasonable efforts to secure confidential treatment of such information and will only disclose that portion of Confidential Information that is legally required to be disclosed as advised by its legal counsel. In any event, each Party agrees to take all reasonable action to avoid disclosure of Confidential Information of the other Party hereunder.

11.5 Publications. Partner will not publicly present or publish any Clinical Trial data, non-clinical or preclinical data, or any associated results or conclusions generated by or on behalf of Partner pursuant to this Agreement (each such proposed presentation or publication, a "Publication") without Kiniksa's prior written consent, not to be unreasonably withheld, and subject to the additional limitations set forth in this Section 11.5 (Publications) and Section 11.6 (Publication and Listing of Clinical Trials**)**. If Partner desires to publicly present or publish a Publication in accordance with the foregoing sentence, then Partner will provide Kiniksa (including the Alliance Manager and all Kiniksa members of the JSC) with a copy of such proposed Publication to review, discuss, and determine whether to approve at least [***] days prior to the earlier of its presentation or intended submission for publication (such applicable period, the "**Review Period**"). Partner will not submit or present any Publication until (a) Kiniksa has approved such Publication or provided written comments thereon, in each case, during such Review Period, or (b) the applicable Review Period has elapsed without approval or written comments from Kiniksa, in which case Partner may proceed and the Publication will be considered approved in its entirety. If Partner receives written comments from Kiniksa on any Publication during the applicable Review Period, then it will incorporate such comments where appropriate. Notwithstanding any provision to contrary set forth in this Agreement, Partner will (i) delete any Confidential Information of Kiniksa that Kiniksa identifies for deletion in Kiniksa's written comments, (ii) delete any Clinical Trial data, results, conclusions, or other related information for the Licensed Product, the publication of which Kiniksa determines, in its sole discretion, could conflict with Kiniksa's global publication strategy with respect to the Licensed Product, and (iii) delay such Publication for a period of up to an additional [***] days after the end of the applicable Review Period to enable Kiniksa to draft and file one or more patent applications with respect to any subject matter to be made public in such Publication. Partner will provide Kiniksa a copy of the Publication at the time of the submission or presentation thereof. Partner agrees to acknowledge the contributions of Kiniksa and the employees of Kiniksa, in each case, in all Publications as scientifically appropriate. In addition, Kiniksa agrees to acknowledge the contributions of Partner and the employees of Partner, in each case, in all presentations and publications as scientifically appropriate to the extent related to any Global Clinical Trials in which Partner assists in the enrollment of patients from the Territory. Partner will require its Affiliates and Sublicensees to comply with the obligations of this Section 11.5 (Publications) as if they were Partner, and Partner will be liable for any non-compliance of such Persons.

11.6 Publication and Listing of Clinical Trials. With respect to the listing of Clinical Trials or the publication of Clinical Trial results for the Licensed Product and to the extent applicable to a Party's activities conducted under this Agreement, each Party will comply with (a) the Pharmaceutical

Research and Manufacturers of America (PhRMA) Guidelines on the listing of Clinical Trials and the Publication of Clinical Trial results, and (b) any Applicable Law or applicable court order, stipulations, consent agreements, and settlements entered into by such Party. The Parties agree that any such listings or publications made pursuant to this Section 11.6 (Publication and Listing of Clinical Trials) will be considered a Publication for purposes of this Agreement and will be subject to Section 11.5 (Publications).

11.7 Publicity; Use of Names.

11.7.1 **Press Release**. The Parties will each issue a press release announcing this Agreement, as set forth on Schedule 11.7.1(a) (Kiniksa Press Release) and Schedule 11.7.1(b) (Partner Press Release), to be issued by the Parties on such date and time as may be agreed by the Parties. Other than the press releases set forth on Schedule 11.7.1(a) (Kiniksa Press Release) and Schedule 11.7.1(b) (Partner Press Release) and the public disclosures permitted by this Section 11.7 (Publicity; Use of Names), and Section 11.4 (Authorized Disclosures), the Parties agree that except as permitted under Section 11.7.2 (Disclosures by the Parties), the portions of any other news release or other public announcement relating to this Agreement or the performance hereunder that would disclose information other than that already in the public domain will first be reviewed and approved by both Parties (with such approval not to be unreasonably withheld, conditioned, or delayed).

11.7.2 **Disclosures by the Parties**.

(a) Notwithstanding any provision to the contrary set forth in this Agreement, Kiniksa or its designees may publicly disclose (in written, oral, or other form): (a) the achievement of Milestone Events under this Agreement (including the amount, payment, and timing of any such Milestone Event); (b) the commencement, completion, material data, or key results of any Global Clinical Trials or Territory-Specific Clinical Trials for the Licensed Product conducted under this Agreement; (c) any information relating to any Global Clinical Trial, including the commencement, completion, material data, or key results; and (d) the receipt of Regulatory Approval or Reimbursement Approval for the Licensed Product.

(b) Notwithstanding any provision to the contrary set forth in this Agreement, Partner its designees may publicly disclose (in written, oral, or other form): (a) the achievement of Milestone Events under this Agreement (including the amount, payment, and timing of any such Milestone Event); (b) with Kiniksa's prior written approval, the commencement, completion, material data, or key results of any Global Clinical Trials as it relates to the Territory or Territory-Specific Clinical Trials for the Licensed Product conducted under this Agreement; (c) with Kiniksa's prior written approval, any other information relating to any Global Clinical Trial as it relates to the Territory, including the commencement, completion, material data, or key results; and (d) the receipt of Regulatory Approval or Reimbursement Approval within the Territory for the Licensed Product.

11.7.3 **Use of Names**. Other than the press releases set forth on Schedule 11.7.1(a) (Kiniksa Press Release) and Schedule 11.7.1(b) (Partner Press Release) and the use of names in public disclosures permitted by Section 11.4 (Authorized Disclosures), the Parties agree that except as permitted under Section 11.7.2 (Disclosures by the Parties), each Party's use of

other Party's name and logo in presentations, its website, collateral materials, and corporate overviews to describe the collaboration relationship, as well as in taglines of press releases issued pursuant to this Section 11.7 (Publicity; Use of Names) will first be reviewed and approved by both Parties (with such approval not to be unreasonably withheld, conditioned, or delayed). Except as permitted under this Section 11.7 (Publicity; Use of Names) or with the prior express written permission of the other Party, neither Party will use the name, trademark, trade name, or logo of the other Party or its Affiliates or their respective employees in any publicity, promotion, news release, or disclosure relating to this Agreement or its subject matter except as may be required by Applicable Law. Each Party will use the other Party's corporate name in all publicity relating to this Agreement, including the initial press release and all subsequent press releases. Partner will include explanatory text such as "*Licensed from Kiniksa*" in all publicity, promotion, news releases, or disclosures relating to the Licensed Product or such other similar text provided by Kiniksa and reasonably acceptable to Partner.

11.7.4 **Repeated Disclosures**. The Parties agree that after (a) the issuance of a disclosure or press release made in accordance with Section 11.7.1 (Press Release) or Section 11.4 (Authorized Disclosures), (b) the use of the other Party's name or logo by a Party in presentations, its website, collateral materials, or corporate overviews to describe the collaboration relationship in accordance with Section 11.7.3 (Use of Names), or (c) use of the other Party's name or logo by a Party in any taglines of press releases issued pursuant to Section 11.7.1 (Press Release) or Section 11.4 (Authorized Disclosures), in each case ((a) – (c)), the disclosing Party may make subsequent public disclosures reiterating such information without having to obtain the other Party's prior consent and approval so long as the information in such press release, other public announcement, or other materials remains true, correct, and the most current information with respect to the subject matters set forth therein. Similarly, after a Publication has been made available to the public, each Party may post such Publication or a link to it on its corporate website (or any website managed by such Party in connection with a Clinical Trial for the Licensed Product, as appropriate) without the prior written consent of the other Party, so long as the information in such Publication remains true, correct, and the most current information with respect to the subject matters set forth therein. Notwithstanding any provision to the contrary set forth in this Agreement, neither Party will use the other Party's corporate name in such manner that the distinctiveness, reputation, and validity of any trademarks and corporate or trade names of such other Party will not be impaired, and consistent with best practices used by such other Party for its other collaborators.

ARTICLE 12
REPRESENTATIONS, WARRANTIES, AND COVENANTS

12.1 Representations and Warranties of Each Party. Each Party represents and warrants to the other Party as of the Effective Date as follows:

12.1.1 It (a) is a corporation or limited company duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization; (b) has the full right, power and authority to enter into this Agreement and to perform its obligations hereunder, including the legal right to grant the licenses granted by it hereunder in accordance with the terms of this Agreement; and (c) has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder.

12.1.2 It has not been Debarred/Excluded and no proceeding that could result it in being Debarred/Excluded is pending, and neither it nor any of its Affiliates has used, in any capacity in the performance of obligations relating to the Licensed Product, any employee, Subcontractor, consultant, agent, representative, or other Person who has been Debarred/Excluded.

12.1.3 All consents, approvals, and authorizations from all Governmental Authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained.

12.1.4 This Agreement has been duly executed by it and is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any Applicable Law or regulation of any court, governmental body, or administrative or other agency having jurisdiction over it.

12.2 Representations and Warranties of Kiniksa. Kiniksa represents and warrants to Partner as of the Effective Date as follows:

12.2.1 It has the right under the Kiniksa Technology to grant to Partner the licenses set forth in this Agreement, and it has not granted any license or other right under the Kiniksa Technology that is inconsistent with the licenses granted to Partner hereunder.

12.2.2 With respect to any such Kiniksa Patent Right identified on Schedule 1.104 (Kiniksa Patent Rights) as being owned by Kiniksa, Kiniksa owns all rights, title, and interests in and to such Kiniksa Patent Rights.

12.2.3 Except as otherwise disclosed to Partner in writing, there is no pending or, to Kiniksa's Knowledge, threatened litigation, nor has Kiniksa received any written notice from any Third Party, asserting or alleging that the Exploitation of the Licensed Product infringes or misappropriates the intellectual property rights of such Third Party.

12.2.4 There are no pending or, to Kiniksa's Knowledge, threatened, adverse actions, suits, or proceedings against Kiniksa or any of its Affiliates or to Kiniksa's Knowledge, any of its licensees, sublicensees or licensors involving the Kiniksa Technology or Kiniksa Manufacturing Technology (including, to Kiniksa's Knowledge, any action to invalidate Kiniksa Patent Rights).

12.2.5 To Kiniksa's Knowledge, Kiniksa has not withheld from Partner any information with respect to the Kiniksa Technology that, in Kiniksa's reasonable determination, would materially adversely affect the Development, Manufacture, or Commercialization of the Licensed Product in the Territory as contemplated under this Agreement. To Kiniksa's Knowledge, (a) true, complete, and correct copies of all portions of Regulatory Submissions that is material for the Licensed Product in the Territory; and (b) all material adverse written information with respect to the safety of the Licensed Product have been provided or made available to Partner prior to the Effective Date. To Kiniksa's Knowledge, the information provided by Kiniksa to Partner regarding the Kiniksa Technology is accurate, true, and correct in all material respects.

12.2.6 To Kiniksa's Knowledge, neither Kiniksa nor any of its Affiliates have employed nor used a contractor or consultant that has employed any Person Debarred/Excluded, or any Person

that is the subject of an investigation or proceeding that could result in such Person being Debarred/Excluded, in any capacity in connection with this Agreement.

12.2.7 There are no legal claims, judgments, or settlements against or owed by Kiniksa or any of its Affiliates, or pending or, to Kiniksa's Knowledge, threatened, legal claims or litigation, in each case, relating to antitrust, anti-competition, or Anti-Corruption Law violations.

12.2.8 A redacted copy of the Regeneron License Agreement has been provided to Partner prior to the date hereof. Except for the redactions in such copy, Kiniksa has provided Partner with true, complete and correct copies of the Regeneron License Agreement. Other than the Regeneron License Agreement, there are no agreements between Kiniksa and any Third Party pursuant to which Kiniksa Controls any Kiniksa Technology licensed to Partner under this Agreement.

12.2.9 The Regeneron License Agreement is a valid, binding agreement, enforceable in accordance with its terms and neither Kiniksa nor the counterparty to the Regeneron License Agreement has in writing alleged or threatened that the other party has breached the Regeneron License Agreement (which has not been cured) or, to Kiniksa's Knowledge, threatened in writing to terminate the Regeneron License Agreement.

12.2.10 To its Knowledge, neither Kiniksa nor any of its Affiliates, or its or their directors, officers, employees, distributors, agents, representatives, sales intermediaries, or other Third Parties acting on behalf of Kiniksa or any of its Affiliates:

(a) has taken any action in violation of any applicable Anti-Corruption Laws; or

(b) has corruptly offered, paid, given, promised to pay or give, or authorized the payment or gift of anything of value, directly or indirectly, to any Public Official, for the purposes of:

(i) influencing any act or decision of any Public Official in his or her official capacity;

(ii) inducing such Public Official to do or omit to do any act in violation of his or her lawful duty;

(iii) securing any improper advantage; or

(iv) inducing such Public Official to use his or her influence with a government, governmental entity, or commercial enterprise owned or controlled by any government (including state-owned or controlled veterinary, laboratory or medical facilities) in obtaining or retaining any business whatsoever.

12.3 Representations and Warranties of Partner. Partner represents and warrants to Kiniksa as of the Effective Date as follows:

12.3.1 No Partner Technology exists as of the Effective Date.

12.3.2 There are no Partner Patent Rights owned by or exclusively licensed to Partner or any of its Affiliates.

12.3.3 There are no legal claims, judgments, or settlements against or owed by Partner or any of its Affiliates, or pending or, to Partner's Knowledge, threatened, legal claims or litigation, in each case, relating to antitrust, anti-competition, or Anti-Corruption Law violations.

12.3.4 Partner has sufficient financial wherewithal to (a) perform all of its obligations set forth under this Agreement, and (b) meet all of its obligations that come due in the ordinary course of business.

12.3.5 Partner has, or can readily obtain, sufficient technical, clinical, and regulatory expertise to perform all of its obligations pursuant to this Agreement, including its obligations relating to Development, Manufacturing, performance of Medical Affairs, Commercialization, and obtaining Regulatory Approvals, in each case, of the Licensed Product as contemplated under this Agreement.

12.3.6 To its Knowledge, neither Partner nor any of its Affiliates, or its or their directors, officers, employees, distributors, agents, representatives, sales intermediaries, or other Third Parties acting on behalf of Partner or any of its Affiliates:

(a) has taken any action in violation of any applicable Anti-Corruption Laws; or

(b) has corruptly offered, paid, given, promised to pay or give, or authorized the payment or gift of anything of value, directly or indirectly, to any Public Official, for the purposes of:

(i) influencing any act or decision of any Public Official in his or her official capacity;

(ii) inducing such Public Official to do or omit to do any act in violation of his or her lawful duty;

(iii) securing any improper advantage; or

(iv) inducing such Public Official to use his or her influence with a government, governmental entity, or commercial enterprise owned or controlled by any government (including state-owned or controlled veterinary, laboratory or medical facilities) in obtaining or retaining any business whatsoever.

12.3.7 Except as otherwise disclosed on Schedule 12.3 (Partner Disclosures), none of the officers, directors, or employees of Partner or of any of its Affiliates or agents acting on behalf of Partner or any of its Affiliates, in each case, that are employed or reside outside the United States, is a Public Official.

12.4 Covenants of Partner. Partner covenants to Kiniksa that:

12.4.1 Partner will conduct all Clinical Development activities for the Licensed Product solely in accordance with, and will not conduct any Clinical Development activities other than as set forth in, the applicable Territory Development Plan or Global Development Plan. Partner will conduct all Medical Affairs and Commercialization activities for the Licensed Product solely in accordance with, and will not conduct any Medical Affairs or

Commercialization activities other than as set forth in, the applicable Medical Affairs Plan or Commercialization Plan, respectively.

12.4.2 Partner will only engage Clinical Trial sites under a Global Development Plan or a Territory Development Plan that conduct all Clinical Trials in compliance with Applicable Law, including cGCP and the GCP guidelines and that are approved by the applicable Regulatory Authority in the country or region in the Territory in which such Clinical Trial site is located.

12.4.3 Partner will permit, or will cause any of its applicable Affiliates, Sublicensees, or Subcontractors to permit, Kiniksa, its Affiliates, or Representatives to visit and inspect, no more than [***] per Calendar Year any of Partner's or its Affiliates', Sublicensees', or Subcontractors' facilities that perform Pre-Clinical Development, Medical Affairs, or Commercialization of the Licensed Product (or any component thereof) upon Kiniksa's request during normal business hours and upon no less than [***] days' prior notice and at Kiniksa's sole cost; *provided* that all such inspections will be conducted in accordance with Partner's and its Affiliates', Sublicensees' or Subcontractors confidentiality requirements and on-site policies (as applicable), in each, to the extent communicated to Kiniksa in writing in advance.

12.5 Covenants of Kiniksa and Partner.

12.5.1 **Compliance with Regeneron License Agreement**. In the course of performing its obligations or exercising its rights under this Agreement, each Party will comply with all terms of the Regeneron License Agreement.

12.5.2 **Compliance with Applicable Law**. In the course of performing its obligations or exercising its rights under this Agreement, each Party will comply with all Applicable Law, including, as applicable, cGCP and cGLP, and will not employ or engage, and if so employed and engaged, will thereafter terminate any Person who has been Debarred/Excluded, or is the subject of any proceedings that could result in such Person being Debarred/Excluded.

12.5.3 **Anti-Corruption**. Each Party agrees, in its performance of its obligations under this Agreement, to comply, and to cause its Affiliates to comply, with all Applicable Laws, including the FCPA, U.S. Export Control Laws, and all other Anti-Corruption Laws. Each Party will not knowingly take any action that would cause the other Party to be in violation of the FCPA, U.S. Export Control Laws, or any other applicable Anti-Corruption Laws. Further, each Party will immediately notify the other Party if such Party has any information or suspicion that there may be a violation of the FCPA, U.S. Export Control Laws, or any other Anti- Corruption Law in connection with the performance of activities under this Agreement.

12.5.4 **No Bribery**. Each Party and its employees and agents will not, directly or indirectly through Third Parties, knowingly pay, promise, or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value, to a Public Official or entity or other person for purposes of corruptly obtaining or retaining business for or with, or directing business to, any Person, including either Party, by (a) influencing any official act, decision or omission of such Public Official or entity; (b) inducing such Public Official or entity to do or omit to do any act in violation of the

lawful duty of such Public Official or entity; (c) securing any improper advantage; or (d) inducing such Public Official or entity to affect or influence any act or decision of another Public Official or entity.

12.5.5 **No Kickbacks**. Each Party and its employees and agents have not and will not knowingly promise, offer or provide any corrupt payment, gratuity, emolument, bribe, kickback, excessive gift or hospitality or other illegal or unethical benefit to a customer or a Third Party customer or to a Public Official or entity. In addition, each Party and its employees and agents will ensure that no part of any payment, commission, reimbursement or fee paid by either Party pursuant to this Agreement or otherwise will be used knowingly as a corrupt payment, gratuity, emolument, bribe, kickback, excessive gift or hospitality or other illegal or unethical benefit to a customer or to a Third Party customer or to a Public Official or entity.

12.5.6 **Compliance with Anti-Corruption Laws**. Notwithstanding any provision to the contrary set forth in this Agreement, each Party agrees as follows:

(a) It will, no later than [***] days following the end of each Calendar Year, verify in writing that to its Knowledge, there have been no violations of Anti-Corruption Laws by it or its Affiliates or Sublicensees, or persons employed by or Subcontractors used by it or its Affiliates or Sublicensees in the performance of this Agreement, or will provide details of any exception to the foregoing.

(b) It will maintain records (financial and otherwise) and supporting documentation related to the subject matter of this Section 12.5.6 (Compliance with Anti-Corruption Laws) in order to document or verify compliance with the provisions of this Section 12.5.6 (Compliance with Anti-Corruption Laws), and upon request of other Party upon reasonable advance notice, will provide the other Party or its representative with access to such records for purposes of verifying compliance with the provisions of this Section 12.5.6 (Compliance with Anti-Corruption Laws).

(c) It will promptly provide the other Party with written notice of the following events: (i) upon becoming aware of any breach or violation by the other Party of any covenant or undertaking set out in this Section 12.5.6 (Compliance with Anti-Corruption Laws); or (ii) upon receiving a formal notification that it is the target of a formal investigation by a Governmental Authority for a material Anti-Corruption Law violation or upon receipt of information from its Affiliates, agents, representatives, consultants, and Sublicensees, subcontractors hired in connection with the subject matter of this Agreement that any of them is the target of a formal investigation by a Governmental Authority for a material Anti-Corruption Law violation.

12.6 NO OTHER WARRANTIES. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 12 (REPRESENTATIONS, WARRANTIES, AND COVENANTS), (A) NO REPRESENTATION, CONDITION, OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF KINIKSA OR PARTNER; AND (B) ALL OTHER CONDITIONS AND WARRANTIES WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE ARE EXPRESSLY EXCLUDED, INCLUDING ANY CONDITIONS AND WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, OR NON-

INFRINGEMENT. ANY INFORMATION PROVIDED BY KINIKSA OR ITS AFFILIATES IS MADE AVAILABLE ON AN "AS IS" BASIS WITHOUT WARRANTY WITH RESPECT TO COMPLETENESS, COMPLIANCE WITH REGULATORY STANDARDS OR REGULATIONS, OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER KIND OF WARRANTY WHETHER EXPRESS OR IMPLIED.

12.7 **Time for Claims**. Except in the case of any fraud or intentional misrepresentation by a Party: (a) the representations and warranties of the Parties contained in Section 12.1 (Representations and Warranties of Each Party), Section 12.2 (Representations and Warranties of Kiniksa), and Section 12.3 (Representations and Warranties of Partner) will survive until the date that is [***] months after the Effective Date, (b) no claim may be made or suit instituted alleging breach or seeking indemnification pursuant to Article 12 (Representations, Warranties, and Covenants) for any breach of, or inaccuracy in, any representation or warranty contained in Section 12.1 (Representations and Warranties of Each Party), Section 12.2 (Representations and Warranties of Kiniksa), and Section 12.3 (Representations and Warranties of Partner) unless a written notice is provided to the Indemnifying Party at any time prior to the date that is [***] months following the Effective date, and (c) after such [***] month period, no Party may bring any claim against the other Party arising from or relating to such other Party's breach of such representations and warranties.

ARTICLE 13
INDEMNIFICATION

13.1 **By Partner**. Partner will indemnify and hold harmless Kiniksa and its Affiliates, and their respective directors, officers, employees, successors, heirs and assigns, and agents (individually and collectively, the "**Kiniksa Indemnitees**") from and against all Losses incurred in connection with any Third Party Claims to the extent arising from or relating to (a) the Exploitation of the Licensed Product by or on behalf of Partner or any of its Affiliates, Sublicensees, or Subcontractors, including product liability and intellectual property claims arising from such Exploitation, (b) any failure to initiate a recall or market withdrawal of the Licensed Product in the Territory, (c) the negligence or willful misconduct of Partner or any of its Affiliates, Sublicensees, or Subcontractors, (d) breach by Partner or any of its Affiliates, Sublicensees, or Subcontractors of any of Partner's representations, warranties, covenants, or obligations set forth in or entered into pursuant to this Agreement, (e) the failure of Partner or any of its Affiliates, Sublicensees, or Subcontractors to abide by any Applicable Law, (f) any claim or demand from any employee or contractor of Partner or its Affiliate who is an inventor of any Assigned Collaboration Technology, or Joint Collaboration Technology with respect to the ownership thereof under Applicable Law in the Territory, or (g) the holding by Kiniksa of, or action by Kiniksa related to, any Regulatory Submissions, Regulatory Approvals, or Reimbursement Approvals on behalf of Partner, in each case of clauses (a) through (g) above, except to the extent such Third Party Claims arise out of a Kiniksa Indemnitee's negligence or willful misconduct, breach of this Agreement, or failure to abide by any Applicable Law or to the extent otherwise indemnifiable by Kiniksa under Section 13.2 (Indemnification; By Kiniksa).

13.2 **By Kiniksa**. Kiniksa will indemnify and hold harmless Partner, its Affiliates, and their directors, officers, employees, successors, heirs and assigns, and agents (individually and collectively, the "**Partner Indemnitees**") from and against all Losses incurred in connection with any Third Party Claims to the extent from or relating to (a) the Exploitation of the Licensed Product, by or on behalf of Kiniksa or any of its Affiliates, licensees (not including Partner or its Affiliates, Sublicensees, or its Subcontractors), including product liability and intellectual property claims arising from such Exploitation, and including such Exploitation after the effective date of termination of this

Agreement, (b) the negligence or willful misconduct of Kiniksa or any of its Affiliates, licensees (not including Partner or its Affiliates, Sublicensees, or its Subcontractors), Sublicensees (not including Partner or its Affiliates, Sublicensees, or Subcontractors), or Subcontractors, (c) breach by Kiniksa or any of its Affiliates, licensees (not including Partner or its Affiliates, Sublicensees, or Subcontractors), Sublicensees (not including Partner or its Affiliates, Sublicensees, or Subcontractors), or Subcontractors of any of Kiniksa's representations, warranties, covenants, or obligations set forth in or entered into pursuant to this Agreement, (d) the failure of Kiniksa or any of its Affiliates, licensees (not including Partner or its Affiliates, Sublicensees, or Subcontractors), Sublicensees (not including Partner or its Affiliates, Sublicensees, or Subcontractors), or Subcontractors to abide by any Applicable Law, in each case of clauses (a) through (d) above, except to the extent such Third Party Claims arise out of any of a Partner Indemnitee's negligence or willful misconduct, breach of this Agreement or failure to abide by any Applicable Law or to the extent otherwise indemnifiable by Partner under Section 13.1 (Indemnification; By Partner).

13.3 **Indemnification Procedure**. If either Party is seeking indemnification under Section 13.1 (Indemnification; By Partner) or Section 13.2 (Indemnification; By Kiniksa) (the "**Indemnified Party**"), then it will inform the other Party (the "**Indemnifying Party**") of the Third Party Claim giving rise to such indemnification obligations within [***] days after receiving written notice of the Third Party Claim (it being understood and agreed, however, that the failure or delay by an Indemnified Party to give such notice of a Third Party Claim will not affect the Indemnifying Party's indemnification obligations hereunder except to the extent the Indemnifying Party will have been actually and materially prejudiced as a result of such failure or delay to give notice). The Indemnifying Party will have the right to assume the defense of any such Third Party Claim for which it is obligated to indemnify the Indemnified Party. The Indemnified Party will cooperate with the Indemnifying Party and the Indemnifying Party's insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party's cost and expense. The Indemnified Party will have the right to participate, at its own expense and with counsel of its choice, in the defense of any Third Party Claim that has been assumed by the Indemnifying Party. Neither Party will have the obligation to indemnify the other Party in connection with any settlement made without the Indemnifying Party's written consent, which consent will not be unreasonably withheld, conditioned, or delayed. The Indemnifying Party will not admit liability of the Indemnified Party without the Indemnified Party's prior written consent, which consent will not be unreasonably withheld, conditioned, or delayed. If the Parties cannot agree as to the application of Section 13.1 (Indemnification; By Partner) or Section 13.2 (Indemnification; By Kiniksa) as to any Third Party Claim, pending resolution of the Dispute pursuant to Article 16 (Dispute Resolution), then the Parties may conduct separate defenses of such Third Party Claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 13.1 (Indemnification; By Partner) or Section 13.2 (Indemnification; By Kiniksa), as applicable, upon resolution of the underlying Third Party Claim.

13.4 **Insurance**. Each of Kiniksa and Partner will procure and maintain during the Term of this Agreement and until the later of: (a) [***] years after termination or expiration of this Agreement, or (b) the date that all statutes of limitation covering claims or suits that may be instituted for personal injury based on the sale or use of the Licensed Product have expired, commercial general liability insurance from a minimum of "A-" AM Bests rated insurance company or insurer reasonably acceptable to the other Party, including contractual liability and product liability or clinical trials, if applicable, with coverage limits of not less than $[***] per occurrence and $[***] in the aggregate. Such policies will name the other Party and its Affiliates as additional insureds and provide a waiver of subrogation in favor of Kiniksa and its Affiliates or Partner and its Affiliates (as the case may be). Such insurance policies will be primary and non-contributing with

respect to any other similar insurance policies available to Kiniksa or its Affiliates or Partner and its Affiliates (as the case may be). Each of Kiniksa and Partner will provide the other Party with evidence of such insurance promptly following execution by both Parties of this Agreement, upon a Party's request, and prior to expiration of any one coverage. Each of Kiniksa and Partner will provide the other Party with reasonable advanced written notice prior to the cancellation or non-renewal of, or material changes in, such insurance. Such insurance will not be construed to create a limit of Kiniksa's or Partner's liability with respect to its indemnification obligations under this Article 13 (Indemnification).

ARTICLE 14
INTELLECTUAL PROPERTY

14.1 Inventions.

14.1.1 **Ownership**. As between the Parties, (a) Kiniksa will solely own all (i) Assigned Collaboration Technology, and (ii) Kiniksa Collaboration Technology, (b) Partner will solely own all Partner Collaboration Technology, and (c) the Parties will jointly own all Joint Collaboration Technology.

14.1.2 **Disclosure**. Partner will promptly disclose to Kiniksa all inventions within the Collaboration Know-How that it develops or invents, whether solely or jointly with others (in any event, prior to the filing of any patent application with respect to such inventions), including all invention disclosures or other similar documents submitted to Partner by its or its Affiliates' employees, agents, or independent contractors relating thereto. Partner will also promptly respond to reasonable requests from Kiniksa for additional information relating thereto.

14.1.3 **Assignment by Partner**. Partner will and hereby does assign to Kiniksa all of its rights, title, and interests in and to all Assigned Collaboration Technology, and Kiniksa hereby accepts such assignment. Partner will take (and cause its Affiliates and Sublicensees, and their respective employees, agents, and contractors to take) such further actions reasonably requested by Kiniksa to evidence such assignment and to assist Kiniksa in obtaining patent and other intellectual property rights protection for inventions within the Assigned Collaboration Know-How, including executing further assignments, consents, releases, and other commercially reasonable documentation and providing good faith testimony by affidavit, declaration, in-person, or other proper means in support of any effort by Kiniksa to establish, perfect, defend, or enforce its rights in any Assigned Collaboration Technology through prosecution of governmental filings, regulatory proceedings, litigation, and other means, including through the filing, prosecution, maintenance, and enforcement of the Assigned Collaboration Technology. Partner will obligate its Affiliates, Sublicensees, and Subcontractors to assign all Assigned Collaboration Technology to Partner (or directly to Kiniksa) so that Partner can comply with its obligations under this Section 14.1.3 (Assignment by Partner), and Partner will promptly obtain such assignment. Without limitation, Partner will cooperate with Kiniksa if Kiniksa applies for U.S. or ex-U.S. patent protection for such Assigned Collaboration Technology and will obtain the cooperation of the individual inventors of any such Collaboration Technology. If Partner is unable to assign to Kiniksa any Assigned Collaboration Technology, then Partner hereby grants and agrees to grant to Kiniksa a royalty-free, fully paid-up, exclusive (even as to Partner, subject to the terms of this Agreement, including the licenses granted to Partner pursuant to Section 2.1 (License Grants to Partner)), perpetual, irrevocable license (with

the right to grant sublicenses through multiple tiers) under such Assigned Collaboration Technology, as applicable, for any and all purposes.

14.1.4 **Practice Under and other Use of Joint Collaboration Technology**. Subject to the rights granted under and the restrictions set forth in this Agreement (including Section 2.8 (Exclusivity Covenants)), neither Party will have any obligation to account to the other Party for profits, or to obtain any approval of the other Party to license, assign, or otherwise exploit any Joint Collaboration Technology by reason of joint ownership thereof, and each Party hereby waives any right it may have under the Applicable Law of any jurisdiction to require any such approval or accounting. To the extent any further consent is required to enable a Party to so license or exploit its interest in the Joint Collaboration Technology, the other Party hereby grants such consent.

14.1.5 **Employee Assignment**. Partner and its Affiliates and Sublicensees performing activities or exercising rights under this Agreement will enter into with each of their respective employees legally binding and sufficient agreements or employment policies providing for the payment by Partner or its Affiliate of any reward or remuneration required under Applicable Law in a particular country or region in the Territory in consideration for the development of inventions by such employees. Without limiting the generality of the foregoing, Partner and its Affiliates will, and will cause its Sublicensees to, enter into an agreement or employment policy with each of its employees performing activities under this Agreement that (a) compels prompt disclosure to Partner (or its Sublicensee, as applicable) of all Collaboration Technology discovered or developed, invented, or filed by such employee during any performance under this Agreement; (b) automatically assigns to Partner (or its Sublicensee, as applicable) all rights, title, and interests in and to all Collaboration Technology, and requires each employee to execute all documents and take such other actions as may be necessary to effectuate such assignment; (c) includes an invention and patent reward and remuneration policy providing for the payment by Partner of any reward or remuneration required under Applicable Law in such country or region in consideration for the development of inventions by such employees that is legally sufficient under Applicable Law in the applicable country or region in the Territory; and (d) includes a waiver of pre-emption rights under any Applicable Law in such country or region, including in the case of an employee in the PRC, Article 326 of the Contract Law of the PRC to the effect that the employee will confirm that he/she will not have any right or claim with respect to any Collaboration Technology derived from his/her work, except for the reward and remuneration he/she is entitled to under the invention and patent reward and remuneration policy.

14.1.6 **Payments in Consideration of Assignments of Intellectual Property**.

(a) **Payment by Kiniksa**. In consideration of the assignment by Partner to Kiniksa of all Assigned Collaboration Technology, Kiniksa will pay to Partner a one-time payment of [***] which payment will be payment in-full for the assignment of all Assigned Collaboration Technology hereunder, regardless of how many patent applications are filed or patents are issued Covering the Assigned Collaboration Know-How. Kiniksa will notify Partner of Kiniksa's filing of the first patent application claiming any Assigned Collaboration Know-How with respect to which an employee of Partner is an inventor. Promptly thereafter, Partner will invoice Kiniksa for the foregoing amount, and Kiniksa will pay the undisputed invoiced amounts within [***] days after the date of such invoice. The Parties

expressly acknowledge that the foregoing amount is reasonable compensation paid in consideration of the assignments of Assigned Collaboration Technology contemplated under this Agreement and is sufficient to satisfy the requirements under Applicable Law in the Territory regarding amounts to be paid in consideration of the assignment of intellectual property rights by Persons domiciled in the PRC to Persons domiciled outside of the PRC.

(b) **Reward and Remuneration Payments to Partner Employees**. As between the Parties, Partner will be solely responsible for the payment of, and Partner will pay, any rewards and remuneration for inventions and technical achievements required by Applicable Law to be paid to its employees for the development or invention of any Collaboration Technology, regardless of the form of such payment (including, for example, as a royalty). Notwithstanding any provision to the contrary in this Agreement, no payment made by Partner pursuant to Section 14.1.3 (Assignment by Partner) as reward or remuneration for any employee invention may be used as a credit against, or may otherwise reduce, any payment owed by Partner to Kiniksa under this Agreement.

14.2 CREATE Act. Notwithstanding any provision to the contrary set forth in this Agreement, Partner may not invoke the Cooperative Research and Technology Enhancement Act, 35 U.S.C. § 102(c) (the "**CREATE Act**") when exercising its rights under this Agreement without the prior written approval of Kiniksa. If Partner intends to invoke the CREATE Act, then it will notify Kiniksa and if agreed by the Parties, Kiniksa will cooperate and coordinate its activities with Partner with respect to any filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in the CREATE Act.

14.3 Patent Prosecution.

14.3.1 **Kiniksa Patent Rights and Kiniksa Manufacturing Patent Rights**.

(a) **Right to Prosecute**. As between the Parties, Kiniksa or its Affiliate will have the first right, in its sole discretion, to control the Patent Prosecution of all Kiniksa Patent Rights throughout the world. Partner will obtain any necessary assignment documents for Kiniksa with respect to the Patent Prosecution of such Patent Rights, will render all signatures that will be necessary for such patent filings, and will assist Kiniksa or its Affiliate in all other reasonable ways that are necessary for the issuance of such Patent Rights as well as for the Patent Prosecution of such Patent Rights. Partner will be responsible for [***]% of the reasonable out-of-pocket costs incurred by or on behalf of Kiniksa or its Affiliate with respect to the Patent Prosecution of such Patent Rights in the Territory, and will reimburse Kiniksa for such costs within [***] days after receiving an invoice with reasonable supporting documentation for such costs.

(b) **Review and Consult**. Kiniksa will consult with Partner and keep Partner reasonably informed regarding the Patent Prosecution of the Kiniksa Patent Rights in the Territory and will provide Partner with substantive correspondence received from any patent authority in the Territory in connection therewith no later than [***] days after Kiniksa's receipt thereof. In addition, Kiniksa will provide Partner with drafts (in English) of proposed substantive filings in the Territory and correspondence to any patent authority in the Territory in connection with the

Patent Prosecution of the Kiniksa Patent Rights in the Territory for Partner's review and comment prior to the submission of such proposed filings and correspondence, which comments (if any) Partner must provide no later than [***] Business Days after receipt of the applicable filing or correspondence. Further, Kiniksa will notify Partner of any decision to cease Patent Prosecution of any Kiniksa Patent Rights in the Territory. Kiniksa will consider Partner's reasonable comments on Patent Prosecution, but will have final decision-making authority under this Section 14.3.1(b) (Review and Consult). The Parties, through their respective IP counsels, will discuss the strategy for the portfolio of Patent Rights Covering the Licensed Product in the Territory.

(c) **Abandonment**. If Kiniksa or its Affiliate decides that it is no longer interested in the Patent Prosecution of a particular Kiniksa Patent Right in the Territory during the Term, then, unless Kiniksa or its Affiliate has a strategic rationale for ceasing such Patent Prosecution or such Patent Prosecution is otherwise inconsistent with any Third Party IP Agreement, it will provide written notice to Partner of such decision at least [***] days prior to the date that such the applicable Patent Right will become abandoned. To the extent consistent with the rights granted to Kiniksa or its Affiliate under any Third Party IP Agreement, Partner may, upon written notice to Kiniksa, cause Kiniksa or its Affiliate not to cease the Patent Prosecution of any such Patent Right with respect to which Kiniksa or its Affiliate does not have a strategic rationale for the abandonment thereof.

(d) **Manufacturing Patent Rights**. As between the Parties, Kiniksa or its Affiliate will have the sole right to control the Patent Prosecution of the Kiniksa Manufacturing Patent Rights worldwide, including in the Territory at Kiniksa's sole cost and expense.

14.3.2 **Partner Collaboration Patent Rights**.

(a) **Right to Prosecute**. As between the Parties, Partner will have the right to control the Patent Prosecution of all Partner Collaboration Patent Rights throughout the world. Partner will be responsible for [***]% of the costs and expenses incurred with respect to the Patent Prosecution of such Patent Rights throughout the world.

(b) **Review and Consult**. Partner will consult with Kiniksa and keep Kiniksa reasonably informed regarding the Patent Prosecution of the Partner Collaboration Patent Rights and will provide Kiniksa with all substantive correspondence received from any patent authority in connection therewith. In addition, Partner will provide Kiniksa with drafts of all proposed substantive filings and correspondence to any patent authority in connection with the Patent Prosecution of the Partner Collaboration Patent Rights for Kiniksa's review and comment at least [***] days prior to the submission of such proposed filings and correspondence, which comments (if any) Kiniksa must provide no later than [***] Business Days after receipt of the applicable filing or correspondence. Further, Partner will notify Kiniksa of any decision to cease Patent Prosecution of any Partner Collaboration Patent Rights. Partner will consider Kiniksa's reasonable comments on Patent Prosecution and will incorporate such comments where appropriate.

(c) **Abandonment**. If Partner decides that it is no longer interested in continuing the Patent Prosecution of a particular Partner Collaboration Patent Right during the Term, then, unless Partner has a strategic rationale for ceasing such Patent Prosecution, it will provide written notice to Kiniksa of such decision at least [***] days prior to the date on which such Patent Right will become abandoned. Kiniksa or its Affiliate may, upon written notice to Partner, cause Partner not to cease such Patent Prosecution of such Partner Collaboration Patent Right with respect to which Partner does not have a strategic rationale for the abandonment thereof. In such event, Kiniksa will be responsible for [***]% of the costs and expenses of the Patent Prosecution of such Patent Right.

14.3.3 **Joint Collaboration Patent Rights**. During the Term, the Parties and their respective patent counsel will jointly determine the strategy for the Patent Prosecution of any Joint Collaboration Patent Right. Each Party will conduct its activities with respect to Patent Prosecution of any Joint Collaboration Patent Right in a reasonable manner that does not unduly prejudice the rights of the other Party in the other Party's territory, and each Party will provide all assistance reasonably requested by the other Party in relation to the Patent Prosecution of the Joint Collaboration Patent Rights in the other Party's territory.

14.4 Patent Enforcement.

14.4.1 **Notice**. Each Party will notify the other within [***] days after becoming aware of any suspected or actual infringement by a Third Party product in the Territory of any of the (a) Kiniksa Patent Rights in the Territory, (b) Kiniksa Manufacturing Patent Rights in the Territory, or (c) Partner Collaboration Patent Rights in the Territory, and, in each case, any related declaratory judgment or equivalent action alleging the invalidity, unenforceability, or non-infringement of such Patent Rights (collectively "**Kiniksa Patent Right Infringement**"). Each Party will also notify the other Party within [***] days after becoming aware of any alleged or threatened infringement by a Third Party of any Kiniksa Patent Right, Kiniksa Manufacturing Patent Right, or Partner Collaboration Patent Right that adversely affects or is expected to adversely affect the Licensed Product outside of the Territory, including any related declaratory judgment or equivalent action alleging the invalidity, unenforceability or non-infringement of any such Patent Rights (an "**Ex-Territory Infringement**"). For clarity, Kiniksa Patent Right Infringement and Ex-Territory Infringement each exclude any adversarial Patent Prosecution proceedings.

14.4.2 **Enforcement Rights**.

(a) **First Right and Step-In for Kiniksa Patent Right Infringement**.

(i) **Kiniksa Sole Right**. Except as expressly provided in this Section 14.4.2 (Enforcement Rights), Kiniksa or its Affiliate will have the sole right, in its discretion, to bring and control any legal action to enforce Kiniksa Patent Rights and Kiniksa Manufacturing Patent Rights.

(ii) **Kiniksa First Right**. Kiniksa or its Affiliate will have the first right, in its discretion, to bring and control any legal action to enforce a Kiniksa Patent Rights against any Kiniksa Patent Right Infringement related a product of a Third Party that is competitive with the Licensed Product in the Territory (a "**Competitive Infringement**") as it reasonably determines

appropriate, and Kiniksa will consider the interests of Partner in such enforcement of such Kiniksa Patent Right against any Competitive Infringement in the Territory.

(iii) **Partner First Right**. Partner will have the first right to bring and control any legal action to enforce the Partner Collaboration Patent Rights against any Competitive Infringement in the Territory as it reasonably determines appropriate, and Partner will consider the interests of Kiniksa in such enforcement of the Partner Collaboration Patent Rights against such Competitive Infringement.

(iv) **Joint Collaboration Patent Rights**. The Parties and their respective patent counsel will jointly determine which Party will have the first right to bring and control any legal action to enforce the Joint Collaboration Patent Rights against any Competitive Infringement in the Territory.

(v) **Step-In Rights**. The Party with the first right to bring and control any legal action to enforce the Kiniksa Patent Rights or Partner Collaboration Patent Rights, as applicable, pursuant to Section 14.4.2(a)(ii) (Kiniksa First Right) or Section 14.4.2(a)(iii) (Partner First Right) will be referred to herein as the "**Controlling Party**." If the Controlling Party or its designee fails to abate such Competitive Infringement in the Territory or to file an action to abate such Competitive Infringement in the Territory within [***] months after a written request from the other Party to do so, or if the Controlling Party discontinues the prosecution of any such action after filing without abating such infringement, then, in either case, to the extent consistent with the rights granted to Kiniksa or its Affiliate under any Third Party IP Agreement, the other Party will have the right to enforce the applicable Patent Rights against such Competitive Infringement (A) with respect to Kiniksa as the non-Controlling Party, both in and outside of the Territory, or (B) with respect to Partner as the non-Controlling Party, only in the Territory, in each case ((A) and (B)) as such non-Controlling Party reasonably determines appropriate, *provided* that (1) the Controlling Party does not provide reasonable rationale for not doing so or continuing to do so (including a substantive concern regarding counter-claims by the infringing Third Party), and (2) the other Party will not enter into any settlement admitting the invalidity of, or otherwise impairing, any such Patent Rights without the prior written consent of the Controlling Party. In addition, Partner may not enter into any settlement related to any Competitive Infringement, or otherwise, that grants any licenses under Kiniksa Patent Rights or Joint Collaboration Patent Rights or binds Kiniksa to any monetary settlements.

14.4.3 **Cooperation**. At the request of the Party bringing an action related to infringement of any Kiniksa Patent Right or Partner Collaboration Patent Right in accordance with this Section 14.4 (Patent Enforcement) either inside or outside the Territory, the other Party will provide reasonable assistance reasonably requested by the enforcing Party in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery, and joining as a party to the action if required by Applicable Law to pursue such action.

14.4.4 **Recoveries**. Any recoveries resulting from an enforcement action relating to a Competitive Infringement in the Territory will be first applied against payment of each Party's costs and expenses in connection therewith. Any such recoveries in excess of such costs and expenses will be split as follows: (a) [***]% will be paid to the Party initiating such suit, action, or proceeding and (b) [***]% will be paid to the non-initiating Party.

14.5 Infringement of Third Party Rights.

14.5.1 **Notice**. If the Licensed Product used or sold by Partner or its Affiliates or Sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent Right or other rights in the Territory that are owned or controlled by such Third Party, then Partner will promptly notify Kiniksa within [***] Business Days after receipt of such claim or assertion and will include in such notice a copy of any summons or complaint (or the equivalent thereof) received regarding the foregoing. Thereafter, the Parties will promptly meet to consider the claim or assertion and the appropriate course of action and may, if appropriate, agree on and enter into a "common interest agreement" wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute. The Parties will assert and not waive the joint defense privilege with respect to any communications between the Parties in connection with the defense of such claim or assertion.

14.5.2 **Defense**. Partner will be solely responsible for the defense of any such infringement claims brought against Partner, at Partner's cost and expense; *provided* that Partner will not agree to any settlement, consent to judgment, or other voluntary final disposition in connection with such defense action without Kiniksa's prior written consent if such settlement, consent to judgment, or other voluntary final disposition would (a) result in the admission of any liability or fault on behalf of Kiniksa or any of its Affiliates, (b) result in or impose any payment obligations upon Kiniksa or any of its Affiliates, or (c) subject Kiniksa or any of its Affiliates to an injunction or otherwise limit Kiniksa's or any of its Affiliates' ability to take any actions or refrain from taking any actions under this Agreement or with respect to the Licensed Product or the Third Party's Patent Rights or other rights. Partner will keep Kiniksa informed on the status of such defense action, and Kiniksa or its Affiliate will have the right, but not the obligation, to participate and be separately represented in such defense action at its sole option and at its own expense.

14.6 Patent Listings. With respect to patent listings in any patent listing system established by any applicable Regulatory Authority in a region in the Territory or under Applicable Law, including, (a) in the PRC, under Article 76 of the Patent Law of the PRC and its implementing measures and interpretations promulgated by relevant PRC Governmental Authorities, including the National Medical Products Administration (NMPA), the China National Intellectual Property Administration (CNIPA), and the Supreme People's Court, and (b) other equivalents thereof in the Territory, for Kiniksa Patent Rights or Collaboration Patent Rights Covering the Licensed Product, the Parties will discuss and agree which Patent Rights to list in such patent listing in such region (the "**Listing Patent Rights**") (i) prior to the submission of the first and any subsequent MAA for the Licensed Product in such region to such applicable Regulatory Authority, (ii) within [***] days, but in any event reasonably in advance of the deadline for listing under Applicable Laws, after the receipt of the first and any subsequent Regulatory Approval in such region for the Licensed Product from such Regulatory Authority, including any additional Indication for the Licensed Product, (iii) within [***] days, but in any event reasonably in advance of the deadline for listing under Applicable Laws, after the issuance in such region of a patent included in the Listing Patent Rights, and (iv) within [***] days following the submission of a new patent application in such region

Covering the Licensed Product included in the Kiniksa Patent Rights or Collaboration Patent Rights that has not been previously considered in any prior discussion and agreement of the Parties regarding Listing Patent Rights; *provided* that, except as otherwise permitted under Applicable Laws, the Party holding the MAA for the Licensed Product in the Territory will not list, and will not be obligated to list, as of the date of listing, (A) any unissued patent, (B) any Patent Right that does not Cover the Licensed Product, (C) any patent that is of a type or that contains patent claims that are of a type not permitted to be listed under Applicable Law, or (D) any patent that such Party knows or has a reasonable basis to know is reasonably likely to be declared invalid by a competent Governmental Authority in such region. In furtherance of the foregoing clause (D), if either Party has such knowledge or reasonable basis, such Party will promptly notify and inform the Party of all facts and circumstances it is aware of underlying such knowledge or reasonable basis. If the Parties are unable to agree on which Patent Rights to list by the time required as provided under clause (i) to (iv) above, subject to the above proviso, then Kiniksa will have the final decision-making right over whether the Party holding the MAA for the Licensed Product in the Territory will list any Kiniksa Patent Rights or Joint Collaboration Patent Rights, and Partner will have the final decision-making right over whether the Party holding the MAA for the Licensed Product in the Territory will list any issued patents included in the Partner Collaboration Patent Rights. The Party holding the MAA for the Licensed Product in the Territory will promptly, and in any event at least [***] days prior to the applicable deadline for listing under Applicable Laws, list the Listing Patent Rights in the applicable patent listing system in the applicable regions in the Territory *provided*, that, without limiting the foregoing, if the Party holding the MAA for the Licensed Product in the Territory has not listed the Listing Patent Rights in the patent listing system of an applicable region before [***] days prior to the deadline for listing in the applicable region, then the other Party may list the Listing Patent Rights at anytime when permitted by Applicable Laws by providing prior written notice to the Party holding the MAA for the Licensed Product in the Territory. The Party holding the MAA for the Licensed Product in the Territory will provide copies of all documentation to be filed in connection with any such listing of Listing Patent Rights to the other Party prior to filing thereof and will consider the other Party's comments with respect to such documentation. The Party holding the MAA for the Licensed Product in the Territory will cooperate with the other Party to the extent reasonably requested by the other Party to effectuate the intent of this Section 14.6 (Patent Listings), including providing all documentation, certifications, and consents necessary to effectuate the foregoing and setting up an account to list patents on the applicable patent listing system, and granting the other Party access to and a right to use such account as reasonably necessary to effectuate the intent of this Section 14.6 (Patent Listings). Neither Party will list any patent in any patent listing system in a region in the Territory for the Licensed Product, except in accordance with this Section 14.6 (Patent Listings).

14.7 **Patent Term Extensions**. With respect to any system for extending the term of Patent Rights in the Territory or supplementary protection certificates and any other extensions that are now or become available in the future under Applicable Laws in any country or region in the Territory, in each case, due to the time needed to obtain Regulatory Approval of a pharmaceutical product established by any applicable Regulatory Authority or other Governmental Authority in any region in the Territory (a "**Patent Term Extension**"), or adjusting the term of Patent Rights in the Territory due to the time needed to prosecute and obtain a grant of a Patent Right under Applicable Laws in any region in the Territory (a "**Patent Term Adjustment**"), (a) Kiniksa will have the right, but not the obligation, and will be solely responsible for making all decisions regarding Patent Term Extensions or Patent Term Adjustments in the Territory that are applicable to Kiniksa Patent Rights, or Joint Collaboration Patent Rights and that become available for a patent included in the Kiniksa Patent Rights, or Joint Collaboration Patent Rights *provided* that Kiniksa will consult with Partner with respect to such decisions and consider the reasonable comments and concerns raised by

Partner; and (b) Partner will have the right, but not the obligation, and will be solely responsible for making all decisions regarding Patent Term Extensions, and Patent Term Adjustments in the Territory that are applicable to Partner Collaboration Patent Rights and that become available for the Licensed Product in the Territory or following issuance of a patent included in the Partner Collaboration Patent Rights; *provided* that Partner will consult with Kiniksa with respect to such decisions and consider the reasonable comments and concerns raised by Kiniksa. The Party holding the MAA for the Licensed Product in the Territory will make the appropriate filings and applications in the Territory in order to effectuate each Party's decisions regarding Patent Term Extensions, or Patent Term Adjustments in the Territory in accordance with the foregoing sentence. Each Party will cooperate with the other Party to the extent reasonably required by the other Party to effectuate the intent of this Section 14.7 (Patent Term Extensions), including providing to the other Party all documentation, certifications, and consents necessary to make and prosecute such application and obtain such Patent Term Extension or Patent Term Adjustment.

14.8 Filing of Agreement with CNIPA. The Parties will file a redacted copy of this Agreement with the CNIPA as required by Applicable Law in the Territory no later than the date required under such Applicable Law.

14.9 Product Trademarks.

14.9.1 **Global Brand Elements**. Partner acknowledges that Kiniksa or its Affiliate may decide to develop and adopt certain distinctive colors, logos, images, symbols, and trademarks to be used in connection with the Commercialization of the Licensed Product on a global basis (such branding elements, collectively, the "**Global Brand Elements**").

14.9.2 **Product Marks in the Territory**. Partner will have the right to brand the Licensed Product in the Territory using trademarks, logos, and trade names that it determines appropriate for the Licensed Product, including, subject to the terms of this Agreement, the Existing Product Trademarks, which may vary by region or within a country or region in the Territory, and that are consistent with Kiniksa's Global Brand Elements (such marks, including the Existing Product Trademarks, the "**Product Marks**"); *provided*, *however*, that Partner will provide Kiniksa with a reasonable opportunity to review and provide comments on each proposed Product Mark, and Partner will consider and incorporate Kiniksa's reasonable comments before selecting any Product Mark. Partner will not use any trademarks of Kiniksa (including Kiniksa's corporate name), or any of its licensor's trademarks under the Regeneron License Agreement, or any trademark confusingly similar thereto except as expressly permitted hereunder without Kiniksa's prior written consent.

14.9.3 **Ownership**. As between the Parties, Kiniksa will be the sole and exclusive owner of all Product Marks and Global Brand Elements, including all trademark registrations and applications therefor inside and outside of the Territory and all goodwill associated therewith. To the extent Partner acquires any rights, title, or interests in or to any Product Mark or Global Brand Element (including any trademark registration or application therefor or goodwill associated with any Product Mark), Partner will, and hereby does, assign the same to Kiniksa. As between the Parties, Kiniksa will have the sole right to register, prosecute, and maintain the Product Marks in the Territory that it determines reasonably necessary in Kiniksa's name, at Partner's cost and expense, and Partner will reimburse Kiniksa within [***] days after receiving Kiniksa's invoice therefor.

14.9.4 **Use and Quality**. Partner agrees that it and its Affiliates and Sublicensees will Commercialize the Licensed Product in the Territory in a manner consistent with the Global Brand Elements and will: (a) ensure that all Licensed Product that are sold bearing the Product Marks and Global Brand Elements are of a high quality consistent with industry standards for global pharmaceutical and biologic therapeutic products; (b) ensure that each use of the Global Brand Elements and Product Marks by Partner and its Affiliates and Sublicensees is accompanied by an acknowledgment that such Global Brand Elements and Product Marks are owned by Kiniksa; (c) not use such Global Brand Elements or Product Marks in a way that might materially prejudice their distinctiveness or validity or the goodwill of Kiniksa therein and includes the trademark registration symbol ® or ™ as appropriate; (d) not use any trademarks or trade names so resembling any of such Global Brand Elements or Product Marks as to be likely to cause confusion or deception; (e) place and display the Global Brand Elements and the Product Marks on and in connection with the Licensed Product in a way that acknowledges Kiniksa's role in discovering the Licensed Product and that the Licensed Product is under license from Kiniksa; and (f) accompany all uses of the Existing Product Trademarks with a statement that the Existing Product Trademarks are registered trademarks of Regeneron Pharmaceuticals, Inc. To the extent permitted by Applicable Law, Partner will include the words "*Licensed from Kiniksa.*" on all packaging and labeling for the Licensed Product and in relevant scientific, medical, and other Licensed Product-related communications to the extent such communications address the Development, performance of Medical Affairs, or Commercialization of such the Licensed Product, or such other similar text provided by Kiniksa and reasonably acceptable to Partner.

14.10 Patent Marking; Product Attribution. Partner will mark all Licensed Product in accordance with the applicable patent marking laws, and will require all of its Affiliates and Sublicensees to do the same. To the extent permitted by Applicable Law, Partner will indicate on the product packaging, advertisement and promotional materials that the Licensed Product is in-licensed from Kiniksa. In addition, subject to Applicable Law in all cases, unless otherwise agreed in writing by Kiniksa, Partner will include on all materials containing any Existing Product Trademark that the Licensed Product was discovered by Regeneron Pharmaceuticals, Inc.

ARTICLE 15
TERM AND TERMINATION

15.1 Term. This Agreement will be effective as of the Effective Date and, if not otherwise terminated earlier pursuant to this Article 15 (Term and Termination), will continue, as applicable, on country-by-country or region-by-region basis, until the expiration of the Royalty Term in such country or region (the "**Term**"); *provided*, *however*, that Partner will be obligated to pay to Kiniksa any Milestone Payment achieved during the [***] year period after the expiration of the Term. As applicable, on a country-by-country or region-by-region basis, upon the natural expiration of this Agreement as contemplated in this Section 15.1 (Term) (but not termination), (a) so long as Partner (i) is not at such time in material breach of any obligation under this Agreement based on receipt on or prior to such date of written notification from Kiniksa as required under Section 15.2.2 (Termination for Material Breach) or (ii) if Partner is so in material breach of any obligation under this Agreement, then only if such breach is timely cured in accordance with Section 15.2.2 (Termination for Material Breach) prior to the expiration of the Agreement, the license granted to Partner under Section 2.1.1 (License Grants to Partner; In the Territory) will become fully paid-up, perpetual, and exclusive for a period of [***] years after the effective date of expiration of this

Agreement and non-exclusive thereafter; and (b) the license granted to Kiniksa under Section 2.3 (License Grant to Kiniksa) will become fully paid-up, perpetual, and irrevocable.

15.2 Termination.

15.2.1 **Termination by Partner for Convenience**. Partner may terminate this Agreement in its entirety by providing a written notice of termination to Kiniksa that includes an effective date of termination of at least [***] months after the date of such notice.

15.2.2 **Termination for Material Breach**. If either Party believes that the other is in material breach of any of its obligations hereunder, then the non-breaching Party may deliver notice of such breach to the other Party stating the cause and proposed remedy ("**Breach Notification**"). For any breach arising from a failure to make a payment set forth in this Agreement, the allegedly breaching Party will have [***] Business Days from the receipt of the applicable Breach Notice to dispute or cure such breach. For all breaches other than a failure to make a payment as set forth in this Agreement, the allegedly breaching Party will have [***] days from the date of the Breach Notification to dispute or cure such breach. If the Party receiving notice of breach fails to cure, or fails to dispute, that breach within the applicable period set forth above, then the Party originally delivering the Breach Notification may terminate this Agreement effective on written notice of termination to the other Party. The Parties stipulate and agree that a breach of (a) a Party's obligations set forth under (i) the second sentence of Section 2.5 (Restrictions), or (ii) Section 2.8 (Exclusivity Covenant), or (b) Partner's payment obligations set forth under Article 10 (Payments), in each case ((a) – (b)), will each be considered a material breach of a material obligation under this Agreement for purposes of this Section 15.2.2 (Termination for Material Breach).

15.2.3 **Termination for Patent Challenge**. Except to the extent unenforceable under Applicable Law, Kiniksa may terminate this Agreement by providing written notice of termination to Partner if Partner or its Affiliates or Sublicensees (individually or in association with any Person) contests or assists a Third Party in contesting the scope, validity, or enforceability of any Kiniksa Patent Right or any foreign counterpart thereof anywhere in the world in any court, tribunal, arbitration proceeding, or other proceeding, including the U.S. Patent and Trademark Office and the U.S. International Trade Commission (a "**Patent Challenge**"). In the event of such a Patent Challenge, Kiniksa will provide prompt written notice of such Patent Challenge to Partner, and Kiniksa may terminate this Agreement by providing written notice of such termination to Partner. If Kiniksa reasonably believes that termination of this Agreement pursuant to this Section 15.2.3 (Termination for Patent Challenge) is not an available remedy under Applicable Law, then in lieu of such termination, Kiniksa may instead increase the amount of all yet unpaid (as of the date of such election) Milestone Payments and Royalty Payments payable under this Agreement by [***]% by providing written notice of such election to Partner. If Kiniksa elects the foregoing [***]% increase in the Milestone Payments and Royalty Payments as liquidated damages, then such increase would be Kiniksa's sole and exclusive remedy for such Patent Challenge. The Parties hereby stipulate and agree that the damages that Kiniksa would suffer as a result of such a Patent Challenge would be uncertain in amount and difficult to prove, and therefore the foregoing [***]% increase in Milestone Payments and Royalty Payments is a reasonable liquidated damages remedy and not a penalty. As used herein, a Patent Challenge includes: (a) filing an action under 28 U.S.C. §§ 2201-2202 seeking a declaration of invalidity or unenforceability of any such Patent Right; (b) citation to the

United States Patent and Trademark Office pursuant to 35 U.S.C. § 301 of prior art patents or printed publications or statements of the patent owner concerning the scope of any such Patent Rights; (c) filing a request under 35 U.S.C. § 302 for re-examination of any such Patent Rights; (d) becoming a party to an interference with an application for any such Patent Rights pursuant to 35 U.S.C. § 135; (e) filing, or joining in, a petition under 35 U.S.C. § 311 to institute *inter partes* review of any such Patent Right; (f) filing, or joining in, a petition under 35 U.S.C. § 321 to institute post-grant review of any such Patent Right or any portion thereof; (g) filing or commencing any opposition, nullity, or similar proceedings challenging the validity of any such Patent Right in any country or region; or (h) any foreign equivalent of clauses (a), (b), (c), (d), (e), (f), or (g).

15.2.4 **Termination in** [***]. If Partner does not (a) file an MAA for the Licensed Product or (b) Initiate a Clinical Trial for the Licensed Product, in each case ((a) and (b)) in at least [***] within [***] years after the Effective Date, then, unless otherwise agreed in writing by Kiniksa in its sole discretion, (i) all licenses and rights granted to Partner in each of [***] will terminate, (ii) if Partner has conducted any Clinical Development or Commercialization activities in any such country, then the applicable effects of Section 15.3 (Effects of Termination) will apply to such country(ies), and (iii) the definition of Territory will no longer include [***] for purposes of this Agreement.

15.2.5 **Cessation of Development and Commercialization in the PRC**. If Partner and its Affiliates do not conduct any material Development or Commercialization activities with respect to the Licensed Product in the PRC for a continuous period of longer than [***] months, and such suspension of activity is not: (a) contemplated in the Territory Development Plan (except to the extent such inactivity was approved by Partner through exercise of its final decision-making authority over the Territory Development Plan pursuant to Section 3.6.2(b) (Partner Final Decision-Making Authority)) or Global Development Plan or otherwise by written agreement of the Parties, (b) a result of Partner's reasonable response to written guidance from or action by a Regulatory Authority in the Territory (such as a clinical hold, or a recall or withdrawal), (c) a Force Majeure event pursuant to Section 17.4 (Force Majeure), or (d) due to Kiniksa's failure to supply the Licensed Product in accordance with the terms of the Clinical Supply Agreement or, if applicable, the Commercial Supply Agreement, then Kiniksa may, at its election, terminate this Agreement upon [***] days' prior written notice to Partner with respect to the Licensed Product, if Partner has not performed any material Development or Commercialization activities with respect to the Licensed Product in the PRC during such [***] day period. For the avoidance of doubt, any activities that Partner conducts in furtherance of making alternative arrangements for Development of the Licensed Product in the PRC in response to Kiniksa's material failure to perform its obligations under the Global Development Plan with respect to the Licensed Product will be deemed material Development activities for purposes of this Section 12.2.6 (Cessation of Development and Commercialization in the PRC).

15.2.6 **Termination for Insolvency**. Each Party will have the right to terminate this Agreement upon delivery of written notice to the other Party if (a) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (b) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within [***] days of its filing,

or (c) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors.

15.2.7 **Full Force and Effect During Notice Period**. This Agreement will remain in full force and effect until the expiration of the applicable termination notice period.

15.3 Effects of Termination. Upon the termination of this Agreement:

15.3.1 **Partial Termination**. In the event that this Agreement is terminated pursuant to Section 15.2.4 (Termination in [***]) with respect to only certain countries or regions in the Territory, then Section 15.3 (Effects of Termination), Section 15.4 (Survival), and Section 15.5 (Cumulative Remedies; Termination Not Sole Remedy) will apply solely with respect to the terminated countries or regions, and all other rights and obligations of the Parties under this Agreement will otherwise remain in full force and effect.

15.3.2 **Licenses**. As of the effective date of termination of this Agreement, all licenses and all other rights granted by Kiniksa to Partner under the Kiniksa Technology will terminate and all sublicenses granted and Subcontractors engaged by Partner will also terminate. In addition, upon the termination of this Agreement, Kiniksa will have, and Partner hereby grants to Kiniksa, effective upon such termination, a worldwide, fully-paid, perpetual, irrevocable, and sublicensable (through multiple tiers) license under the Partner Technology Controlled by Partner as of the effective date of such termination solely to Exploit the Licensed Product. If this Agreement is terminated by Partner pursuant to Section 15.2.2 (Termination for Material Breach), then Kiniksa will have the right to elect whether the license will be either non-exclusive, royalty-free, and fully paid-up, or exclusive, and if Kiniksa elects an exclusive license, then the license granted to Kiniksa will be royalty-bearing at a royalty rate to be agreed by the Parties upon termination of this Agreement. In addition, Partner will assign to Kiniksa any Third Party IP Agreement pursuant to which Partner then Controls any Partner Technology, if permitted under such Third Party IP Agreement (and will use reasonable efforts to seek any consent required from the applicable Third Party in connection with such an assignment). If such Third Party IP Agreement cannot be assigned to Kiniksa, then upon Kiniksa's reasonable request, Partner will maintain such Third Party IP Agreement and Kiniksa will pay to Partner [***]% of all payments due to the applicable Third Party under any such Third Party IP Agreement in consideration of the sublicense to Kiniksa and Kiniksa's Exploitation of such Partner Identified Rights. If Partner is unable to assign the Third Party IP Agreement pursuant to which Partner acquired rights to any Partner Identified Rights and is unable to sublicense any Partner Identified Rights to Kiniksa pursuant to this Section 15.3 (Effects of Termination; Licenses) without the consent of the Third Party, then Partner will, on request from Kiniksa (and at Kiniksa's cost and expense), use reasonable efforts to procure such licenses with respect to Licensed Product on behalf of Kiniksa to the extent that it is able to do so, and Kiniksa will pay such fees and agree to be bound by the terms agreed between Partner and the Third Party licensor.

15.3.3 **Appointment as Exclusive Distributor**. If Partner is Commercializing the Licensed Product in any country or region in the Territory as of the effective date of termination, then, at Kiniksa's election (in its sole discretion) on a country-by-country or region-by-region basis, as applicable, in the Territory, until such time as all Regulatory Approvals with respect to the Licensed Product in such country or region have been assigned and transferred to Kiniksa, either (a) Partner will appoint Kiniksa or its designee as its exclusive

distributor of the Licensed Product in such country or region and grant Kiniksa or its designee the right to appoint sub-distributors, to the extent not prohibited by any written agreement between Partner or any of its Affiliates and a Third Party; *provided* that Kiniksa will purchase any and all salable inventory of the Licensed Product held by Partner or its Affiliates as of the effective date of termination with respect to the Licensed Product at a price equal to the price paid by Partner to Kiniksa for such inventory, or (b) Partner will have the continued right to sell the Licensed Product in such country or region from its inventory; *provided*, *however*, that Partner's obligations under this Agreement with respect to all Licensed Product that Partner sells, including the obligation to remit Royalty Payments to Kiniksa hereunder, will continue in full force and effect during such period.

15.3.4 **Regulatory Submissions and Regulatory Approvals**. Partner will and hereby does, and will cause its Affiliates and Sublicensees to, (a) no later than [***] days after the effective date of termination of this Agreement (or such longer period as may be required under Applicable Law), assign and transfer to Kiniksa or its designee all of Partner's rights, title, and interests in and to all Regulatory Submissions and Regulatory Approvals for the Licensed Product then owned or Controlled by Partner or any of its Affiliates or Sublicensees, and (b) to the extent assignment pursuant to clause (a) is delayed or is not permitted by the applicable Regulatory Authority, permit Kiniksa to cross-reference and rely upon any Regulatory Submissions and Regulatory Approvals filed by Partner or any of its Affiliates or Sublicensees with respect to the Licensed Product. Partner will take all steps necessary to transfer ownership of all such assigned Regulatory Submissions and Regulatory Approvals to Kiniksa, including submitting to each applicable Regulatory Authority a letter or other necessary documentation (with a copy to Kiniksa) notifying such Regulatory Authority of the transfer of such ownership of each Regulatory Submission and Regulatory Approval. In addition, upon Kiniksa's written request, Partner will, at its cost and expense, provide to Kiniksa copies of all substantive related documentation, including non-clinical, preclinical, and clinical data that are held by or reasonably available to Partner or its Affiliates or Sublicensees. The Parties will discuss and establish appropriate arrangements with respect to safety data exchange, *provided* that Kiniksa will assume all safety and safety database activities with respect to the Licensed Product no later than [***] days after the effective date of termination of this Agreement.

15.3.5 **Assignment and Disclosure**. To the extent requested by Kiniksa following the date that a Party provides notice of termination of this Agreement, Partner will promptly upon request (and in any event within [***] days after the effective date of termination):

(a) subject to Partner's confidentiality obligations to Third Parties, provide to Kiniksa for its review unredacted copies of all clinical trial agreements, manufacturing and supply agreements, distribution agreements (to the extent assignable and not cancelled), and confidentiality and other agreements, in each case, relating to the Licensed Product and that are [***] for the Exploitation of the Licensed Product, and, following such review, upon Kiniksa's request and solely to the extent permitted under the terms of such agreements, assign and transfer to Kiniksa or its designee all of Partner's rights, title, and interests in and to any such agreements. If such agreement is not assignable, then Partner will cooperate with Kiniksa in all reasonable respects to secure the consent of the applicable Third Party to such assignment or to cause such Third Party to enter into a separate agreement with Kiniksa on terms substantially similar to those granted to Partner;

(b) assign to Kiniksa information relating to the pricing, reimbursement, marketing, promotion, distribution, offering for sale, or selling of the Licensed Product, including information about pharmaco-economic studies justifying pricing, analysis of competitive products and environment, product positioning (including unique selling proposition and understanding of competitors' positioning strategies) and promotional strategies (including promotional materials), virtual product and clinical support information (webpage), ongoing medical education strategies, and strategies used for building relationships with health insurance and managed care entities;

(c) use reasonable efforts, and subject to Kiniksa's reasonable assistance, to the extent legally permissible, assign and transfer to Kiniksa all of Partner's (and Affiliates') worldwide rights, title, and interests in and to Existing Product Trademarks or registered internet domain names owned by Partner or its Affiliates as of the effective date of termination that are specific to and exclusively used for the Licensed Product (it being understood that the foregoing will not include any trademarks or internet domain names that contain the corporate or business name of Partner or any of its Affiliates or any other products of Partner or any of its Affiliates);

(d) disclose to Kiniksa or its designee all data, information, documents, records, and materials related to the Licensed Product that are controlled by Partner or that Partner is able to obtain using reasonable efforts, and that embody the foregoing; and

(e) assign and transfer to Kiniksa or its designee all of Partner's rights, title, and interests in and to any promotional materials, training materials, medical education materials, packaging and labeling, and all other literature or other information related to the Licensed Product and copyrights and any registrations for the foregoing.

Unless this Agreement is terminated by Partner pursuant to Section 15.2.2 (Termination for Material Breach) or Section 15.2.6 (Termination for Insolvency), Partner will bear the costs and expenses associated with the assignments set forth in this Section 15.3.5 (Assignment and Disclosure). To the extent that any agreement or other asset described in this Section 15.3.5 (Assignment and Disclosure) is not assignable by Partner, then such agreement or other asset will not be assigned, and upon the request of Kiniksa, Partner will take such steps as may be necessary to allow Kiniksa to obtain and to enjoy the benefits of such agreement or other asset, without additional payment therefor, in the form of a license or other right to the extent Partner has the right and ability to do so. For clarity, Kiniksa will have the right to request that Partner take any or all of the foregoing actions in whole or in part, or with respect to all or any portion of the assets set forth in this Section 15.3.5 (Assignment and Disclosure).

15.3.6 **Regulatory Transfer Support**. In furtherance of the assignment of Regulatory Submissions and Regulatory Approvals and other data pursuant to Section 15.3.4 (Regulatory Submissions and Regulatory Approvals) and Section 15.3.5 (Assignment and Disclosure), Partner will appoint Kiniksa as Partner's or its Affiliate's agent for all Licensed Product-related matters involving Regulatory Authorities until all Regulatory

Approvals, Regulatory Submissions, and other governmental or regulatory filings that are not then in Kiniksa's or its Affiliate's name have been assigned to Kiniksa or its designee. In the event of failure to obtain such assignment, Partner hereby consents and grants to Kiniksa the right to access and reference (without any further action required on the part of Partner, whose authorization to file this consent with any Regulatory Authority is hereby granted) any such item with respect to the Licensed Product.

15.3.7 **Transfer of Prosecution and Maintenance Responsibilities**. Partner will transfer to Kiniksa any and all responsibilities for Patent Prosecution for the Kiniksa Patent Rights, including transferring all files related to the Patent Prosecution of such Kiniksa Patent Rights, and at the request of Kiniksa, Partner will make appropriate personnel available to Partner to answer such reasonable questions as Kiniksa may have in connection with such transfer of Patent Prosecution of such Patent Rights.

15.3.8 **Know-How Transfer Support**. In furtherance of the assignment of Know-How pursuant to Section 15.3.5 (Assignment and Disclosure), Partner will, for a period of [***] months from the effective date of termination of this Agreement, provide such reasonable consultation or other reasonable assistance as Kiniksa may reasonably request to assist Kiniksa in becoming familiar with such Know-How in order for Kiniksa to undertake further Exploitation of the Licensed Product at Kiniksa's cost and expense at Partner's FTE Rate.

15.3.9 **Inventory**. At Kiniksa's election and request, unless Kiniksa elects to grant to Partner the continued right to sell the Licensed Product in such country or region from its inventory pursuant to clause (b) of Section 15.3.3 (Appointment as Exclusive Distributor), Partner will either (a) transfer to Kiniksa or its designee some or all inventory of, or (b) destroy, in each case ((a) and (b)), the Licensed Product (including all final product, bulk drug substance, intermediates, works-in-process, formulation materials, reference standards, drug product clinical reserve samples, packaged retention samples, and the like) then in the possession or Control of Partner, its Affiliates or Sublicensees. In the event that Kiniksa elects to proceed under clause (a), then Kiniksa will pay Partner a price equal to the price paid by Partner to Kiniksa for such transferred Licensed Product.

15.3.10 **Wind Down and Transition**. Except as provided under Section 15.3.14 (Termination by Partner for Kiniksa's Breach or Insolvency), Partner will be responsible, at its own cost and expense, for the wind-down of Partner's and its Affiliates' and its Sublicensees' Exploitation of the Licensed Product. Partner will, and will cause its Affiliates and Sublicensees to, reasonably cooperate with Kiniksa to facilitate orderly transition of the Exploitation of the Licensed Product to Kiniksa or its designee, including (a) assigning or amending as appropriate, upon request of Kiniksa, any agreements or arrangements with Third Party vendors (including distributors) to Exploit the Licensed Product or, to the extent any such Third Party agreement or arrangement is not assignable to Kiniksa, reasonably cooperating with Kiniksa to arrange to continue to provide such services for a reasonable time after termination of this Agreement with respect to the Licensed Product; and (b) to the extent that Partner or its Affiliate is performing any activities described in the foregoing clause (a), reasonably cooperating with Kiniksa to transfer such activities to Kiniksa or its designee and continuing to perform such activities on Kiniksa's behalf for a reasonable time after termination of this Agreement with respect to the Licensed Product until such transfer is completed.

15.3.11 **Ongoing Clinical Trials**.

(a) **Transfer to Kiniksa**. If, as of the effective date of termination of this Agreement with respect to the Licensed Product, Partner or its Affiliates are conducting any Clinical Trials for the Licensed Product, then, at Kiniksa's election on a Clinical Trial-by-Clinical Trial basis, Partner will fully cooperate, and will ensure that its Affiliates fully cooperate, with Kiniksa to transfer the conduct of such Clinical Trial to Kiniksa or its designees. If Kiniksa so elects, then Partner will continue to conduct such Clinical Trial, at Kiniksa's cost, to enable such transfer to be completed without interruption of any such Clinical Trial (including the assignment of all related Regulatory Submissions and investigator and other agreements related to such Clinical Trials). Partner will provide such knowledge transfer and other training to Kiniksa or its designated Affiliate or Third Party as reasonably necessary for Kiniksa or such designated Affiliate or Third Party to continue such Clinical Trial for the Licensed Product.

(b) **Wind-Down**. If Kiniksa does not elect to assume control of any such Clinical Trials for the Licensed Product, then Partner will, in accordance with accepted pharmaceutical industry norms and ethical practices, wind-down the conduct of any such Clinical Trial in an orderly manner. Except for Partner's termination of this Agreement under Section 15.2.2 (Termination for Material Breach) or Section 15.2.6 (Termination for Insolvency), Partner will be responsible for any costs and expenses associated with such wind-down.

15.3.12 **Return of Confidential Information**. At the Disclosing Party's election, the Receiving Party will return (at Disclosing Party's expense) or destroy all tangible materials comprising, bearing, or containing any Confidential Information of the Disclosing Party relating to the Licensed Product that are in the Receiving Party's or its Affiliates' or Sublicensees' possession or control and provide written certification of such destruction (except to the extent any information is the Confidential Information of both Parties or to the extent that the Receiving Party has the continuing right to use the Confidential Information under this Agreement); *provided* that the Receiving Party may retain one copy of such Confidential Information for its legal archives. Notwithstanding any provision to the contrary set forth in this Agreement, the Receiving Party will not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information.

15.3.13 **Further Assistance**. Except as provided under Section 15.3.14 (Termination by Partner for Kiniksa's Breach), Partner will provide any other assistance or take any other actions, in each case, reasonably requested by Kiniksa as necessary to transfer to Kiniksa the Exploitation of the Licensed Product or as otherwise required to comply with the terms of any Third Party IP Agreement, and will execute all documents as may be reasonably requested by Kiniksa in order to give effect to this Section 15.3 (Effects of Termination).

15.3.14 **Termination by Partner for Kiniksa's Breach or Insolvency**. Notwithstanding any provision to the contrary in this Article 15 (Term and Termination), if Partner terminates this Agreement pursuant to Section 15.2.2 (Termination for Material Breach) or Section 15.2.6 (Termination for Insolvency), then Kiniksa will be responsible for the reasonable

out-of-pocket costs incurred by Partner directly in connection with the performance of the activities set forth in this Section 15.3 (Effects of Termination). Partner will invoice Kiniksa [***] for the foregoing costs incurred by or on behalf of Partner in such Calendar Quarter, and Kiniksa will pay the undisputed invoiced amounts within [***] days after the date of any such invoice.

15.4 **Survival**. Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, the following provisions of this Agreement will survive the expiration or termination of this Agreement: Article 1 (Definitions), Section 2.3 (License Grant to Kiniksa), Section 10.3.4 (Royalty Reports and Payments) (solely with respect to Net Sales during the Term), Section 10.6 (No Refunds) (with respect to amounts that come due during the Term), Section 10.7 (Accounting Standards) (solely with respect to amounts that come due during the Term), Section 10.8 (Currency; Exchange Rate) (solely with respect to amounts that come due during the Term), Section 10.9 (Blocked Payments) (solely with respect to amounts that become due during the Term), Section 10.10 (Late Payments) (solely with respect to amounts that become due during the Term), Section 10.11 (Financial Records and Audits) (only for so long as payments may be due under this Agreement), Section 10.12 (Taxes), Section 10.13 (VAT Credits), Section 11.1 (Duty of Confidence), Section 11.2 (Confidential Information), Section 11.3 (Exemptions), Section 11.4 (Authorized Disclosures), Section 12.7 (Time for Claims), Section 13.1 (Indemnification; By Partner), Section 13.2 (Indemnification; By Kiniksa), Section 13.3 (Indemnification Procedure), Section 13.4 (Insurance), Section 14.1.1 (Ownership), Section 14.1.3 (Assignment by Partner), Section 14.1.4 (Practice Under and other Use of Joint Collaboration Technology), Section 14.3.3 (Joint Collaboration Patent Rights), Section 14.4.2(a)(iv) (Joint Collaboration Patent Rights), Section 14.4.4 (Recoveries) (as to recoveries resulting from an enforcement action of a Joint Collaboration Patent Right), Section 15.1 (Term), Section 15.3 (Effects of Termination), Section 15.4 (Survival), Section 15.5 (Cumulative Remedies; Termination Not Sole Remedy), Article 16 (Dispute Resolution), and Article 17 (Miscellaneous).

15.5 **Cumulative Remedies; Termination Not Sole Remedy**. Except for Kiniksa's exercise of its rights under Section 15.2.3 (Termination for Patent Challenge) to obtain the sole and exclusive remedy of increasing the Milestone Payments and Royalty Payments as liquidated damages if Kiniksa determines that termination is not an available remedy in the event of Partner's Patent Challenge, no other remedies referred to in this Agreement are intended to be exclusive, but each will be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Applicable Law. Without limiting the generality of the foregoing, termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding any provision to the contrary set forth in this Agreement, all other remedies will remain available except as expressly set forth herein.

ARTICLE 16
DISPUTE RESOLUTION

16.1 **General**. The Parties recognize that a dispute may arise relating to this Agreement (a "**Dispute**"). Except as otherwise expressly set forth in this Agreement, any Dispute, including Disputes that may involve the Affiliates of any Party, will be resolved in accordance with this Article 16 (Dispute Resolution).

16.2 **Continuance of Rights and Obligations During Pendency of Dispute Resolution**. If the alleged breaching Party disputes in good faith the existence of a breach specified in a notice provided by the other Party in accordance with Section 15.2.2 (Termination for Material Breach) and such

alleged breaching Party provides the other Party notice of such Dispute within the applicable cure period with respect to such breach, then the cure period set forth in Section 15.2.2 (Termination for Material Breach) will be tolled during the pendency of the dispute resolution process as set forth in Article 16 (Dispute Resolution) and the non-breaching Party will not have the right to terminate this Agreement under Section 15.2.2 (Termination for Material Breach) unless and until such dispute resolution process has been completed and such process results in a determination that the alleged breaching Party has materially breached this Agreement and failed to cure such breach within the applicable cure period. During the pendency of such dispute, all of the terms and conditions of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder.

16.4 **Negotiation; Escalation**. The Parties will negotiate and use reasonable efforts to settle any Dispute under this Agreement, other than matters subject to resolution under Article 3 (Governance). Any Dispute as to the breach, enforcement, interpretation, or validity of this Agreement will be referred to the Executive Officers for attempted resolution. If the Executive Officers are unable to resolve such Dispute within [***] Business Days after such Dispute is referred to them, then, upon the written request of either Party to the other Party, other than a Dispute relating to the scope, validity, enforceability, or infringement of any Patent Rights or trademark rights (which will be submitted for resolution to a court of competent jurisdiction in the country or region in which such Patent Rights or trademark rights were granted or arose), the Dispute will be subject to arbitration in accordance with Section 16.5 (Arbitration).

16.5 **Arbitration**. If any Dispute that was subject to Section 16.4 (Negotiation; Escalation) remains [***] Business Days after such Dispute is referred to the Executive Officers, then either Party may at any time after such [***] Business Day period submit such Dispute to be settled by arbitration under the Rules of Arbitration of the International Chamber of Commerce (the "**ICC Rules**"), in accordance with the procedural rules of the ICC Rules in effect at the time of submission. The arbitration will be conducted before an arbitral tribunal composed of three arbitrators, the chairperson of whom will be appointed by the two party arbitrators, and all of whom will have previous judicial experience and experience with the life sciences industry. If, however, the aggregate award sought by the Parties is less than $[***] and equitable relief is not sought, then, unless otherwise agreed by the Parties a single arbitrator will be appointed by agreement of the parties, or, failing such agreement, in accordance ICC Rules. Unless otherwise agreed by the Parties, all such arbitration proceedings will be held in New York, New York, USA, *provided* that proceedings may be conducted by telephone conference call with the consent of the Parties and the arbitrator(s). All arbitration proceedings will be conducted in the English language. The arbitrator(s) will have no authority to award punitive damages. The allocation of expenses of the arbitration, including reasonable attorney's fees, will be determined by the arbitrator(s), or, in the absence of such determination, each party will pay its own expenses. All arbitration proceedings must be completed within [***] days of the notice of commencement of arbitration proceedings. The parties hereby agree that the arbitrator(s) have authority to issue rulings and orders regarding all procedural and evidentiary matters that the arbitrator(s) deem reasonable and necessary with or without petition therefore by the Parties as well as the final ruling and judgment. Rulings will be issued by written order summarizing the arbitration proceedings no more than [***] days after the final submissions of the Parties. All rulings by the arbitrator(s) will be final and binding on the Parties. The provisions of this Section 16.5 (Arbitration) may be enforced and judgment on the award (including without limitation equitable remedies) granted in any arbitration hereunder may be entered in any court having jurisdiction over the award or any of the parties or any of their respective assets.

16.6 **Injunctive Relief**. Without prejudice to such provisional or interim remedies in aid of arbitration as may be available under the jurisdiction of a competent court, the arbitral tribunal will have authority to grant provisional or interim remedies and to award damages for the failure of any Party to the dispute to respect the arbitral tribunal's order to that effect. Notwithstanding the foregoing, in the event of an actual or threatened breach hereunder, the aggrieved Party may seek equitable relief (including restraining orders, specific performance or other injunctive relief) in any court or other forum, without first submitting to the dispute resolution procedures set forth in Section 16.4 (Negotiation; Escalation) pending a decision by the arbitral tribunal in accordance with Section 16.5 (Arbitration).

16.7 **Waiver of Right to Jury Trial**. IN CONNECTION WITH THE PARTIES' RIGHTS UNDER SECTION 16.5 (ARBITRATION), EACH PARTY, TO THE EXTENT PERMITTED BY APPLICABLE LAWS, KNOWINGLY, VOLUNTARILY, AND INTENTIONALLY WAIVES ITS RIGHT TO A TRIAL BY JURY IN ANY ACTION OR OTHER LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE TRANSACTIONS IT CONTEMPLATES. THIS WAIVER APPLIES TO ANY ACTION OR LEGAL PROCEEDING, WHETHER SOUNDING IN CONTRACT, TORT, OR OTHERWISE.

16.8 **Confidentiality**. Any and all activities conducted under this Article 16 (Dispute Resolution), including any and all non-public proceedings and decisions under Section 16.5 (Arbitration), will be the Confidential Information of each of the Parties, and will be subject to the terms of Article 11 (Confidentiality; Publication).

ARTICLE 17
MISCELLANEOUS

17.1 **Assignment**. This Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the prior written consent of the other Party. Notwithstanding the foregoing, (a) Kiniksa may assign (i) its rights to receive payments under this Agreement to one or more Persons without consent of Partner (including as part of a royalty monetization transaction), (ii) this Agreement in whole or in part to any Affiliate, or (iii) this Agreement in whole to its successor-in-interest in connection with the sale of all or substantially all of its assets to which this Agreement relates, whether in a merger, acquisition, or similar transaction or series of related transactions, and (b) Partner may assign this Agreement in whole or in part to any Subsidiary with Kiniksa's prior written consent, not to be unreasonably withheld, conditioned, or delayed. Any attempted assignment of this Agreement not in accordance with this Section 17.1 (Assignment) will be null, void, and of no legal effect. Any permitted assignee will assume all assigned obligations of its assignor under this Agreement. The terms of this Agreement will be binding upon, and will inure to the benefit of, the Parties and their respected successors and permitted assigns.

17.2 **Limitation of Liability**. NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES, LOSS OF PROFIT (EVEN IF DEEMED DIRECT DAMAGES) ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT IN CONNECTION WITH THIS AGREEMENT, IN EACH CASE, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 17.2 (LIMITATION OF LIABILITY) IS INTENDED TO OR WILL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 13.1 (INDEMNIFICATION; BY PARTNER) OR SECTION 13.2 (INDEMNIFICATION; BY KINIKSA), DAMAGES AVAILABLE TO EITHER PARTY FOR THE OTHER PARTY'S

BREACH OF Article 11 (CONFIDENTIALITY; PUBLICATION), OR DAMAGES AVAILABLE TO EITHER PARTY FOR THE OTHER PARTY'S FRAUD, GROSS NEGLIGENCE, WILLFUL MISCONDUCT, OR BREACH OF ITS OBLIGATIONS HEREUNDER RELATING TO SECTION 2.8 (EXCLUSIVITY COVENANTS) OR AMOUNTS OWED BY EITHER PARTY HEREUNDER (INCLUDING UNDER ARTICLE 10 (PAYMENTS)), OR MISAPPROPRIATION OR INFRINGEMENT OF INTELLECTUAL PROPERTY OWNED OR CONTROLLED BY EITHER PARTY.

17.3 **Severability**. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality, and enforceability of the remaining provisions contained herein will not in any way be affected or impaired thereby, then unless the absence of the invalidated provisions adversely affects the substantive rights of the Parties. The Parties will in such an instance use their best efforts to replace the invalid, illegal or unenforceable provisions with valid, legal, and enforceable provisions that, insofar as practical, implement the purposes of this Agreement.

17.4 **Force Majeure**. Both Parties will be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by Force Majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse will continue only so long as the condition constituting Force Majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. When the Force Majeure no longer exists, the affected Party must promptly resume performance. For purposes of this Agreement, "Force Majeure" will include conditions beyond the reasonable control of the non-performing Party, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, pandemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, failure of plant or machinery and act (or failure to act) of a government of any country or of any Governmental Authority (other than as a result of the non-performing Party's failure to comply with Applicable Law). The Parties agree the effects of the COVID-19 pandemic that is ongoing as of the Effective Date may be invoked as a Force Majeure for the purposes of this Agreement even though the pandemic is ongoing to the extent those effects are not reasonably foreseeable by the Parties as of the Effective Date. Notwithstanding the foregoing, a Party will not be excused from making payments owed hereunder because of a Force Majeure affecting such Party. The affected Party will notify the other Party in writing of any Force Majeure circumstances that may affect its performance under this Agreement as soon as reasonably practical, will provide a good faith estimate of the period for which its failure or delay in performance under the Agreement is expected to continue based on currently available information, and will undertake reasonable efforts necessary to mitigate and overcome such Force Majeure circumstances and resume normal performance of its obligations hereunder as soon as reasonably practicable under the circumstances. Throughout the duration of the Force Majeure event, the affected Party will update such notice to the other Party on a bi-weekly basis, or more frequently if requested by the other Party, to provide updated summaries of its mitigation efforts and its estimates of when normal performance under the Agreement will be able to resume. In any event, if a Party's failure to perform its obligations under this Agreement as a result of a Force Majeure event continues for longer than [***] days, then the other Party may terminate this Agreement by providing written notice to the Party affected by the Force Majeure event.

17.5 **Notices**. All notices that are required or permitted hereunder will be in writing and sufficient if delivered by internationally-recognized overnight courier or sent by registered or certified mail,

postage prepaid, return receipt requested, and in each case, addressed as follows (with a courtesy copy sent by email, which will not constitute notice):

If to Kiniksa:
Kiniksa Pharmaceuticals (UK), Ltd.
Third Floor
23 Old Bond Street
London, UK, W1S 4PZ
Attention: Chief Commercial Officer

with a copy to:
Kiniksa Pharmaceuticals Corp.
100 Hayden Ave.
Lexington, MA 02421
United States
Attention: General Counsel

with a copy to (which will not constitute notice):
Ropes & Gray LLP
800 Boylston Street; Prudential Tower
Boston, MA 02199
Attention: Hannah H. England
Email: Hannah.England@ropesgray.com

If to Partner:
Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd.
No.866, Moganshan Road
Hangzhou, People's Republic of China
Attention: [**]
Email: [**]

with a copy to (which copy will not constitute notice):

Greenberg Traurig LLP
3333 Piedmont Road
Suite 2500
Atlanta, Georgia 30305
Attention: [**]
Email: [**]

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given: (a) on the Business Day after dispatch if sent by internationally-recognized overnight courier; or (b) on the [***] Business Day after dispatch if sent by registered or certified mail, postage prepaid, return receipt requested.

17.6 **Governing Law**. This Agreement, and all claims or causes of action (whether in contract, tort or statute) that may be based upon, arise out of or relate to this Agreement, or the negotiation, execution or performance of this Agreement or the breach thereof (including any claim or cause of

action based upon, arising out of or related to any representation or warranty made in or in connection with this Agreement or as an inducement to enter into this Agreement), will be governed by, and enforced in accordance with, the internal laws of the State of New York, including its statutes of limitations without giving effect to the conflicts of law provisions thereunder.

17.7 **Entire Agreement; Amendments**. This Agreement, together with the Schedules hereto, contains the entire understanding of the Parties with respect to the collaboration and the licenses granted hereunder. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the collaboration and the licenses granted hereunder are superseded by the terms of this Agreement. The Schedules to this Agreement are incorporated herein by reference and will be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of each Party. The foregoing will not be interpreted as a waiver of any remedies available to either Party or its Affiliates as a result of any breach, prior to the Effective Date, by the other Party or its Affiliates of such Party's or its Affiliate's obligations pursuant to the Confidentiality Disclosure Agreement.

17.8 **Headings**. The captions to the several Article**s**, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections of this Agreement.

17.9 **Independent Contractors**. It is expressly agreed that Kiniksa and Partner will be independent contractors and that the relationship between the two Parties will not constitute a partnership, joint venture or agency. Neither Kiniksa nor Partner will have the authority to make any statements, representations, or commitments of any kind, or to take any action that is binding on the other Party without the prior written consent of the other Party.

17.10 **Performance by Affiliates or Subsidiaries**. Notwithstanding any provision to the contrary set forth in this Agreement, Kiniksa will have the right to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any Affiliate of Kiniksa, and Partner will have the right to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any Subsidiary of Partner. Kiniksa hereby guarantees the performance by its Affiliates of Kiniksa's obligations under this Agreement and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Partner hereby guarantees the performance by its Subsidiaries of Partner's obligations under this Agreement and will cause its Subsidiaries to comply with the provisions of this Agreement in connection with such performance.

17.11 **Waiver**. Any waiver of any provision of this Agreement will be effective only if in writing and signed by Kiniksa and Partner. No express or implied waiver by a Party of any default under this Agreement will be a waiver of a future or subsequent default. The failure or delay of any Party in exercising any rights under this Agreement will not constitute a waiver of any such right, and any single or partial exercise of any particular right by any Party will not exhaust the same or constitute a waiver of any other right provided in this Agreement.

17.12 **Waiver of Rule of Construction**. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement will be construed against the drafting Party will not apply.

17.13 Business Day Requirements. If any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business Day, then such notice or other action or omission will be deemed to be required to be taken on the next occurring Business Day.

17.14 Further Actions. Each Party agrees to execute, acknowledge, and deliver such further instruments, and to do all such other acts, as necessary or appropriate in order to carry out the purposes and intent of this Agreement.

17.15 Construction. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words "include," "includes," and "including" will be deemed to be followed by the phrase "without limitation," (c) the word "will" will be construed to have the same meaning and effect as the word "shall," (d) any definition of or reference to any agreement, instrument, or other document herein will be construed as referring to such agreement, instrument, or other document as from time to time amended, supplemented, or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person will be construed to include the person's successors and assigns, (f) the words "herein," "hereof," and "hereunder" and words of similar import, will each be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Articles, Sections, Schedules, or Exhibits will be construed to refer to Articles, Sections, Schedules, or Exhibits of this Agreement, and references to this Agreement include all Schedules hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent," "approve," or the like will require that such agreement, consent, or approval be specific and in writing, whether by written agreement, letter, approved minutes, or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or Section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or."

17.16 Language; Translations. This Agreement is in the English language only, which language will be controlling in all respects, and all versions hereof in any other language will be for accommodation only and will not be binding upon the Parties. All communications and notices to be made or given by one Party to the other pursuant to this Agreement, and any dispute proceeding related to or arising hereunder, will be in the English language. If there is a discrepancy between the English version of this Agreement and any non-English translation of this Agreement, then the English version of this Agreement will prevail. If there is a discrepancy between the non-English original version and the English translation of any agreement with a Sublicensee or Material Subcontractor, audit report, Regulatory Submission, or other communication to or from a Governmental Authority in the Territory regarding the Licensed Product, in each case, that is delivered under this Agreement, then the non-English original version thereof will prevail. Upon Kiniksa's request, Partner will provide to Kiniksa any documentation that is already in English and in Partner's possession to the extent Partner is required to furnish such documentation to Kiniksa in accordance with the terms of this Agreement.

Except as expressly set forth in this Agreement, for other data, information, documents, or other materials, Partner will provide to Kiniksa a high-level summary in English upon Kiniksa's reasonable request. In addition, at Kiniksa's request, Partner will provide a full English translation of such data, information, or other materials at Kiniksa's cost and expense. Each Party will invoice the other Party quarterly for the foregoing

costs incurred by or on behalf of such Party in such Calendar Quarter, and the other Party will pay the undisputed amount invoiced within [***] days after the date of any such invoice. Kiniksa acknowledges and agrees that any and all translations provided by Partner under this Agreement will not be certified translations (unless agreed by the Parties).

17.17 Counterparts. This Agreement may be executed in counterparts, all of which taken together will be regarded as one and the same instrument. Counterparts may be delivered via electronic mail, including Adobe™ Portable Document Format (PDF) or any electronic signature complying with the U.S. Federal ESIGN Act of 2000, and any counterpart so delivered will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

[Remainder of the Page Intentionally Left Blank; Signature Page Follows]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this License and Collaboration Agreement to be executed by their respective duly authorized representatives as of the Effective Date.

Kiniksa Pharmaceuticals (UK), Ltd.

By: /s/ Ross Moat

Name: Ross Moat

Title: Director

Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd.

By: /s/ Liang Lu

Name: Liang Lu

Title: Chairman & CEO

Schedule 1.57

Existing Product Trademarks

[***]

Schedule 1.104

Kiniksa Patent Rights

[***]

Schedule 5.2

Territory Development Plan

[***]

Schedule 5.3

Global Development Plan

[***]

Schedule 11.7.1(a)

Kiniksa Press Release

Kiniksa Pharmaceuticals and Huadong Medicine Announce Strategic Collaboration

– Collaboration includes rights to develop and commercialize ARCALYST® and mavrilimumab in the Asia Pacific Region (excluding Japan) –

– Kiniksa to receive $22 million upfront; eligible to receive development and commercial milestone payments and tiered royalties –

HAMILTON, BERMUDA – February 22, 2022 – Kiniksa Pharmaceuticals, Ltd. (Nasdaq: KNSA) (Kiniksa), a biopharmaceutical company with a portfolio of assets designed to modulate immunological pathways across a spectrum of diseases, and Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd., a wholly-owned subsidiary of Huadong Medicine Co., Ltd. (Huadong Medicine), today announced a strategic collaboration to develop and commercialize Kiniksa's ARCALYST® and mavrilimumab in the Asia Pacific Region.

"This collaboration aims to bring Kiniksa's therapeutics to patients in the Asia Pacific Region suffering from severe autoimmune and inflammatory diseases. With extensive regional experience, proven development and regulatory execution, and deep relationships with a broad network of hospitals and clinics, Huadong Medicine is an ideal partner to help drive value," said Sanj K. Patel, Chairman and Chief Executive Officer of Kiniksa. "The collaboration also provides non-dilutive capital, cost-sharing, and resources for clinical trials to accelerate our drug development and commercialization efforts."

"Kiniksa is an emerging leader in the development of immune-modulating therapies, for which there is significant unmet need across the Asia Pacific Region," said Liang Lv, Chairman and CEO of Huadong Medicine. "In addition to ARCALYST, the first and only FDA-approved treatment for recurrent pericarditis, the compelling clinical data generated to-date for mavrilimumab provide foundational support for development

across a range of underserved diseases. We look forward to working closely with Kiniksa to leverage our clinical, regulatory, and commercial capabilities in the Asia Pacific Region."

Under the terms of the collaboration, Kiniksa will receive $22 million upfront and is eligible to receive up to approximately $640 million in specified development, regulatory and sales-based milestones. Kiniksa is also eligible to receive tiered royalties ranging from the low-teens to the low-twenties on annual net sales. Huadong Medicine will obtain exclusive rights and responsibility for the development and commercialization of ARCALYST and mavrilimumab in the Asia Pacific Region including Greater China, South Korea, Australia, and 18 other countries, but excluding Japan. Kiniksa will otherwise retain all existing development and commercialization rights for both assets.

About Kiniksa
Kiniksa is a biopharmaceutical company focused on discovering, acquiring, developing, and commercializing therapeutic medicines for patients suffering from debilitating diseases with significant unmet medical need. Kiniksa's portfolio assets, ARCALYST, mavrilimumab, vixarelimab and KPL-404, are based on strong biologic rationale or validated mechanisms, target underserved conditions, and offer the potential for differentiation. These assets are designed to modulate immunological pathways across a spectrum of diseases. For more information, please visit www.kiniksa.com.

About ARCALYST
ARCALYST is a weekly, subcutaneously injected recombinant dimeric fusion protein that blocks interleukin-1 alpha (IL-1α) and interleukin-1 beta (IL-1β) signaling. ARCALYST was discovered by Regeneron and is approved by the U.S. Food and Drug Administration (FDA) for recurrent pericarditis, cryopyrin-associated periodic syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome and Muckle-Wells Syndrome, and deficiency of IL-1 receptor antagonist (DIRA). The FDA granted Breakthrough Therapy designation to ARCALYST for the treatment of recurrent pericarditis in 2019 and Orphan Drug designation to ARCALYST for the treatment of pericarditis in 2020. The European Commission granted Orphan Drug Designation to ARCALYST for the treatment of idiopathic pericarditis in 2020.

IMPORTANT SAFETY INFORMATION ABOUT ARCALYST

- ARCALYST may affect your immune system and can lower the ability of your immune system to fight infections. Serious infections, including life-threatening infections and death, have happened in patients taking ARCALYST. If you have any signs of an infection, call your doctor right away. Treatment with

ARCALYST should be stopped if you get a serious infection. You should not begin treatment with ARCALYST if you have an infection or have infections that keep coming back (chronic infection).

- While taking ARCALYST, do not take other medicines that block interleukin-1, such as Kineret® (anakinra), or medicines that block tumor necrosis factor, such as Enbrel® (etanercept), Humira® (adalimumab), or Remicade® (infliximab), as this may increase your risk of getting a serious infection.
- Talk with your doctor about your vaccine history. Ask your doctor whether you should receive any vaccines before you begin treatment with ARCALYST.
- Medicines that affect the immune system may increase the risk of getting cancer.
- Stop taking ARCALYST and call your doctor or get emergency care right away if you have any symptoms of an allergic reaction.
- Your doctor will do blood tests to check for changes in your blood cholesterol and triglycerides.
- Common side effects include injection-site reactions (which may include pain, redness, swelling, itching, bruising, lumps, inflammation, skin rash, blisters, warmth, and bleeding at the injection site), upper respiratory tract infections, joint and muscle aches, rash, ear infection, sore throat, and runny nose.

For more information about ARCALYST, talk to your doctor and see the Product Information.

About Mavrilimumab
Mavrilimumab is an investigational fully human monoclonal antibody that blocks activity of granulocyte macrophage colony stimulating factor (GM-CSF) by specifically binding to the alpha subunit of the GM-CSF receptor (GM-CSFRα). Phase 2 clinical trials of mavrilimumab in rheumatoid arthritis and giant cell arteritis achieved their primary and secondary endpoints with statistical significance.

About Huadong Medicine
Huadong Medicine Co., Ltd. (SZ.000963) is a leading Chinese pharmaceutical company based in Hangzhou, China. Founded in 1993, Huadong Medicine has fully integrated R&D, manufacturing, distribution, sales, and marketing capabilities. Huadong Medicine's product portfolio and pipeline are specialized in oncology, immunology, nephrology, and diabetes. The company has 11,000 employees and one of the most extensive commercial coverage and marketing capabilities in China. 'Patient Centered, Science Driven' is Huadong Medicine's value. For additional information, please visit www.eastchinapharm.com/en.

Kiniksa Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these identifying words. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation, statements regarding the multi-product collaboration between Kiniksa and Huadong Medicine, including anticipated milestone and royalty payments under the collaboration; expectations regarding Kiniksa’s ability to expand its programs for ARCALYST and mavrilimumab globally and in the licensed territory; and statements regarding Kiniksa’s efforts to bring multiple therapeutics to patients suffering from severe autoimmune and inflammatory diseases globally and in the licensed territory.

These forward-looking statements are based on management’s current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including without limitation, the following: delays or difficulty in enrollment of patients in, and activation or continuation of sites for, our clinical trials; delays or difficulty in completing our clinical trials as originally designed; potential for changes between final data and any preliminary, interim, top-line or other data from clinical trials; our inability to replicate results from our earlier clinical trials or studies; impact of additional data from us or other companies, including the potential for our data to produce negative, inconclusive or commercially uncompetitive results; potential undesirable side effects caused by our products and product candidates; our inability to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities; potential for applicable regulatory authorities to not accept our filings, delay or deny approval of any of our product candidates or require additional data or trials to support approval; inability to successfully execute on our commercial strategy for ARCALYST; our reliance on third parties as the sole source of supply of the drug substance and drug product used in our products and product candidates; our reliance on Regeneron as the sole manufacturer of ARCALYST; raw materials, important ancillary products and drug substance and/or drug product shortages; our reliance on third parties to conduct research, clinical trials, and/or certain regulatory activities for our product candidates; complications in coordinating requirements, regulations and guidelines of regulatory authorities across jurisdictions for our clinical trials; the impact of the COVID-19

pandemic and measures taken in response to the pandemic on our business and operations as well as the business and operations of our manufacturers, CROs upon whom we rely to conduct our clinical trials, and other third parties with whom we conduct business or otherwise engage, including the FDA and other regulatory authorities; changes in our operating plan and funding requirements; and existing or new competition.

These and other important factors discussed in our filings with the U.S. Securities and Exchange Commission (the "SEC"), including under the caption "Risk Factors" contained therein, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. Except as required by law, we disclaim any intention or obligation to update or revise any forward-looking statements. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

Every Second Counts!®

Kiniksa Investor and Media Contact

Rachel Frank
(339) 970-9437
rfrank@kiniksa.com

Huadong Medicine Investor and Media Contact

Bo Chen
+86 571 8990 3300
ir@eastchinapharm.com

Schedule 11.7.1(b)

Partner Press Release

华东医药宣布与Kiniksa公司签署战略合作协议

- 华东医药将获得ARCALYST®和Mavrilimumab在亚太区（不包括日本）的独家开发、注册和商业化权益。
- Kiniksa将获得2,200万美元的首付款，并获得开发、注册和销售里程碑付款及分级的销售额提成费。

中国杭州市，2022年2月22日，华东医药股份有限公司（[illegible]）的全资子公司杭州中美华东制药有限公司（以下简称“华东医药”）与美国上市公司Kiniksa Pharmaceuticals, Ltd. (Nasdaq: KNSA)的全资子公司Kiniksa Pharmaceuticals (UK), Ltd.（以下简称“Kiniksa”），一家拥有多款调节免疫信号通路治疗自身免疫疾病药物的全球性生物公司，宣布签署战略合作协议。Kiniksa授予华东医药ARCALYST®和Mavrilimumab在亚太区的独家开发、注册和商业化权益。

华东医药董事长兼首席执行官吕梁表示：“Kiniksa是免疫调节疗法开发领域的新兴领导者，该治疗领域在亚太地区存在巨大未被满足的临床需求。ARCALYST®是目前第一款也是唯一一款FDA批准的用于治疗复发性心包炎的药物。此外，Mavrilimumab迄今为止产生的临床数据也为一系列难治疾病的治疗提供了基础支持。我们期待与Kiniksa密切合作，充分发挥华东医药在亚太地区的临床，注册和商业化能力。”

Kiniksa的董事长兼首席执行官Sanj K. Patel表示：“本次合作旨在将Kiniksa的治疗方法惠及整个亚太地区患有严重自身免疫和炎症疾病的患者。华东医药在亚太地区拥有丰富的区域经验，成熟的开发、注册能力，以及广泛的营销网络。华东医药是帮助ARCALYST®和Mavrilimumab在亚太区的实现最大价值的理想合作伙伴。本次合作提供的资金，成本分摊及其他资源，将有助于加快产品的临床开发和商业化。”

根据协议条款，Kiniksa 将获得2,200万美元的首付款，并有权在实现开发、注册及销售里程碑后，获得最高不超过6.4亿美元的里程碑付款，Kiniksa还将获得分级的两位数的净销售额提成费。华东医药将获得ARCALYST®和Mavrilimumab在亚太区（包括中国、韩国、澳大利亚和其他18个国家和地区，但不包括日本）的独家开发、注册和商业化权益。Kiniksa将保留许可产品在许可区域以外的开发和商业化权益。

关于华东医药

华东医药股份有限公司（SZ.000963）总部位于中国杭州，公司成立于1993年，具有完整的产品研发，生产，经销能力。产品管线主要专注于肿瘤，免疫，肾科以及糖尿病领域，覆盖中药、化学药、生物药、医疗器械等多个品类。2020年公司年收入超过 50 亿美元，拥有员工11,000余人，

“以科研为基础,以患者为中心”是华东医药秉承的企业理念。更多信息请登录更多信息请浏览www.eastchinapharm.com

关于Kiniksa

Kiniksa是一家以满足患者临床需求为企业愿景，致力于发现、获取、开发和商业化调节免疫信号通路治疗药物的全球性生物制药公司。Kiniksa的4款产品ARCALYST®，Mavrilimumab，Vixarelimab，KPL-404都基于坚实的生物学原理或经过验证的机制，用于调节一系列免疫疾病的免疫信号通路，具有实现差异化的巨大潜力。
更多信息请浏览www.kiniksa.com

关于ARCALYST®

ARCALYST®是一种每周进行皮下注射给药的重组二聚体融合蛋白，可阻断白细胞介素-1α（IL-1α）和白细胞介素-1β（IL-1β）的信号传导。
ARCALYST®最早由Regeneron研发，获得FDA批准用于治疗冷吡啉相关的周期性综合征（CAPS），包括家族性寒冷型自身炎症综合征和穆-韦二氏综合征，以及IL-1受体拮抗剂缺乏症（DIRA）。2019年，ARCALYST®获得FDA突破性疗法认定，用于治疗复发性心包炎。2020年，FDA授予ARCALYST®用于治疗心包炎的孤儿药认定。2020年，欧盟委员会授予ARCALYST®孤儿药认定，用于治疗特发性心包炎。

关于Mavrilimumab

Mavrilimumab是一种全人源单克隆抗体，可特异性结合粒细胞-巨噬细胞集落刺激因子受体α（GM-CSFRα），并抑制粒细胞-巨噬细胞集落刺激因子（GM-CSF）的信号传导。Mavrilimumab针对类风湿性关节炎和巨细胞动脉炎（GCA）的2期临床研究都达到了主要和次要终点，并具有统计学意义。

投资者关系及媒体
华东医药
+86 571 8990 3300
ir@eastchinapharm.com

Kiniksa
Rachel Frank
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rfrank@kiniksa.com

Schedule 12.3

Partner Disclosures

[***]

COLLABORATION AND LICENSE AGREEMENT

by and between

Kiniksa Pharmaceuticals (UK), Ltd.

and

Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd.

Dated as of February 21, 2022

[**] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(a)(6)

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10)(iv). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

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COLLABORATION AND LICENSE AGREEMENT

This Collaboration and License Agreement (this "**Agreement**") is made as of February 21, 2022 (the "**Effective Date**") by and between Kiniksa Pharmaceuticals (UK), Ltd., a United Kingdom corporation ("**Kiniksa**"), having a place of business at Third Floor, 23 Old Bond Street, London, United Kingdom, W1S 4PZ, and Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd ("**Partner**"), having a place of business at No. 866 Moganshan Road, GongShu District, Hangzhou City, Zheijiang Province, People's Republic of China. Kiniksa and Partner are referred to in this Agreement individually as a "**Party**" and collectively as the "**Parties**."

Recitals

WHEREAS, Kiniksa, including its Affiliates, is a biopharmaceutical company focused on discovering, acquiring, developing, and commercializing therapeutic medicines for patients suffering from debilitating diseases with significant unmet medical need, including mavrilimumab;

WHEREAS, Kiniksa Controls certain Know-How and Patent Rights relating to such product;

WHEREAS, Partner is a pharmaceutical company engaged in the research, development, and commercialization of pharmaceutical and biologic products in the greater China region; and

WHEREAS, Partner wishes to obtain from Kiniksa an exclusive license to perform Clinical Development of, perform Medical Affairs for, and Commercialize the Licensed Product in the Territory and a non-exclusive license to Manufacture, and to have Manufactured, the Licensed Product in the Territory, and Kiniksa is willing to grant such licenses to Partner, as such terms are defined herein and all in accordance with the terms and conditions set forth herein.

AGREEMENT

NOW, **THEREFORE**, the Parties hereby agree as follows:

ARTICLE 1
DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms will have the respective meanings set forth below, whether used in the singular or plural:

1.1 "**Accounting Standards**" means GAAP or IFRS (as applicable to a Party).

1.2 "**Acquired Party**" has the meaning set forth in Section 2.7.3 (Business Combinations).

1.3 "**Affiliate**" means, with respect to a Person, any other Person that controls, is controlled by, or is under common control with such Person. For the purpose of this definition only, "control" (including, with correlative meaning, the terms "controlled by" and "under the common control") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of any Person, whether by the ownership of more than 50% of the voting security of such Person, by contract or otherwise. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than 50%, and that in such case such lower percentage will be substituted in the preceding sentence; provided that such foreign investor has the power to direct the management and policies of such entity. Notwithstanding the foregoing, neither Baker Brothers Advisors nor any other financial investor (excluding a financial investor that is the

investment entity of a pharmaceutical or biotechnology company), nor any funds affiliated with Baker Brothers Advisors or entities controlled by Baker Brothers Advisors or any other financial advisor (excluding a financial investor that is the investment entity of a pharmaceutical or biotechnology company) will be considered an Affiliate of Kiniksa.

1.4 "**Agreement**" has the meaning set forth in the Preamble.

1.5 "**Alliance Manager**" has the meaning set forth in Section 3.1 (Alliance Managers).

1.6 "**Anti-Corruption Laws**" means all local or other laws prohibiting or regulating public or private-sector corruption, bribery, kickbacks, speed or facilitation payments, ethical business conduct, money laundering, embezzlement, political contributions, gifts, gratuities, expenses, entertainment, hospitalities, agency relationships, commissions, lobbying, books and records, and financial controls, including the United States Foreign Corrupt Practices Act, the U.S. Travel Act, the UK Bribery Act 2010, and other anti-corruption laws, in each case, as amended.

1.7 "**Applicable Law**" means collectively all laws, rules, regulations, ordinances, decrees, judicial and administrative orders (and any license, franchise, permit, or similar right granted under any of the foregoing), and any policies and other requirements of any applicable Governmental Authority that govern or otherwise apply to a Party, including all Anti-Corruption Laws.

1.8 "**Approved Labeling**" means, with respect to the Licensed Product: (a) the Regulatory Authority-approved full prescribing information for the Licensed Product; and (b) the Regulatory Authority-approved labels and other written, printed, or graphic materials on any container, wrapper, or any package insert that is used with or for the Licensed Product.

1.9 "**Assigned Collaboration Know-How**" means any Collaboration Know-How developed or invented by Representatives of Partner or its Affiliates or its or their licensees (other than Kiniksa), Sublicensees, or Subcontractors, or any Persons contractually required to assign or license such Collaboration Know-How to Partner or any Affiliate of Partner, whether alone or jointly with others (including jointly with Kiniksa), that (a) is directed to (i) [***] (ii) [***] or (iii) [***]

1.10 "**Assigned Collaboration Patent Rights**" means all Collaboration Patent Rights that Cover Assigned Collaboration Know-How.

1.11 "**Assigned Collaboration Technology**" means the Assigned Collaboration Know-How and the Assigned Collaboration Patent Rights.

1.12 "**Biosimilar Competition**" means, with respect to a Biosimilar Product in a country or region in the Territory and particular Calendar Quarter following the Biosimilar Launch Quarter for such Biosimilar Product in such country or region, the decrease in the Net Sales in such country or region for the Licensed Product during the applicable Calendar Quarter, as compared to the average quarterly Net Sales of the Licensed Product in such country or region during the four Calendar Quarters immediately preceding such Biosimilar Launch Quarter.

1.13 "**Biosimilar Launch Quarter**" means, with respect to a Biosimilar Product to the Licensed Product in a country or region in the Territory, the Calendar Quarter in which the First Commercial Sale of the applicable Biosimilar Product in such country or region occurred following the receipt of all necessary Regulatory Approvals from the applicable Regulatory Authorities in such country or region to market and sell such Biosimilar Product as a therapeutic product for one or more Indication included in the Approved Labeling for the Licensed Product in such country or region.

1.14 "**Biosimilar Product**" means, with respect to the Licensed Product in a particular country or region, after receipt of Regulatory Approval of the Licensed Product in such country or region, any other therapeutic drug product designated for human use that [***]

1.15 "**Breach Notification**" has the meaning set forth in Section 15.2.2 (Termination for Material Breach).

1.16 "**Business Day**" means a day other than a Saturday, Sunday, or a day on which banking institutions in Boston, Massachusetts, Beijing, China, or Hong Kong are required by Applicable Law to remain closed.

1.17 "**Calendar Quarter**" means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30, and December 31.

1.18 "**Calendar Year**" means each 12-month period commencing on January 1.

1.19 "**cGMP**" means all current Good Manufacturing Practices and regulations applicable to the Manufacture of the Licensed Product that are promulgated by any applicable Regulatory Authority having jurisdiction over the Manufacture of the Licensed Product, including, as applicable, as promulgated under and in accordance with (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820, (b) European Directive 2003/94/EC and Eudralex 4, (c) the principles detailed in the International Conference on Harmonization's Q7 Guideline, and (d) the equivalent Applicable Law in any relevant country or region, each as may be amended and applicable from time to time.

1.20 "**Change of Control**" means, with respect to a Party, that: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of such Party, or if the percentage ownership of such Third Party in the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing more than 50% of the total voting power of all of the then outstanding voting securities of such Party; (b) any merger, consolidation, recapitalization, or reorganization of such Party is consummated that would result in shareholders or equity holders of such Party immediately prior to such transaction owning 50% or less of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; (c) the shareholders or equity holders of such Party approve any plan of complete liquidation of such Party, or an agreement for the sale or disposition by such Party of all or substantially all of such Party's assets, in each case, through one or more related transactions, other than to an Affiliate or pursuant to one or more related transactions that would result in shareholders or equity holders of such Party immediately prior to such transaction owning more than 50% of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; or (d) the sale or transfer to any Third Party, in one or more related transactions, of all or substantially all of such Party's consolidated assets taken as a whole.

1.21 "**Clinical Development**" has the meaning set forth in Section 1.48 (Development).

1.22 "**Clinical Supply Agreement**" has the meaning set forth in Section 7.1.1 (Development Supply).

1.23 "**Clinical Trial**" means any clinical trial in humans that is conducted in accordance with cGCP and is designed to generate data (a) under an IND, (b) to address a commitment or requirement under a Regulatory Approval or Reimbursement Approval (as applicable), or (c) to support an expansion of an Indication.

1.24 "**CMO**" means a contract manufacturing organization.

1.25 "**Collaboration Know-How**" means any Know-How developed or invented during the Term by Representatives of a Party or its Affiliates or its or their licensees, Sublicensees, or Subcontractors, or any Persons contractually required to assign or license such Know-How to a Party or any Affiliate of a Party, whether alone or jointly with Representatives of the other Party or its Affiliates or its or their licensees, Sublicensees, or Subcontractors, or any Persons contractually required to assign or license such Know-How to the other Party or any Affiliate of the other Party, in each case, in the performance of activities under this Agreement.

1.26 "**Collaboration Patent Right**" means any Patent Right that (a) has a priority date after the Effective Date and (b) Covers any invention included in the Collaboration Know-How.

1.27 "**Collaboration Technology**" means Collaboration Know-How and Collaboration Patent Rights.

1.28 "**Commercial Supply Agreement**" has the meaning set forth in Section 7.1.2 (Commercial Supply).

1.29 "**Commercialization**" means with respect to any product, any and all activities directed to the marketing, promotion, distribution, pricing, reimbursement, import, export, offering for sale, and sale of such product and interacting with Regulatory Authorities following receipt of Regulatory Approval in the applicable country or region for such product regarding the foregoing, including seeking and maintaining any required Reimbursement Approval, but excluding any activities directed to Manufacturing, Development, or Medical Affairs. "**Commercialize**," "**Commercializing**," and "**Commercialized**" will be construed accordingly.

1.30 "**Commercialization Plan**" means, with respect to the Licensed Product, the written high-level strategic and tactical plans for the Commercialization activities for the Licensed Product to be conducted in the Territory that will be prepared and updated by or on behalf of Partner as provided in Section 9.2 (Commercialization Plan), and will include for the Licensed Product in each country or region in the Territory: (a) the general strategies for promoting, marketing, and distributing the Licensed Product, (b) pre-launch Commercialization activities and the expected date of First Commercial Sale, (c) the nature of promotional activities anticipated, (d) non-binding summary-level market and sales forecasts for the Licensed Product, (e) non-binding projection of Net Sales for the Licensed Product, (f) plans regarding distribution and supply chain management, and (g) reimbursement and pricing information.

1.31 "**Commercially Reasonable Efforts**" means, with respect to the Exploitation of the Licensed Product by Partner, [***].

1.32 "**Competitive Activities**" has the meaning set forth in Section 2.7.1 (Partner Exclusivity).

1.33 "**Competitive Infringement**" has the meaning set forth in Section 14.4.2(a)(ii) (Kiniksa First Right).

1.34 "**Competitive Product**" means any product, other than the Licensed Product, that [***].

1.35 "**Confidential Information**" means, subject to Section 11.3 (Exemptions), (a) Know-How and any technical, scientific, trade, research, manufacturing, business, financial, marketing, product, supplier, intellectual property, and other non-public or proprietary data or information (including unpublished patent applications) that may be disclosed by one Party or its Affiliates to the other Party or its

Affiliates pursuant to this Agreement (including information disclosed prior to the Effective Date pursuant to the Confidentiality Disclosure Agreement), regardless of whether such information is specifically marked or designated as confidential and regardless of whether such information is in written, oral, electronic, or other form, and (b) the terms of this Agreement.

1.36 "**Confidentiality Disclosure Agreement**" means the Confidentiality Disclosure Agreement by and between the Parties dated March 8, 2021 (as amended from time to time).

1.37 "**Continuing Know-How Transfer**" has the meaning set forth in Section 4.3 (Continuing Know-How Transfer).

1.38 "**Control**" or "**Controlled**" means the possession by a Party (whether by ownership, license, or otherwise other than pursuant to this Agreement) of, (a) with respect to any tangible Know-How, the legal authority or right to physical possession of such tangible Know-How, with the right to provide such tangible Know-How to the other Party on the terms set forth herein, (b) with respect to Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How, or other intellectual property rights, the legal authority or right to grant a license, sublicense, access, or right to use (as applicable) to the other Party under such Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How, or other intellectual property rights on the terms set forth herein, in each case ((a) and (b)), without breaching or otherwise violating the terms of any arrangement or agreement with a Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right to use, license, or sublicense and without being required to make any payment to any Third Party or incurring any payment obligations under any such arrangement or agreement, other than payment obligations pursuant to Third Party IP Agreements in accordance with Section 2.6 (Third Party In-Licenses) or if Kiniksa determines, in its sole discretion, that Partner need not be responsible for any costs associated with the grant of a sublicense thereunder, and (c) with respect to any product, the legal authority or right to grant an exclusive license or sublicense under Patent Rights that Cover such product or Know-How that relates to such product. Notwithstanding the foregoing, a Party and its Affiliates will not be deemed to "**Control**" any of the foregoing (a) – (c) that, (i) prior to the consummation of a Change of Control of such Party, is owned or in-licensed by a Third Party that becomes an Affiliate of such acquired Party (or that merges or consolidates with such Party) after the Effective Date as a result of such Change of Control and (ii) was not, at the time of such Change of Control already Controlled by such Party undergoing such Change of Control.

1.39 "**Controlling Party**" has the meaning set forth in Section 14.4.2(a)(v) (Step-In Rights).

1.40 "**Cover**" means, with respect to a particular subject matter at issue and a relevant Patent Right, that the manufacture, use, sale, offer for sale, or importation of such subject matter would fall within the scope of one or more claims in such Patent Right.

1.41 "**CPI**" means (a) with respect to Kiniksa, the Consumer Price Index-Urban Wage Earners and Clerical Workers, U.S. City Average, All Items 1982-84=100, published by the United States Department of Labor, Bureau of Labor Statistics (or its successor equivalent index), in the United States and (b) with respect to Partner, the consumer price index for Beijing as published by The National Bureau of Statistics of China.

1.42 "**CREATE Act**" has the meaning set forth in Section 14.2 (CREATE Act).

1.43 "**CRO**" means a contract research organization.

1.44 "**CSO**" means a contract sales organization.

1.45 "**Debarred/Excluded**" means any Person becoming debarred or suspended under 21 U.S.C. §335(a) or (b), the subject of a conviction described in Section 306 of the FD&C Act, excluded, or having previously been excluded, from a federal or governmental health care program, debarred from federal contracting, convicted of or pled *nolo contendere* to any felony, or to any federal or state legal violation (including misdemeanors) relating to prescription drug products or fraud, the subject to OFAC sanctions or on the OFAC list of specially designated nationals, or the subject of any similar sanction of any Governmental Authority in the Territory.

1.46 "**Deficient Site**" has the meaning set forth in Section 5.8.2 (Deficient Sublicensees or Sites and Replacement).

1.47 "**Deficient Sublicensee**" has the meaning set forth in Section 5.8.2 (Deficient Sublicensees or Sites and Replacement).

1.48 "**Development**" means, with respect to any product, any and all internal and external research, development and regulatory activities regarding such product, including (a) research, process development, non-clinical testing, toxicology, non-clinical activities, GLP toxicology and other preclinical studies (the conduct of those development activities described in the foregoing clause (a), "**Pre-Clinical Development**") and (b) Clinical Trials, preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct Clinical Trials and to obtain, support, or maintain Regulatory Approval of such product (such as post-marketing approval studies and observational studies for an indication, if required by any Regulatory Authority in any country in the Territory to support or maintain Regulatory Approval for a product in such indication in such country) (the conduct of Clinical Trials and the conduct of those regulatory activities described in the foregoing clause (b), to the extent related to the conduct of Clinical Trials, "**Clinical Development**") but in each case of (a) and (b) excluding any activities directed to Manufacturing, Medical Affairs, or Commercialization. Development will include research, development, and regulatory activities for additional presentations or indications for a product after receipt of Regulatory Approval of such product, including Clinical Trials commenced following receipt of Regulatory Approval or any Clinical Trial to be conducted after receipt of Regulatory Approval that was mandated by the applicable Regulatory Authority as a condition of such Regulatory Approval with respect to an approved indication (such as post-marketing approval studies and observational studies, if required by any Regulatory Authority in any country in the Territory to support or maintain Regulatory Approval for a product in such country). "**Develop**," "**Developing**," and "**Developed**" will be construed accordingly.

1.49 "**Development Milestone Events**" has the meaning set forth in Section 10.2.1 (Development Milestone Events and Payments).

1.50 "**Development Milestone Payments**" has the meaning set forth in Section 10.2.1 (Development Milestone Events and Payments).

1.51 "**Disclosing Party**" has the meaning set forth in Section 11.1.1 (Duty of Confidence).

1.52 "**Dispute**" has the meaning set forth in Section 16.1 (Dispute Resolution; General).

1.53 "**Dollar**" means the U.S. dollar, and "$" will be interpreted accordingly.

1.54 "**Effective Date**" has the meaning set forth in the Preamble.

1.55 "**Ex-Territory Infringement**" has the meaning set forth in Section 14.4.1 (Patent Enforcement; Notice).

1.56 "**Examined Party**" has the meaning set forth in Section 10.11 (Financial Records and Audits).

1.57 "**Executive Officers**" has the meaning set forth in Section 3.6.3 (Decisions of the JSC).

1.58 "**Existing In-Licenses**" means any agreement between Kiniksa (or any of its Affiliates) and any Third Party entered into prior to the Effective Date under which such Third Party grants Kiniksa (or any of its Affiliates) a license to any of the Kiniksa Technology that is sublicensed to Partner hereunder as of the Effective Date. The Existing In-Licenses as of the Effective Date are set forth on Schedule 1.58 (Existing In-Licenses).

1.59 "**Exploit**" means to make, have made, use, import, export, offer to sell, sell, Develop, Manufacture, perform Medical Affairs activities for, Commercialize, or otherwise exploit. "**Exploitation**" will be construed accordingly.

1.60 "**FD&C Act**" means the United States Federal Food, Drug and Cosmetic Act, as amended from time to time, together with any rules, regulations, and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.61 "**FDA**" means the United States Food and Drug Administration or any successor entity thereto having essentially the same function.

1.62 "**Field**" means all human diagnostic, prophylactic, and therapeutic uses, subject to any restrictions or limitations in any Third Party IP Agreement.

1.63 "**First Commercial Sale**" means, with respect to the Licensed Product or Biosimilar Product (as applicable) in any country or region, the first sale of the Licensed Product or Biosimilar Product (as applicable) to a Third Party for distribution, use, or consumption in such country or region after receipt of Regulatory Approval for the Licensed Product in such country or region. First Commercial Sale excludes any sale or other distribution of the Licensed Product for use in a Clinical Trial or other Development activity or for compassionate or named-patient use, in each case, sold at or below cost of goods sold.

1.64 "**Force Majeure**" has the meaning set forth in Section 17.4 (Force Majeure).

1.65 "**FTE**" means the equivalent of the work of one duly qualified employee of a Party full time for one year (consisting of a total of [***] hours per year) carrying out Development, Manufacturing, Medical Affairs activities, or other scientific or technical work under this Agreement. Overtime and work on weekends, holidays, and the like, in each case, will not be counted with any multiplier (*e.g.*, time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution. The portion of an FTE billable by a Party for one individual during a given accounting period will be determined by dividing the number of hours worked directly by such individual on the work to be conducted under this Agreement during such accounting period and the number of FTE hours applicable for such accounting period based on [***] working hours per Calendar Year.

1.66 "**FTE Rate**" means the amount for an FTE per Calendar Year, which for the Calendar Year ending on December 31, 2022 will be (a) with respect to Kiniksa, $[***] per FTE; and (b) with respect to Partner, $[***] per FTE, in each case, pro-rated for the period beginning on the Effective Date and ending on December 31, 2022. Beginning on January 1, 2023 and on January 1 of each subsequent Calendar Year during the Term, each FTE Rate is subject to annual adjustment by the percentage increase or decrease in the applicable CPI comparing the levels of the applicable CPI as of December 31 of the two most recently completed Calendar Years.

1.67 "**Fully Burdened Manufacturing Cost**" means, with respect to the Licensed Product, in each case, supplied by or on behalf of the applicable Party or its Affiliates to the other Party or its Affiliates hereunder:

(a) if and to the extent the Licensed Product (or any precursor or intermediate thereof), as applicable, is Manufactured by a Third Party manufacturer, [***]; *or*

(b) if and to the extent the Licensed Product (or any precursor or intermediate thereof), as applicable, is Manufactured by a Party or its Affiliate, [***]. Such fully burdened costs will be calculated in accordance with applicable Accounting Standards, consistently applied.

1.68 "**GAAP**" means United States generally accepted accounting principles, consistently applied.

1.69 "**GCP**" or "**cGCP**" means all applicable current good clinical practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Trials, including, as applicable (a) as set forth in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonized Tripartite Guideline for Good Clinical Practice E6 (the "**GCP Guideline**") and any other guidelines for good clinical practice for trials on medicinal products in the Territory, (b) the Declaration of Helsinki (2013) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards), and 312 (Investigational New Drug Application), as may be amended from time to time, and (d) the equivalent Applicable Law in each country or region in the Territory, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

1.70 "**Global Brand Elements**" has the meaning set forth in Section 14.9.1 (Global Brand Elements).

1.71 "**Global Brand Strategy**" has the meaning set forth in Section 9.2 (Commercialization Plan).

1.72 "**Global Clinical Trial**" means a Clinical Trial for the Licensed Product the data from which is intended to be used to obtain or support Regulatory Approval both inside and outside of the Territory.

1.73 "**Global Development Plan**" has the meaning set forth in Section 5.3 (Global Development Plan).

1.74 "**GLP**" or "**cGLP**" means all applicable good laboratory practice standards, including, as applicable, as set forth in the then-current good laboratory practice standards promulgated or endorsed by the U.S. Food and Drug Administration, as defined in 21 C.F.R. Part 58, and the equivalent Applicable Law in each country or region in the Territory, each as may be amended and applicable from time to time.

1.75 "**Governmental Authority**" means any federal, national, state, provincial, or local government, or political subdivision thereof, or any multinational organization or any authority, agency, regulatory body, or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, or any court or tribunal (or any department, bureau or division of any of the foregoing, or any governmental arbitrator or arbitral body). Governmental Authorities

include all Regulatory Authorities.

1.76 "**ICC Rules**" has the meaning set forth in Section 16.4 (Arbitration).

1.77 "**IDL**" has the meaning set forth in Section 1.119 (Marketing Authorization Application).

1.78 "**IFRS**" means International Financial Reporting Standards, consistently applied.

1.79 "**IND**" means an Investigational New Drug application required pursuant to 21 C.F.R. Part 312 required to commence human clinical trials in the U.S. or, to the extent required in any country or region in the Territory, any equivalent application in such country or region, and including all supplements or amendments that may be filed with respect to the foregoing.

1.80 "**Indemnified Party**" has the meaning set forth in Section 13.3 (Indemnification Procedure).

1.81 "**Indemnifying Party**" has the meaning set forth in Section 13.3 (Indemnification Procedure).

1.82 "**Indication**" means a separate and distinct disease, disorder, or medical condition that the Licensed Product is intended to treat, prevent, cure, or ameliorate in the indication section of the Approved Labeling for the Licensed Product, or that is the subject of a Clinical Trial and where it is intended that the data and results of such Clinical Trial (if successful) will be used to support a Regulatory Submission and Regulatory Approval that is intended to result in distinct labeling in the indication section of the Approved Labeling relevant to usage of the Licensed Product in such disease, disorder, or medical condition that is separate and distinct from another disease, disorder, or medical condition.

1.83 "**Initial Know-How Transfer**" has the meaning set forth in Section 4.1 (Initial Know-How Transfer).

1.84 "**Initiate**" means, with respect to a Clinical Trial, the first patient, first visit in such Clinical Trial.

1.85 "**Invoiced Sales**" has the meaning set forth in Section 1.128 (Net Sales).

1.86 "**JDC**" has the meaning set forth in Section 3.3.1 (Formation and Purpose of the JDC).

1.87 "**JMC**" has the meaning set forth in Section 3.4.1 (Formation and Purpose of the JMC).

1.88 "**Joint Collaboration Know-How**" means all Collaboration Know-How, other than Assigned Collaboration Know-How, developed or invented jointly by Representatives of a Party or its Affiliates or its or their licensees, Sublicensees, or Subcontractors, or any Persons contractually required to assign or license such Collaboration Know-How to such Party or any Affiliate of such Party, on the one hand, and Representatives of the other Party or its Affiliates or its or their licensees, Sublicensees, or Subcontractors, or any Persons contractually required to assign or license such Collaboration Know-How to such Party or any Affiliate of such Party, on the other hand.

1.89 "**Joint Collaboration Patent Rights**" means all Collaboration Patent Rights that Cover Joint Collaboration Know-How.

1.90 "**Joint Collaboration Technology**" means the Joint Collaboration Know-How and the

Joint Collaboration Patent Rights.

1.91 "**JSC**" has the meaning set forth in Section 3.2.1 (Formation and Purpose of JSC).

1.92 "**JSC Chairperson**" has the meaning set forth in Section 3.2.1 (Formation and Purpose of JSC).

1.93 "**Key Country**" has the meaning set forth in Section 6.2.3 (Review of Regulatory Submissions).

1.94 "**Kiniksa**" has the meaning set forth in the Preamble.

1.95 "**Kiniksa Collaboration Know-How**" means any Collaboration Know-How developed or invented solely by Representatives of Kiniksa or its Affiliates or its or their licensees (other than Partner), Sublicensees (other than Partner), or Subcontractors, or any Persons contractually required to assign or license such Collaboration Know-How to Kiniksa or any Affiliate of Kiniksa, but expressly excluding Kiniksa Manufacturing Know-How.

1.96 "**Kiniksa Collaboration Patent Rights**" means any Patent Rights that Cover any Kiniksa Collaboration Know-How.

1.97 "**Kiniksa Collaboration Technology**" means the Kiniksa Collaboration Know-How and the Kiniksa Collaboration Patent Rights.

1.98 "**Kiniksa Identified Rights**" has the meaning set forth in Section 2.6.1 (Kiniksa Identified Rights).

1.99 "**Kiniksa Indemnitee(s)**" has the meaning set forth in Section 13.1 (Indemnification; By Partner).

1.100 "**Kiniksa Know-How**" means any Know-How that is Controlled by Kiniksa or any of its Affiliates as of the Effective Date or during the Term (including Kiniksa Collaboration Know-How and Kiniksa's interest in the Joint Collaboration Know-How), and [***] to perform Clinical Development, Pre-Clinical Development (solely to the extent permitted in accordance with Section 5.2.2 (Pre-Clinical Development)), or Medical Affairs with respect to, or Commercialize the Licensed Product in the Territory in the Field, but expressly excluding Kiniksa Manufacturing Know-How.

1.101 "**Kiniksa Manufacturing Know-How**" means any Know-How that is Controlled by Kiniksa or any of its Affiliates as of the Effective Date or during the Term (including Kiniksa Collaboration Know-How), and is necessary for the Manufacturing of the Licensed Product in the Territory in the Field.

1.102 "**Kiniksa Manufacturing Patent Rights**" means any Patent Rights that are Controlled by Kiniksa or any of its Affiliates as of the Effective Date or during the Term (including Kiniksa Collaboration Patent Rights), and are necessary for the Manufacturing of the Licensed Product in the Territory in the Field.

1.103 "**Kiniksa Manufacturing Technology**" means all Kiniksa Manufacturing Know-How and Kiniksa Manufacturing Patent Rights.

1.104 "**Kiniksa P&L Process and Specifications**" has the meaning set forth in Section 4.1 (Initial Know-How Transfer).

1.105 "**Kiniksa Patent Right Infringement**" has the meaning set forth in Section 14.4.1 (Patent Enforcement; Notice).

1.106 "**Kiniksa Patent Rights**" means any Patent Right that (a) is Controlled by Kiniksa or any of its Affiliates as of the Effective Date or during the Term (including Kiniksa Collaboration Patent Rights and Joint Collaboration Patent Rights), and (b) is [***] (or, with respect to patent applications, would be [***] if such patent applications were to issue as patents) to perform Clinical Development or Pre-Clinical Development (solely to the extent permitted in accordance with Section 5.2.2 (Pre-Clinical Development)) or Medical Affairs with respect to, or Commercialize, the Licensed Product in the Territory in the Field (including any such Patent Right that Covers a composition of matter (*e.g.*, a drug formulation) of the Licensed Product), but expressly excluding Kiniksa Manufacturing Patent Rights. Schedule 1.106 (Kiniksa Patent Rights) sets forth the Kiniksa Patent Rights that are owned or exclusively licensed by Kiniksa or its Affiliates as of the Effective Date in the Territory.

1.107 "**Kiniksa Process and Specifications**" has the meaning set forth in Section 7.2.4 (Process and Specifications).

1.108 "**Kiniksa Technology**" means the Kiniksa Know-How and Kiniksa Patent Rights.

1.109 "**Know-How**" mean any and all proprietary technical, scientific, or other information, data (including physical, chemical, biological, toxicological, pharmacological, clinical and veterinary data), test results, knowledge, know-how, techniques, practices, processes, discoveries, inventions, specifications, strategies, plans, dosage regimens, drug formulations, control assays, product specifications, analytical and quality control data, marketing, pricing, distribution cost and sales data or descriptions, designs (including study designs), trade secrets, Regulatory Submissions, and other technology, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or otherwise protected by trade secret law, in each case, that is not in the public domain or otherwise generally known.

1.110 "**Knowledge**" means the actual knowledge, without any inquiry, investigation, or obligation to conduct any freedom to operate analysis, of (a) with respect to Kiniksa, the Chief Intellectual Property Officer, the Chief Medical Officer, and the Chief Operating Officer, in each case, of Kiniksa or its Affiliates; and (b) with respect to Partner, the Chief Medical Officer, the Chief Business Officer, and the General Counsel.

1.111 "**Licensed Product**" means any product Controlled by Kiniksa or its Affiliates comprised of or that contains mavrilimumab, a human monoclonal antibody targeting granulocyte macrophage colony-stimulating factor receptor alpha (GM-CSFRα).

1.112 "**Listing Patent Rights**" has the meaning set forth in Section 14.6 (Patent Listings).

1.113 "**Local Manufacturing Approval**" has the meaning set forth in Section 6.2.1(a) (Local Manufacturing).

1.114 "**Losses**" means damages, debts, obligations, and other liabilities, losses, claims, taxes, interest obligations, deficiencies, judgments, assessments, fines, fees, penalties, or expenses (including amounts paid in settlement, interest, court costs, costs of investigators, reasonable fees and expenses of attorneys, accountants, financial advisors, consultants, and other experts, and other expenses of litigation).

1.115 "**Manufacture**" means with respect to any product, any and all activities directed to manufacturing, processing, packaging, labeling, filling, finishing, assembly, quality assurance, quality

control, testing, and release, shipping, supply, or storage of such product (or any components or process steps involving such product), as the case may be, including qualification, validation, and scale-up, preclinical, clinical, and commercial manufacture and analytic development, product characterization, and stability testing, but excluding any activities directed to Development, Medical Affairs, or Commercialization. "**Manufacturing**" and "**Manufactured**" will be construed accordingly.

1.116 "**Manufacturing License**" has the meaning set forth in Section 2.1.2 (Manufacturing License).

1.117 "**Manufacturing Technology Transfer**" means the transfer of the Kiniksa Manufacturing Know-How related to the Licensed Product in accordance with the Manufacturing Technology Transfer Plan for the Licensed Product, which includes the provision of any technical assistance to enable the applicable steps of the Manufacture of the Licensed Product to be transferred to those CMOs selected by Partner or, if determined by the JSC in accordance with Section 4.2 (Manufacturing Technology Transfer), to Partner.

1.118 "**Manufacturing Technology Transfer Plan**" means, for each Licensed Product, the plan for the transfer to Partner of the Kiniksa Manufacturing Know-How for the Licensed Product, which plan, among other things, will set forth for the Licensed Product the scope of Manufacturing activities that will be transferred to Partner, the scope of the Kiniksa Manufacturing Know-How that will be necessary for the conduct of such activities, and the work plan and timeline for such transfer, in each case, determined in accordance with Section 4.2 (Manufacturing Technology Transfer).

1.119 "**Marketing Authorization Application**" or "**MAA**" means any new drug application, biologics license application, or other marketing authorization application, in each case, filed with the applicable Regulatory Authority in a country or other regulatory jurisdiction, which application is required to commercially market or sell a pharmaceutical or biologic product in such country or jurisdiction (and any amendments thereto). In the context of imported drugs in the PRC, MAA is also known as the Import Drug License ("**IDL**") application.

1.120 "**Marketing Authorization Holder**" has the meaning set forth in Section 6.2.1(b) (Other Regulatory Approvals).

1.121 "**Material Adverse Impact**" means, with respect to any matter, that such matter could (a) have a materially adverse impact on the Development or Commercialization of the Licensed Product outside of the Territory (including any concern related to quality, safety, toxicity, or side effects), or (b) be inconsistent with Kiniksa's global regulatory strategy or Global Development Plan for the Licensed Product.

1.122 "**Material Subcontractor**" has the meaning set forth in Section 2.2.3 (Right to Subcontract).

1.123 "**Mavrilimumab Agreement**" means the License Agreement between MedImmune, Limited and Kiniksa Pharmaceuticals, Ltd. effective as of December 21, 2017, as amended by Amendment No. 1 effective as of July 9, 2020 and as the same may be amended in accordance with the terms of this Agreement.

1.124 "**Medical Affairs**" means activities conducted by a Party's medical affairs department (or, if a Party does not have a medical affairs department, the equivalent function thereof), including communications with key opinion leaders and clinical or scientific thought leaders, medical education, symposia, advisory boards (to the extent related to medical affairs or clinical guidance), activities performed

in connection with patient registries, and other medical programs and communications, including educational grants, research grants (including those related to investigator-initiated studies), and charitable donations to the extent related to medical affairs and not to other activities that involve the promotion, marketing, sale, or other Commercialization of the Licensed Product and are not conducted by a Party's medical affairs (or equivalent) department. Medical Affairs excludes any activities directed to Manufacturing, Development, or Commercialization.

1.125 "**Medical Affairs Plan**" means, with respect to the Licensed Product, the written high-level strategic and tactical plans for the Medical Affairs activities for the Licensed Product to be conducted in the Territory that will be prepared and updated by Partner as provided in Section 8.1 (Medical Affairs Plan).

1.126 "**Milestone Events**" has the meaning set forth in Section 10.2.3(a) (Notification of Milestone Events).

1.127 "**Milestone Payments**" has the meaning set forth in Section 10.2.3(a) (Notification of Milestone Events).

1.128 "**Net Sales**" means with respect to the Licensed Product for any period, the gross amounts invoiced by Partner or its Affiliates to Third Parties or Sublicensees for sales of the Licensed Product in the Territory (the "**Invoiced Sales**") less the following deductions:

(a) [***];

(b) [***];

(c) [***];

(d) [***]; and

(e) [***].

For the avoidance of doubt, (a) in the case of any sale or other disposal of the Licensed Product between or among Partner and its Affiliates for resale, invoiced sales and Net Sales will be calculated only on the amount invoiced on the first arm's length sale thereafter to a Third Party; and (b) Net Sales will not be imputed to transfers of Licensed Product (i) without consideration or for nominal consideration for use in any Clinical Trials reasonably necessary to comply with any Applicable Law or regulation or any request by a Regulatory Authority in the Territory, (ii) for any *bona fide* charitable, compassionate use or indigent patient, or other similar program purpose where the Licensed Product is sold at or below cost of goods sold, or (iii) in commercially reasonable quantities as samples for promotional purposes.

Subject to the above, Net Sales will be calculated in accordance with the standard internal policies and procedures of Partner, its Affiliates or its or their Sublicensees, which must be in accordance with U.S. GAAP or, if applicable, IFRS.

1.129 "**New Development**" has the meaning set forth in Section 5.4 (New Development by Partner).

1.130 "**New Development Activities**" has the meaning set forth in Section 5.4 (New Development by Partner).

1.131 "**New Development Proposal**" has the meaning set forth in Section 5.4 (New Development by Partner).

1.132 "**New Kiniksa In-Licensed Rights**" has the meaning set forth in Section 2.6.3 (Third Party In-Licenses).

1.133 "**New Territory-Specific Development Activities**" has the meaning set forth in Section 5.4 (New Development by Partner).

1.134 "**New Third Party IP Agreement**" has the meaning set forth in Section 2.6.3 (Third Party In-Licenses).

1.135 "**NMPA**" means the National Medical Products Administration of the People's Republic of China, and local counterparts thereto, and any successor agency or authority thereto having substantially the same function.

1.136 "**OFAC**" means the Office of Foreign Assets Control of the United States Department of the Treasury or any successor agency thereto.

1.137 "**Ongoing Global Clinical Trial**" means any Global Clinical Trial for the Licensed Product that is ongoing as of the Effective Date or Initiated within [***] months following the Effective Date.

1.138 "**Partner**" has the meaning set forth in the Preamble.

1.139 "**Partner Collaboration Know-How**" means Collaboration Know-How, other than Assigned Collaboration Know-How, developed or invented solely by Representatives of Partner or its Affiliates or its or their licensees (other than Kiniksa), Sublicensees, or Subcontractors, or any Persons contractually required to assign or license such Collaboration Know-How to Partner or any Affiliate of Partner.

1.140 "**Partner Collaboration Patent Rights**" means any Collaboration Patent Right that Covers Partner Collaboration Know-How.

1.141 "**Partner Collaboration Technology**" means the Partner Collaboration Know-How and Partner Collaboration Patent Rights.

1.142 "**Partner Identified Rights**" has the meaning set forth in Section 2.6.2 (Partner Identified Rights).

1.143 "**Partner Indemnitee(s)**" has the meaning set forth in Section 13.2 (Indemnification; By Kiniksa).

1.144 "**Partner Know-How**" means all Know-How that is Controlled by Partner or any of its Affiliates as of the Effective Date or during the Term, and [***] to Exploit the Licensed Product, including Partner Collaboration Know-How and Partner's interest in the Joint Collaboration Know-How.

1.145 "**Partner Patent Rights**" means all Patent Rights that are Controlled by Partner or any of its Affiliates as of the Effective Date or during the Term, and [***] (or, with respect to patent applications, would be [***] if such patent applications were to issue as patents) to Exploit the Licensed Product, including all Partner Collaboration Patent Rights and Partner's interest in the Joint Collaboration Patent

Rights.

1.146 "**Partner Process and Specifications**" has the meaning set forth in Section 7.2.4 (Process and Specifications).

1.147 "**Partner Technology**" means Partner Know-How and Partner Patent Rights.

1.148 "**Party**" or "**Parties**" has the meaning set forth in the Preamble.

1.149 "**Patent Challenge**" has the meaning set forth in Section 15.2.3 (Termination for Patent Challenge).

1.150 "**Patent Prosecution**" means activities directed to (a) preparing, filing, and prosecuting applications (of all types) for any Patent Right, (b) maintaining any Patent Right, and (c) deciding whether to abandon or maintain any Patent Right.

1.151 "**Patent Rights**" means any and all (a) patents, patent applications, and utility models in any country or jurisdiction, including provisional applications, priority applications, and international applications, (b) patent applications filed either from such patents or patent applications or from a patent application claiming priority from any of these, including divisionals, provisionals, continuations, and continuations-in-part, (c) patents that have issued or in the future issue from the foregoing patent applications, (d) substitutions, renewals, registrations, confirmations, revalidations, reissues, and re-examinations of the foregoing patents or patent applications, and (e) extensions, restorations, supplemental protection certificates, and the like based on any of the foregoing patents or patent applications.

1.152 "**Patent Term Adjustment**" has the meaning set forth in Section 14.7 (Patent Term Extensions).

1.153 "**Patent Term Extension**" has the meaning set forth in Section 14.7 (Patent Term Extensions).

1.154 "**Paying Party**" has the meaning set forth in Section 10.12.2 (Tax Cooperation).

1.155 "**Person**" means any corporation, limited or general partnership, limited liability company, joint venture, joint stock company, trust, unincorporated association, governmental body, authority, bureau, or agency, or any other entity or body, or an individual.

1.156 "**Phase III Clinical Trial**" means a clinical trial in humans in a manner that is generally consistent with 21 C.F.R. § 312.21(c), as amended (or its successor regulation), or, with respect to any other country or region, the equivalent of such a clinical trial in such other country or region.

1.157 "**Pivotal Clinical Trial**" means any (a) Phase III Clinical Trial, or (b) other Clinical Trial of a pharmaceutical or biologic product on a sufficient number of patients, the results of which, together with prior data and information concerning such product, are sufficient, without any additional Clinical Trial to meet the evidentiary standard for demonstrating the safety, purity, efficacy, and potency of such active substance of such product established by a Regulatory Authority in any particular jurisdiction and that is intended to support the filing of an MAA with a Regulatory Authority in such jurisdiction. Notwithstanding any provision to the contrary set forth in this Agreement, treatment of patients as part of an expanded access program, compassionate sales or use program (including named patient program or single patient program), or an indigent program, in each case, will not be included in determining whether or not a Clinical Trial is a Pivotal Clinical Trial.

1.158 "**PRC**" means the People's Republic of China, which, for purposes of this Agreement, does not include Hong Kong Special Administrative Region, Macau Special Administrative Region, or Taiwan.

1.159 "**Preapproved Subcontractor**" means any Subcontractor to be engaged by Partner to perform its obligations or exercise its rights under this Agreement as further described in Section 2.2.3 (Right to Subcontract) and (a) identified as a Subcontractor in a Territory Development Plan or Global Development Plan that is approved by the JSC or (b) selected by Partner to Manufacture the Licensed Product in the Territory in accordance with Section 4.2 (Manufacturing Technology Transfer).

1.160 "**Pre-Clinical Development Plan**" has the meaning set forth in Section 5.2.2 (Territory Pre-Clinical Development).

1.161 "**Product Marks**" has the meaning set forth in Section 14.9.2 (Product Marks in the Territory).

1.162 "**Public Official**" means (a) any officer, employee or representative of any regional, federal, state, provincial, county or municipal government or government department, agency or other division; (b) any officer, employee or representative of any commercial enterprise that is owned or controlled by a government, including any state-owned or controlled veterinary, laboratory or medical facility; (c) any officer, employee or representative of any public international organization, such as the International Monetary Fund, the United Nations or the World Bank; and (d) any person acting in an official capacity for any government or government entity, enterprise, or organization identified above.

1.163 "**Publication**" has the meaning set forth in Section 11.5 (Publications).

1.164 "**Receiving Party**" has the meaning set forth in Section 11.1.1 (Duty of Confidence).

1.165 "**Recipient**" has the meaning set forth in Section 10.12.2 (Tax Cooperation).

1.166 "**Regulatory Approval**" means, with respect to a particular country or other regulatory jurisdiction, any approval of an MAA or other approval, product, or establishment license, registration, or authorization of any Regulatory Authority necessary for the commercial marketing or sale of a pharmaceutical or biologic product in such country or other regulatory jurisdiction, excluding, in each case, Reimbursement Approval.

1.167 "**Regulatory Authority**" means any applicable Governmental Authority with jurisdiction or authority over the Development, Manufacture, Commercialization, or other Exploitation (including Regulatory Approval or Reimbursement Approval) of pharmaceutical or biologic products in a particular country or other regulatory jurisdiction, including the NMPA, and any corresponding national or regional regulatory authorities.

1.168 "**Regulatory Exclusivity**" means any exclusive marketing rights or data protection or other exclusivity rights conferred by any Regulatory Authority with respect to a pharmaceutical or biologic product in a particular country or other regulatory jurisdiction, but in all cases excluding Patent Rights.

1.169 "**Regulatory Submissions**" means any filing, application, or submission with any Regulatory Authority in support of Developing, Manufacturing, or Commercializing a pharmaceutical or biologic product (including to obtain, support, or maintain Regulatory Approval from that Regulatory Authority) and any proposed Approved Labeling, and all correspondence or communication with or from the relevant Regulatory Authority, as well as minutes of any substantive meetings, telephone conferences, or discussions with the relevant Regulatory Authority. Regulatory Submissions include all INDs, MAAs,

and other applications for Regulatory Approval and their equivalents.

1.170 "**Reimbursement Approval**" means an approval, agreement, determination, or other decision by the applicable Governmental Authority that establishes prices charged to end-users for pharmaceutical or biologic products at which a particular pharmaceutical or biologic product will be reimbursed by the Regulatory Authorities or other applicable Governmental Authorities in the Territory.

1.171 "**Replacement Site**" has the meaning set forth in Section 5.8.2 (Deficient Sublicensees or Sites and Replacement).

1.172 "**Representative**" means any employee, officer, contractor, consultant, or agent of a Party.

1.173 "**Required Pre-Clinical Development**" has the meaning set forth in Section 5.2.2 (Territory Pre-Clinical Development).

1.174 "**Review Period**" has the meaning set forth in Section 11.5 (Publications).

1.175 "**Royalty Patent Rights**" means the Kiniksa Patent Rights and the Kiniksa Manufacturing Patent Rights.

1.176 "**Royalty Payments**" has the meaning set forth in Section 10.3.1 (Royalty Rates).

1.177 "**Royalty Report**" has the meaning set forth in Section 10.3.4 (Royalty Reports and Payments).

1.178 "**Royalty Term**" has the meaning set forth in Section 10.3.2 (Royalty Term).

1.179 "**Safety Agreement**" has the meaning set forth in Section 6.6.1 (Adverse Events Reporting; Safety Agreements).

1.180 "**Sales Milestone Events**" has the meaning set forth in Section 10.2.2 (Sales Milestone Events and Payments).

1.181 "**Sales Milestone Payments**" has the meaning set forth in Section 10.2.2 (Sales Milestone Events and Payments).

1.182 "**Selected Territory GCT Countries**" has the meaning set forth in Section 5.3 (Global Development Plan).

1.183 "**Status Quo Item**" has the meaning set forth in Section 3.7.2(a) (No Change; Status Quo).

1.184 "**Subcontractor**" means (a) a Third Party contractor engaged by a Party to perform certain obligations or exercise certain rights of such Party under this Agreement on a fee-for-service basis (including CROs, CMOs, and CSOs), or (b) a Third Party Distributor. A Subcontractor of Partner may be deemed a Sublicensee for purposes of this Agreement if such Subcontractor requires a sublicense under the rights granted to Partner in Section 2.1 (License Grants to Partner) to perform the applicable activities for which they were engaged.

1.185 "**Sublicensee**" means any Person (a) with respect to Partner, to whom Partner grants a sublicense of, or other authorization or permission granted under, the rights granted to Partner in Section 2.1 (License Grants to Partner), including any Subcontractor (to the extent such Subcontractor requires a sublicense under the rights granted to Partner in Section 2.1 (License Grants to Partner) to perform the

applicable activities for which they were engaged), and (b) with respect to Kiniksa, to whom Kiniksa grants a sublicense of, or other authorization or permission granted under, the rights granted to Kiniksa in Section 2.3 (License Grant to Kiniksa).

1.186 "**Subsidiary**" means, with respect to a Party, any Person that is controlled by such Party. For the purpose of this definition only, "control" (including, with correlative meaning, the terms "controlled by" and "under the common control") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of any Person, whether by the ownership of more than 50% of the voting security of such Person, by contract or otherwise. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than 50%, and that in such case such lower percentage will be substituted in the preceding sentence; *provided* that such foreign investor has the power to direct the management and policies of such entity.

1.187 "**Tax**" or "**Taxes**" means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including any interest thereon), including value add, sales, excise or similar taxes ("**VAT**").

1.188 "**Technology Transfer**" has the meaning set forth in Section 4.3 (Continuing Know-How Transfer).

1.189 "**Term**" has the meaning set forth in Section 15.1 (Term).

1.190 "**Territory**" means, subject to Section 15.2.4 (Termination in [***]), Asia Pacific Region (the People's Republic of China, Hong Kong SAR, Macao SAR, Taiwan Region, South Korea, Indonesia, Singapore, The Philippines, Thailand, Australia, Bangladesh, Bhutan, Brunei, Burma, Cambodia, India, Laos, Malaysia, Maldives, Mongolia, Nepal, New Zealand, Sri Lanka, and Vietnam).

1.191 "**Territory Development**" has the meaning set forth in Section 5.1 (Development Diligence and Responsibilities).

1.192 "**Territory Development Plan**" has the meaning set forth in Section 5.2.1 (Territory Clinical Development).

1.193 "**Territory Sponsor**" means, with respect to a Territory-Specific Clinical Trial or a Global Clinical Trial for the Licensed Product to be conducted at sites in the Territory, the Party that holds the IND from the applicable Regulatory Authority in the Territory for such Clinical Trial in its name.

1.194 "**Territory-Specific Clinical Trial**" means a Clinical Trial for the Licensed Product, the data from which at the time of commencement of such Clinical Trial is intended to be used to obtain Regulatory Approval in the Territory but not to obtain Regulatory Approval outside of the Territory.

1.195 "**Third Party**" means any Person other than a Party or an Affiliate of a Party.

1.196 "**Third Party Claims**" means collectively, any and all Third Party demands, claims, actions, suits, and proceedings (whether criminal or civil, in contract, tort, or otherwise).

1.197 "**Third Party Distributor**" means any Third Party that purchases Licensed Product from Partner or its Affiliates or Sublicensees, takes title to the Licensed Product, and distributes the Licensed Product directly to customers, but does not Develop, Manufacture, or otherwise Commercialize the Licensed Product and does not make any upfront, milestone, royalty, profit-share, or other payment to

Partner or its Affiliates or Sublicensees, other than payment for the purchase of Licensed Product for resale.

1.198 "**Third Party IP Agreements**" has the meaning set forth in Section 2.6.3 (Third Party In-Licenses).

1.199 "**United States**" or "**U.S.**" means the United States of America and its territories and possessions.

1.200 "**Valid Claim**" means, with respect to a particular country or region, (a) a claim of an issued and unexpired patent (as may be extended through supplementary protection certificate or patent term extension or the like) that, in such country or region, has not been revoked, held invalid, or unenforceable by a patent office or other Governmental Authority of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period) and that has not been disclaimed, denied, or admitted to be invalid or unenforceable through reissue, re-examination, or disclaimer or otherwise; or (b) a pending claim of an unissued, pending patent application in such country or region that has not been pending for more than [***] years since the date of the first response on the merits received from the relevant patent office regarding such application, *provided* that such [***] year period will be tolled for the duration of any adverse proceeding (*e.g.*, Third Party oppositions or any appeal of an adverse determination against the Valid Claim) with respect to the patent application at issue.

1.201 "**VAT**" has the meaning set forth in Section 1.187 (Tax).

ARTICLE 2
LICENSES

2.1. License Grants to Partner.

2.1.1. **In the Territory**. Subject to the terms of this Agreement (including Kiniksa's retained rights set forth in Section 2.4 (No Implied Licenses; Retained Rights)), Kiniksa hereby grants to Partner (i) an exclusive, royalty-bearing license, with the right to grant sublicenses solely in accordance with Section 2.2 (Sublicensing and Subcontractors) under its interest in the Kiniksa Technology to perform Clinical Development and Medical Affairs with respect to and Commercialize the Licensed Product in the Field in the Territory and (ii) a non-exclusive license, with the right to grant sublicenses solely in accordance with Section 2.2 (Sublicensing and Subcontractors), under its interest in the Kiniksa Technology to perform Required Pre-Clinical Development in the Field in the Territory solely to the extent permitted under and in accordance with Section 5.2.2 (Territory Pre-Clinical Development), in each case ((i) and (ii)), in accordance with the terms of this Agreement.

2.1.2. **Manufacturing License**. Subject to the terms of this Agreement (including Kiniksa's retained rights set forth in Section 2.4 (No Implied Licenses; Retained Rights)), (a) Kiniksa hereby grants to Partner a non-exclusive, royalty-bearing license, with the right to grant sublicenses solely in accordance with Section 2.2 (Sublicensing and Subcontractors), under its interest in the Kiniksa Manufacturing Technology solely to package and label the Licensed Product in the Territory solely for sale and use of the Licensed Product in the Territory, and (b) with respect to the Licensed Product, Kiniksa hereby grants to Partner a non-exclusive, royalty-bearing license, with the right to grant sublicenses solely in accordance with Section 2.2 (Sublicensing and Subcontractors), under its interest in the Kiniksa Manufacturing Technology solely to perform in the Territory those Manufacturing activities for the Licensed Product (or any components thereof) approved by the JSC in

accordance with Section 3.2.4(f) (JSC Roles and Responsibilities) and, if Partner is to Manufacture the Licensed Product itself, transferred in accordance with the Manufacturing Technology Transfer Plan for the Licensed Product, solely for sale and use of the Licensed Product in the Field in the Territory (such license under the foregoing clause (b), the "**Manufacturing License**").

2.1.3. **Pre-Existing Third Party Rights**. In addition to the other terms and conditions of this Agreement, the licenses granted hereunder are subject to the terms of (a) all New Third Party IP Agreements (and amendments thereto) as further described in, and solely to the extent such New Third Party IP Agreements (and amendments thereto) are entered into in accordance with, Section 2.5.2 (Third Party IP Agreement Amendments) and Section 2.6.3 (Third Party In-Licenses) and (b) the Mavrilimumab Agreement.

2.2. Sublicensing and Subcontractors.

2.2.1. **Right to Sublicense**. Subject to the terms of this Agreement, Partner will have the right to grant sublicenses of the rights granted under Section 2.1 (License Grants to Partner):

(a) to (i) Preapproved Subcontractors (to the extent such Preapproved Subcontractors require a sublicense under the rights granted to Partner in Section 2.1 (License Grants to Partner) to perform the applicable activities for which they were engaged) and, (ii) subject to Kiniksa's prior written consent, not to be unreasonably withheld, conditioned, or delayed, to other Subcontractors (to the extent such other Subcontractors require a sublicense under the rights granted to Partner in Section 2.1 (License Grants to Partner) to perform the applicable activities for which they were engaged);

(b) subject to Kiniksa's prior written approval, not to be unreasonably withheld, conditioned, or delayed, to (i) Partner's Subsidiaries or (ii) other Third Parties that are not Subcontractors;

in each case ((a) and (b)), for the sole purpose of performing Partner's obligations and exercising Partner's rights with respect to the Clinical Development, Pre-Clinical Development (to the extent permitted in accordance with Section 5.2.2 (Territory Pre-Clinical Development)), Manufacture, performance of Medical Affairs activities with respect to, or Commercialization of the Licensed Product in accordance with this Agreement. [***] Each Sublicensee will hold its rights contingent on the rights licensed to Partner under the terms of this Agreement and may not grant any further sublicenses of its rights to any Third Party. Any termination of the licenses granted to Partner under Section 2.1 (License Grants to Partner) as a result of a termination of this Agreement will cause the Sublicensees to automatically lose the same rights under any sublicense.

2.2.2. **Terms of Sublicenses to Third Parties**. Partner will provide prior written notice to Kiniksa identifying its intention to grant a sublicense under Section 2.2.1 (Right to Sublicense) to any Third Party that is not a Preapproved Subcontractor (including a Subcontractor that requires a sublicense under the rights granted to Partner in Section 2.1 (License Grants to Partner) to perform the applicable activities for which they were engaged or another proposed Sublicensee), the purpose of such sublicense, and the identity of the Third Party to whom Partner intends to grant such sublicense, and, to the extent required pursuant to the terms of any Third Party IP Agreement, the substantially final

version of the agreement between Partner and any such Third Party in English for Kiniksa to review and determine whether to approve. Each sublicense to a Third Party (including any Preapproved Subcontractor or other Subcontractor, in each case, that requires a sublicense under the rights granted to Partner in Section 2.1 (License Grants to Partner) to perform the applicable activities for which they were engaged) will be granted under a written agreement that is consistent with and subject to the terms of this Agreement, to the extent required pursuant to the terms of any Third Party IP Agreement that has been approved in writing by Kiniksa, and that:

(a) contains the requirements set forth under Section 2.2.4 (Terms of Sublicenses and Subcontracts with Third Parties);

(b) requires each such Sublicensee to comply with the terms of this Agreement that are applicable to such Sublicensee (including the Milestone Event and Royalty Payment reporting obligations set forth under Section 10.2 (Milestone Payments) and Section 10.3 (Royalty Payments to Kiniksa), the record keeping and audit requirements set forth under Section 5.8 (Clinical Trial Audit Rights), Section 10.11 (Financial Records and Audits), and the intellectual property provisions set forth in Article 14 (Intellectual Property));

(c) requires that each such Sublicensee performs the activities that they are sublicensed or engaged to perform (as applicable) in accordance with the terms of all Third Party IP Agreements, cGLP, cGMP, and cGCP, as applicable, and otherwise in compliance with Applicable Law;

(d) includes Kiniksa as an intended third party beneficiary under the sublicense with the right to enforce the applicable terms of such sublicense;

(e) precludes the granting of further sublicenses without the prior written consent of Kiniksa, not to be unreasonably withheld, conditioned, or delayed;

(f) prohibits such Third Party from engaging in, independently or for or with any other Third Party, any Exploitation of any Competitive Product in the Territory; and

(g) is subject in all respects to any applicable Third Party IP Agreement under which Kiniksa is granted any right that will be sublicensed under such proposed sublicense.

2.2.3. **Right to Subcontract**. Partner will not propose the engagement of any Subcontractor that is Debarred/Excluded. The Preapproved Subcontractors will be set forth in the Territory Development Plan or Global Development Plan, or any amendment thereto approved by the JSC. Subject to the applicable terms of this Agreement (including the terms of Section 2.2.4 (Terms of Sublicenses and Subcontracts with Third Parties) and, if such Preapproved Subcontractor is granted a sublicense under the rights granted to Partner in Section 2.1 (License Grants to Partner), the terms of Section 2.2.2 (Terms of Sublicenses to Third Parties)), Partner may engage any Preapproved Subcontractor to perform Partner's obligations and exercise Partner's rights under this Agreement. In addition, if Partner wishes to engage a Subcontractor that does not require a sublicense, is not already a Preapproved Subcontractor, and is (a) a CMO or CRO or (b) a CSO engaged to operate in [***]% or more of the relevant market in any country or region of the Territory for which Partner is seeking such CSO's assistance (any such Subcontractor described in the

preceding clauses (a) or (b), a "**Material Subcontractor**") to perform its obligations or exercise its rights under this Agreement related to the Clinical Development, Manufacture, Pre-Clinical Development (solely to the extent permitted in accordance with Section 5.2.2 (Territory Pre-Clinical Development)), performance of Medical Affairs with respect to, or Commercialization of the Licensed Product, then at least [***] days before engaging any such Subcontractor, Partner will provide to the JSC, for review and discussion, written notice identifying Partner's intention to engage such Subcontractor, the purpose of engaging such Subcontractor, and the identity of such Subcontractor. The Parties agree that Partner's engagement of Material Subcontractors that do not require a sublicense do not require the approval of the JSC, and if the JSC does not provide to Partner comments with respect to the engagement of any such proposed Material Subcontractors prior to the end of such [***] day period, then Partner may so engage such Material Subcontractors.

2.2.4. **Terms of Sublicenses and Subcontracts with Third Parties**. In addition to the requirements set forth in Section 2.2.2 (Terms of Sublicenses to Third Parties) with respect to any grant of rights to a Sublicensee, any sublicense agreement with a Third Party and any agreement pursuant to which Partner engages any Subcontractor (including any Preapproved Subcontractor) must be consistent with, and subject to, the terms of this Agreement and contain (a) an assignment back to Partner of all Collaboration Know-How and Collaboration Patent Rights developed, invented, or filed (as applicable) by or on behalf of the Sublicensee or Subcontractor, as applicable (including all Assigned Collaboration Technology, Partner Collaboration Technology, and Joint Collaboration Technology), (b) a sublicensable (through multiple tiers) license back to Partner of all other Know-How and Patent Rights developed, invented, or filed (as applicable) by or on behalf of the Sublicensee or Subcontractor, as applicable, that are [***] to Exploit the Licensed Product (such that Partner Controls such Know-How and Patent Rights for the purposes of this Agreement), and (c) confidentiality and non-use provisions that are at least as stringent as those set forth in Article 11 (Confidentiality; Publication).

2.2.5. **Notice of Sublicenses**. Partner will provide Kiniksa with a true and complete copy of each agreement between Partner and any Sublicensee no later than [***] days after the execution thereof, *provided* that, to the extent permitted under any Third Party IP Agreement, Partner may redact any financial terms contained therein that are not necessary for Kiniksa to determine the scope of the rights granted under such sublicense. If any such agreement between Partner and any Sublicensee is not in English, then Partner will also provide to Kiniksa an English translation thereof, at Partner's expense, no later than [***] days following the execution thereof.

2.2.6. **Partner Audits of Sublicensees and Subcontractors**. Partner will provide Kiniksa with copies of any quality oversight or audit reports from audits that Partner (or its agent) has conducted on any Sublicensees or other Material Subcontractors engaged by Partner to perform its obligations or exercise its rights under this Agreement to the extent such reports are relevant to such Sublicensees' or other Subcontractors' performance of such obligations or exercise of such rights no later than [***] Business Days after receiving or preparing, as applicable, any such report. Partner will provide to Kiniksa all quality oversight or audit reports from audits that Partner (or its agent) conducts, and, if any such report is not in English, a summary in English of any such report. Solely to the extent that Kiniksa is required to submit such quality oversight or audit reports to a Regulatory Authority. Partner will reimburse Kiniksa for any translation expenses reasonably incurred by Kiniksa to obtain English translation thereof by translators selected by Kiniksa.

2.2.7. **Responsibility for Sublicensees and Subcontractors**. Notwithstanding any sublicense or subcontracting, Partner will remain primarily liable to Kiniksa for the performance of all of its obligations under, and Partner's and its Sublicensees' and other Subcontractors' compliance with all provisions of, this Agreement. Partner will be fully responsible and liable for any breach of the terms of this Agreement by any of its Sublicensees or other Subcontractors to the same extent as if Partner itself has committed any such breach, and Partner will promptly terminate the sublicense or subcontract, as applicable, with any Sublicensee or other Subcontractor if such Sublicensee or Subcontractor is in material breach of this Agreement and does not cure such breach in a timely manner in accordance with the terms of this Agreement.

2.3. License Grant to Kiniksa. Subject to the terms of this Agreement (including Partner's retained rights set forth in Section 2.4 (No Implied Licenses; Retained Rights)), Partner hereby grants to Kiniksa a non-exclusive, royalty-free, fully paid-up, worldwide, transferable (in accordance with Section 17.1 (Assignment)) license, with the right to grant sublicenses through multiple tiers (a) under the Partner Technology (i) to Manufacture the Licensed Product both inside and outside of the Territory solely for purposes of: (A) use in Commercialization of the Licensed Product outside the Territory, (B) Development of the Licensed Product inside the Territory solely for purposes of performing Kiniksa's obligations and exercising Kiniksa's rights, in each case, under this Agreement, and (C) Development of the Licensed Product outside of the Territory, (ii) to Develop the Licensed Product in the Territory, including to perform Global Clinical Trials and other Development activities for the Licensed Product under the Global Development Plan for purposes of Exploiting the Licensed Product outside the Territory, and (iii) to Exploit Licensed Product outside the Territory, and (b) under the Partner Collaboration Technology to Exploit the Licensed Product, which license under the Partner Collaboration Technology will be irrevocable and perpetual.

2.4. No Implied Licenses; Retained Rights. Nothing in this Agreement will be interpreted to grant a Party any rights under any intellectual property rights owned or Controlled by the other Party, including Kiniksa Technology, Kiniksa Manufacturing Technology, Joint Collaboration Technology, or Partner Technology, in each case, that are not expressly granted herein, whether by implication, estoppel, or otherwise. Any rights not expressly granted to Kiniksa by Partner under this Agreement are hereby retained by Partner. Any rights not expressly granted to Partner by Kiniksa under this Agreement are hereby retained by Kiniksa. Notwithstanding any provision to the contrary set forth in this Agreement, Kiniksa may, and hereby retains (on behalf of itself and its licensees, other than Partner and its Sublicensees), (a) the exclusive right under the Kiniksa Technology to conduct Development that is not Clinical Development involving the Licensed Product worldwide, other than Partner's performance of Pre-Clinical Development in the Field in the Territory to the extent permitted by Kiniksa in accordance with Section 5.2.2 (Territory Pre-Clinical Development), (b) the exclusive right under the Kiniksa Manufacturing Technology to Manufacture Licensed Product outside of the Territory and the co-exclusive (with Partner) right under the Kiniksa Manufacturing Technology to Manufacture the Licensed Product within the Territory solely for use outside of the Territory and for use inside the Territory in accordance with the terms of this Agreement, and (c) in the event that Partner does not participate in any Global Clinical Trial, the non-exclusive right to Clinically Develop Licensed Product in the Territory solely in connection with the performance of such Global Clinical Trial. Partner will not practice the Kiniksa Technology or Kiniksa Manufacturing Technology other than as expressly licensed and permitted under this Agreement or otherwise agreed by the Parties in writing. Kiniksa will not practice the Partner Technology other than as expressly licensed and permitted under this Agreement or otherwise agreed by the Parties in writing.

2.5. Third Party IP Agreements.

2.5.1. **Compliance**. Partner stipulates and agrees that the rights and licenses granted to Partner under this Agreement are subject to the applicable terms of the Third Party IP Agreements with respect to the Kiniksa Technology that is being sublicensed thereunder, and Kiniksa will not be required to take any action or inaction that would cause Kiniksa to be in breach of any Third Party IP Agreement or to grant any rights to Partner hereunder that are in violation of, or inconsistent with, any Third Party IP Agreement. Partner will abide by the applicable terms of the Third Party IP Agreements.

2.5.2. **Third Party IP Agreement Amendments**. During the Term, at least [***] Business Days prior to entering into any amendment to the Mavrilimumab Agreement or any other Existing In-License or New Third Party IP Agreement that would conflict with, or adversely affect, the sublicenses granted to Partner under this Agreement pursuant to the Mavrilimumab Agreement or such other Existing In-License or New Third Party IP Agreement, or would otherwise impose any incremental obligation on Partner, Kiniksa will promptly furnish Partner with a copy of such proposed amendment, from which copy Kiniksa may only redact information that is not necessary for Partner to determine the scope of the rights sublicensed to Partner pursuant to the Mavrilimumab Agreement, or such other Existing In-License or New Third Party IP Agreement or for Partner to determine whether such amendment will relieve or modify Kiniksa's performance of its obligations under this Agreement. Partner will provide to Kiniksa for Kiniksa's reasonable consideration any comments regarding such proposed amendment no later than [***] Business Days after its receipt thereof, and Kiniksa will use reasonable efforts to incorporate Partner's reasonable comments to the extent timely received and applicable to preserving Partner's rights, and Kiniksa's obligations, under this Agreement. Kiniksa will not, without Partner's prior written consent, terminate the Mavrilimumab Agreement or any New Third Party IP Agreement. In addition, Kiniksa will not, without Partner's prior written consent, enter into any amendment to the Mavrilimumab Agreement or any other Existing In-License Agreement or New Third Party IP Agreement, in each case, (a) other than in accordance with the terms of this Section 2.5.2 (Third Party IP Agreement Amendments) or (b) to the extent that doing so would conflict with, or materially and adversely affect, the licenses granted to Partner under Section 2.1 (License Grants to Partner) or Partner's other rights under this Agreement. Kiniksa further acknowledges and agrees that Partner is not obligated to comply with, or incur liability under, those terms of any amendment to the Mavrilimumab Agreement or any other Existing In-License or New Third Party IP Agreement that Kiniksa fails to provide to Partner for its review and comment prior to the execution thereof in accordance with this Section 2.5.2(Third Party IP Agreement Amendments). Further, Kiniksa will not be relieved from performing its obligations under this Agreement under or as a result of any amendment to the Mavrilimumab Agreement or any other Existing In-License or New Third Party IP Agreement that Kiniksa fails to provide to Partner for its review and comment prior to the execution thereof in accordance with this Section 2.5.2 (Third Party IP Agreement Amendments).

2.6. Third Party In-Licenses.

2.6.1. **Kiniksa Identified Rights**. As between the Parties, Kiniksa will remain solely responsible for the payment of all royalties, license fees, milestone payments, and other payment obligations under all Existing In-Licenses. If, after the Effective Date during the Term, Kiniksa or its Affiliate intends to obtain Control of any Know-How or Patent Rights from

a Third Party (whether by acquisition or license) that may be necessary to Exploit the Licensed Product in the Field in the Territory (other than through a Change of Control of Kiniksa or any of its Affiliates or as a result of the acquisition by Kiniksa or any of its Affiliates of a Third Party by merger, acquisition, or similar transaction or series of related transactions) and for which Kiniksa intends Partner to share amounts due in consideration of a grant under such Know-How and Patent Rights (such Know-How and Patent Rights, "**Kiniksa Identified Rights**"), then Kiniksa will notify Partner in writing of such Kiniksa Identified Rights and Section 2.6.3 (Third Party In-Licenses) will apply.

2.6.2. **Partner Identified Rights**. If Partner determines that a license under any Know-How or Patent Rights controlled by a Third Party is necessary to Exploit the Licensed Product in the Field in the Territory (or any country or region therein) ("**Partner Identified Rights**"), then Partner will so notify Kiniksa. Kiniksa will have the first right to acquire rights to any such Partner Identified Rights from such Third Party (whether by acquisition or license), and if Kiniksa intends to acquire such rights, then Kiniksa will notify Partner of such intention no later than [***] days after Kiniksa's receipt of such written notice from Partner, and the terms of Section 2.6.3 (Third Party In-Licenses) will apply. If Kiniksa notifies Partner of its intention not to so acquire such rights within such [***] day period, or otherwise fails within [***] days after the date of Partner's written request to acquire rights under such Partner Identified Rights, then, in each case, Partner will have the right to acquire rights under such Partner Identified Rights from such Third Party (a) solely for the Territory (or any country or region therein), (b) unless such Third Party is only offering rights for the Territory together with rights outside the Territory, in which case, Partner may acquire all Partner Identified Rights being offered, and in each case ((a) and (b)), Partner will use reasonable efforts to ensure that all such Partner Identified Rights are fully sublicensable (through multiple tiers) to Kiniksa to the extent of the licenses granted to Kiniksa hereunder. If thereafter Partner so acquires such rights, then such Know-How or Patent Rights will be included in the Partner Know-How or Partner Patent Rights, as applicable. Upon execution of any agreement pursuant to which Partner acquires any Partner Identified Rights outside of the Territory, Partner will notify Kiniksa in writing and will provide a copy of such agreement to Kiniksa, *provided* that Partner may redact information that is not necessary for Kiniksa to determine the scope of the rights that would be sublicensed to Kiniksa thereunder. If Kiniksa elects to accept a sublicense from Partner under those Partner Identified Rights so acquired by Partner, then Kiniksa will reimburse Partner for (i) [***]% of any payments under such Third Party IP Agreement that solely pertain to, or arise solely as a result of, the Exploitation of the Licensed Product outside the Territory (for example, royalty payments that are solely attributable to sales of Licensed Product outside the Territory or milestone payments payable upon achievement of events solely outside the Territory).

2.6.3. **Third Party In-Licenses.** Prior to Kiniksa's or its Affiliate's execution of an agreement with a Third Party to acquire or license any Kiniksa Identified Rights or Partner Identified Rights that would be licensed to Partner hereunder if Controlled by Kiniksa or its Affiliates (together, "**New Kiniksa In-Licensed Rights**" and any such agreement, a "**New Third Party IP Agreement**," and together with the Existing In-Licenses, the "**Third Party IP Agreements**"), Kiniksa will provide Partner with a copy of the proposed New Third Party IP Agreement from which copy Kiniksa may only redact information that is not necessary for Partner to determine the scope of the rights sublicensed to Partner or for Partner to determine whether such New Third Party IP Agreement will relieve or modify Kiniksa's performance of its obligations under this Agreement and Partner will have an opportunity to review and comment on the terms of the proposed New Third Party IP Agreement that

are applicable to the Territory, the performance of Kiniksa's obligations under this Agreement and other material terms thereof, including any payments that Kiniksa or its Affiliates would be obligated to pay in connection with the grant, maintenance, or exercise of a license or sublicense thereunder (as applicable) to Partner. To the extent Kiniksa is able to exclude the Territory from the territory of such proposed New Third Party IP Agreement, Partner will have the right to decline to take a sublicense under such proposed New Third Party IP Agreement. If Partner does not decline a sublicense under such proposed New Third Party IP Agreement or if Kiniksa is not able to exclude the Territory from the territory of such proposed New Third Party IP Agreement, then Kiniksa will take into consideration Partner's reasonable comments with respect to such New Third Party IP Agreement and Kiniksa will use reasonable efforts to ensure that such New Third Party IP Agreement includes the right to grant a sublicense to Partner in the Field in the Territory under the applicable New Kiniksa In-Licensed Rights such that Kiniksa or its Affiliate Controls such rights as Kiniksa Know-How, Kiniksa Patent Rights, Kiniksa Manufacturing Know-How, or Kiniksa Manufacturing Patent Rights (as applicable). Upon execution of such New Third Party IP Agreement, Kiniksa will notify Partner in writing and will provide a copy of the New Third Party IP Agreement to Partner, *provided* that Kiniksa may only redact information that is not necessary for Partner to determine the scope of the rights sublicensed to Partner or for Partner to determine whether such New Third Party IP Agreement will relieve or modify Kiniksa's performance of its obligations under this Agreement. Kiniksa further acknowledges and agrees that Partner is not obligated to comply with, or incur liability under, any terms of any New Third Party IP Agreement that Kiniksa fails to provide to Partner for its review and comment prior to the execution thereof in accordance with this Section 2.6.3 (Third Party In-Licenses). Further, Kiniksa will not be relieved from performing its obligations under this Agreement under or as a result of any New Third Party IP Agreement that Kiniksa fails to provide to Partner for its review and comment prior to the execution thereof in accordance with this Section 2.6.3 (Third Party In-Licenses). Each New Third Party IP Agreement will be subject to the requirements of Section 2.5.2 (Third Party IP Agreement Amendments) with respect to amendments of such New Third Party IP Agreements. The terms of this Section 2.6.3 (Third Party In-Licenses) and the payment terms under Section 2.6.4 (Responsibility for Costs) will not apply to any agreement pursuant to which Kiniksa is granted rights under Know-How or Patent Rights that are [***] to Exploit the Licensed Product in the Field in the Territory if Kiniksa determines that Partner need not be responsible for any costs thereunder pursuant to Section 2.6.4 (Responsibility for Costs) (but such agreement will be subject to Section 2.5.1 (Compliance) and Section 2.5.2(Third Party IP Agreement Amendments)); *provided, however*, that (a) Partner is not obligated to comply with, or incur liability under, any terms of any New Third Party IP Agreement that Kiniksa fails to provide to Partner for its review and comment prior to the execution thereof in accordance with this Section 2.6.3 (Third Party In-Licenses) and (b) Kiniksa will not be relieved from performing its obligations under this Agreement under or as a result of any such New Third Party IP Agreement that Kiniksa fails to provide to Partner for its review and comment prior to the execution thereof in accordance with this Section 2.6.3 (Third Party In-Licenses). In addition, if any agreement pursuant to which Kiniksa obtains rights to any Kiniksa Identified Rights does not include the Territory (because Partner declines a sublicense under the applicable Kiniksa Identified Rights and Kiniksa is able to obtain rights under such Kiniksa Identified Rights that exclude the Territory), then the payment terms under Section 2.6.4 (Responsibility for Costs) will not apply to such agreement, such agreement will not be a New Third Party IP Agreement for purposes of this Agreement, and the Know-How and Patent Rights licensed to Kiniksa pursuant to such Agreement will not be deemed "Controlled" by Kiniksa for purposes of this Agreement.

2.6.4. **Responsibility for Costs**. Following Kiniksa's or its Affiliate's execution of the applicable New Third Party IP Agreement, to the extent Kiniksa Controls such rights, (a) such New Kiniksa In-Licensed Rights will be included in the Kiniksa Know-How, Kiniksa Patent Rights, Kiniksa Manufacturing Know-How, or Kiniksa Manufacturing Patent Rights (as applicable) and licensed or sublicensed (as applicable) to Partner under the licenses granted in Section 2.1 (License Grants to Partner), subject to the terms of this Agreement and the applicable Third Party IP Agreement, and (b) Partner will reimburse Kiniksa for (i) [***]% of any payments under such Third Party IP Agreement that solely pertain to, or arise solely as a result of, the Exploitation of the Licensed Product in the Territory (for example, royalty payments that are solely attributable to sales of Licensed Product in the Territory or milestone payments payable upon achievement of events solely in the Territory), with the understanding that any milestone payments that pertain to, or arise solely as a result of the Exploitation of the Licensed Product in the Territory will not represent more than [***]% of the total milestone payments due under such Third Party IP Agreement and (ii) [***]% of any upfront payments, milestone payments, or similar payments payable in consideration for any New Kiniksa In-Licensed Rights that pertain to, or arise as a result of, the Exploitation of the Licensed Product both inside and outside of the Territory or that are non-Territory specific (for example, an upfront payment to access technology or worldwide sales milestones).

2.7. Exclusivity Covenants.

2.7.1. **Partner Exclusivity**. Unless otherwise agreed in writing by the Parties or as expressly provided by the terms of this Agreement, during the Term, Partner will not, and will ensure that its Subsidiaries do not, conduct, license, participate in, or fund, directly or indirectly, independently or for or with any Third Party, the Exploitation of any Competitive Product in the Territory (or license or otherwise grant rights or authorize any Third Party to do any of the foregoing) (collectively, the "**Competitive Activities**").

2.7.2. **Kiniksa Exclusivity**. Unless otherwise agreed in writing by the Parties or as expressly provided by the terms of this Agreement, during the Term, Kiniksa will not, and will ensure that its Affiliates do not, conduct, license, participate in, or fund, directly or indirectly, independently or for or with any Third Party, any Competitive Activities.

2.7.3. **Business Combinations**. Neither Party nor its Subsidiaries will be in breach of the restrictions set forth in this Section 2.7 (Exclusivity Covenants) if such Party or any of its Affiliates undergoes a Change of Control with a Third Party (together with such Third Party and its Affiliates following the closing of the applicable Change of Control transaction, the "**Acquired Party**") that (either directly or through an Affiliate, or in collaboration with any Third Party) (a) is performing any Competitive Activities at the closing of the Change of Control transaction or (b) commences any Competitive Activities after the closing of the Change of Control transaction; and such Acquired Party may perform such Competitive Activities in the Territory, as long as (i) no Kiniksa Technology, Kiniksa Manufacturing Technology, or Partner Technology is used directly or indirectly by or on behalf of such Acquired Party or its Affiliates in connection with the performance of any Competitive Activities, and (ii) such Acquired Party institutes commercially reasonable technical and administrative safeguards to ensure the requirements set forth in the foregoing clause (i) are met, including by creating "firewalls" between the personnel performing any Competitive Activities and the personnel teams charged with Exploiting the Licensed Product or having access to data from activities performed under this Agreement or Confidential Information of the Parties.

2.7.4. **Acquisition of a Competitive Product**. Neither Party nor its Subsidiaries (with respect to Partner) or its Affiliates (with respect to Kiniksa) will be in breach of the restrictions set forth in this Section 2.7 (Exclusivity Covenants) if such Party or any of its Subsidiaries (with respect to Partner) or its Affiliates (with respect to Kiniksa) acquires a Competitive Product that is being Exploited in the Territory through an acquisition of, or a merger with, the whole or substantially the whole of a business or assets of another Person, so long as such Party (or its Affiliate) (a) enters into a definitive agreement with a Third Party to divest (whether by exclusive out-license or otherwise) such Competitive Product throughout the Territory within [***] months after the closing of such acquisition or merger or (b) terminates the further Exploitation of such Competitive Product throughout the Territory within [***] days after the closing of such acquisition or merger, and, until the completion of such divestiture or termination, (i) no Kiniksa Technology, Kiniksa Manufacturing Technology, or Partner Technology is used by or on behalf of such Party or its Affiliates in connection with any subsequent Exploitation of such Competitive Products in the Territory, and (ii) such Party and its Affiliates institute commercially reasonable technical and administrative safeguards to ensure the requirements set forth in the foregoing clause (i) are met, including by creating "firewalls" between the personnel Exploiting such Competitive Products and the personnel teams charged with Exploiting the Licensed Product or having access to data from activities performed under this Agreement or Confidential Information of the Parties.

ARTICLE 3
GOVERNANCE

3.1. **Alliance Managers**. Each Party will appoint an individual to act as its alliance manager under this Agreement as soon as practicable after the Effective Date (each an "**Alliance Manager**"). The Alliance Managers will: (a) serve as the primary points of contact between the Parties for the purpose of providing the other Party with information on the progress of a Party's activities under this Agreement; (b) be responsible for facilitating the flow of information and otherwise promoting communication, coordination, and collaboration between the Parties, all of which communications between the Parties will be in English; (c) facilitate the prompt resolution of any disputes; and (d) attend JSC, JDC, or JMC meetings, in each case, as a non-voting member. An Alliance Manager may also bring any matter to the attention of the JSC, JDC, or JMC if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party will use reasonable efforts to keep an appropriate level of continuity but may replace its Alliance Manager at any time upon written notice to the other Party.

3.2. **Joint Steering Committee**.

3.2.1. **Formation and Purpose of JSC**. No later than [***] days after the Effective Date, the Parties will establish a joint steering committee (the "**JSC**") to coordinate and oversee the Exploitation of the Licensed Product in the Territory. The JSC will be composed of an equal number of representatives from each Party and a minimum of three representatives of each Party who are fluent in English and who have the appropriate and direct knowledge and expertise and requisite decision-making authority. Any such representative who serves on the JSC or any committee under this Agreement may also serve on one or more other committees under this Agreement. Each Party may replace any of its representatives on the JSC and appoint a person to fill the vacancy arising from each such replacement. A Party that replaces a representative will notify the other Party at least [***] days prior to the next scheduled meeting of the JSC. Both Parties will use reasonable efforts to keep an appropriate level of continuity in representation. Representatives may be represented at

any meeting by another person designated by the absent representative. A representative of Kiniksa will chair the JSC ("**JSC Chairperson**") until the first anniversary of the Effective Date. Thereafter, a Partner representative will become the JSC Chairperson for the next [***] months of the Term and then the role of JSC Chairperson will rotate between the Parties every [***] months during the Term. Each Party's representatives on the JSC will inform and coordinate within their respective organization to enable each Party to fulfill its obligations as agreed upon between the Parties under this Agreement, including within the time frames set forth hereunder.

3.2.2. **Meeting Agendas**. Each Party will disclose to the other Party the proposed agenda items along with appropriate information at least [***] Business Days in advance of each meeting of the JSC; *provided* that under exigent circumstances requiring JSC input, a Party may provide its agenda items to the other Party within a shorter period of time in advance of a meeting, or may propose that there not be a specific agenda for a particular meeting, so long as such other Party consents to such later addition of such agenda items or the absence of a specific agenda for such JSC meeting.

3.2.3. **Meetings**. The JSC will hold meetings at such times as it elects to do so, but will meet no less frequently than quarterly, unless otherwise agreed by the Parties. All meetings will be conducted in English. The JSC may meet in person or by means of teleconference, Internet conference, videoconference, or other similar communication method; *provided* that, if practicable or permissible in light of travel restrictions due to the COVID-19 pandemic or any other reason, at least one meeting each Calendar Year will be conducted in person at a location selected alternatively by Kiniksa and Partner or such other location as the Parties may agree. Each Party will be responsible for all of its own costs and expenses of participating in any JSC meeting. The Alliance Managers will jointly prepare and circulate minutes for each JSC meeting within [***] Business Days after each such meeting and will ensure that such minutes are reviewed and approved by their respective companies within [***] days thereafter.

3.2.4. **JSC Roles and Responsibilities**. The responsibilities of the JSC will be to:

(a) provide a forum for the discussion of the Parties' activities under this Agreement;

(b) review and discuss matters that Kiniksa believes may have a Material Adverse Impact on the Licensed Product;

(c) review and discuss Partner's engagement of Subcontractors that are not Preapproved Subcontractors, as described in Section 2.2.3 (Right to Subcontract);

(d) establish and oversee the JDC and JMC and settle any disputes that arise within the JDC or JMC, as described in Section 3.6.2 (Resolution of JDC and JMC Disputes);

(e) oversee the implementation of, and the coordination between the Parties of activities to be performed under, the Clinical Supply Agreement, the Commercial Supply Agreement, the Safety Agreements, and any other written agreement between the Parties with respect to the subject matter hereof;

(f) determine the appropriate time to perform the Manufacturing Technology Transfer for the Licensed Product, which in all cases will be conducted with sufficient time

so that Partner can be the Marketing Authorization Holder for the Licensed Product throughout the Territory, either (i) to those CMOs selected by Partner to Manufacture the Licensed Product for use by Partner in the Territory (which CMOs Partner will engage), or (ii) if agreed by the JSC for the Licensed Product, to Partner, as described in Section 4.2 (Manufacturing Technology Transfer).

(g) if the Manufacturing Technology Transfer for the Licensed Product will be to Partner (and not one or more CMOs), review, discuss, and determine whether to approve (i) the Manufacturing Technology Transfer Plan for the Licensed Product and (ii) any change in the scope of Manufacturing activities to be transferred to Partner if agreed by the JSC in connection with the Manufacturing Technology Transfer for the Licensed Product, each as described in Section 4.2 (Manufacturing Technology Transfer);

(h) review, discuss, and determine whether to approve any updates to the Territory Development Plan for the Licensed Product, in each case, as described in Section 5.2.1 (Territory Clinical Development);

(i) [***];

(j) review, discuss, and determine whether to approve any material updates to, the Global Development Plan for the Licensed Product with respect to activities to be conducted by Partner in the Territory, including Partner's participation in the conduct of any Global Clinical Trial, each as described in Section 5.3 (Global Development Plan);

(k) review and discuss if Partner will be the Territory Sponsor for Global Clinical Trials to be conducted under the Global Development Plan (as set forth therein), as described in Section 5.3 (Global Development Plan); *provided* that Partner will have the right, following such review and discussion, to make such determination;

(l) review, discuss, and determine whether to add any countries in the Territory as Selected Territory GCT Countries for a given Global Clinical Trial to be conducted under the Global Development Plan, as described in Section 5.3 (Global Development Plan);

(m) determine the total number of patients to be enrolled in the Territory for a given Global Clinical Trial, as contemplated in the applicable protocol for such Global Clinical Trial, as described in Section 5.3 (Global Development Plan);

(n) review, discuss, and determine whether to approve any New Development Proposal, and review, discuss, and determine whether to approve any New Territory-Specific Development Activities, in each case, as described in Section 5.4 (New Development by Partner);

(o) discuss the status, progress, and results of the Parties' respective Development activities, as described in Section 5.10 (Development Reports);

(p) review, discuss, and determine whether to approve the regulatory strategy for receipt of Regulatory Approval in each country or region in the Territory, as described in Section 6.1 (Regulatory Strategy);

(q) review and discuss Partner's plan for undertaking additional regulatory activities for the Licensed Product delegated by Kiniksa or the JSC to Partner, as described in Section 6.2.1 (Obtaining and Maintaining Regulatory Approvals);

(r) review and discuss the transfer of the Manufacturing of the Licensed Product (or any component thereof) in the Territory to one or more CMOs in the Territory selected by Partner, as described in Section 6.2.1(a) (Local Manufacturing);

(s) review, discuss, and determine whether to permit Partner to Manufacture the Licensed Product in the Territory itself, instead of through one or more CMOs selected by Partner, as described in Section 6.2.1(a) (Local Manufacturing);

(t) review, discuss, and determine whether to approve Partner's plan for undertaking any activities and interactions relating to obtaining and maintaining Local Manufacturing Approvals for the Licensed Product in the Territory, as described in Section 6.2.1(a) (Local Manufacturing);

(u) review, discuss, and determine whether to approve any Regulatory Submissions that are in the name of Kiniksa, as described in Section 6.2.3 (Review of Regulatory Submissions);

(v) facilitate the Parties' review and updating of Partner Process and Specifications and develop a plan for remediation of any deficiencies or limitations with respect to such Partner Process and Specifications, as described in Section 7.2.4 (Process and Specifications);

(w) review, discuss, and determine whether to approve Medical Affairs Plans for the Territory and any updates thereto for the Licensed Product, as described in Section 8.1 (Medical Affairs Plan);

(x) review, discuss, and determine whether to approve the Commercialization Plan for the Territory and any updates thereto for the Licensed Product, as described in Section 9.2 (Commercialization Plan);

(y) review, discuss, and determine whether to approve any brand strategy for the Licensed Product that is specific to the Territory (or any country or region therein) and that is inconsistent with the Global Brand Strategy for the Licensed Product, as described in Section 9.2 (Commercialization Plan);

(z) review, discuss, and determine whether to approve the use of any Product Mark for the Licensed Product in the Territory that deviates from Kiniksa's Global Brand Elements, as described in Section 14.9.2 (Product Marks in the Territory); and

(aa) perform such other functions as expressly set forth in this Agreement or allocated to the JSC by the Parties' written agreement.

3.3. Joint Development Committee.

3.3.1. **Formation and Purpose of the JDC**. Promptly, but no later than [***] days after the Parties establish the JSC, the JSC will establish a Joint Development Committee ("**JDC**") to monitor, coordinate, and facilitate cooperation and information exchange of the

Development of the Licensed Product in the Field in the Territory, which will be a subcommittee of the JSC and will have the responsibilities set forth in this Article 3 (Governance). The JDC will dissolve upon completion of all Development activities with respect to the Licensed Product in the Territory. The JDC will hold meetings at such times as it elects to do so, but will meet no less frequently than quarterly, unless otherwise agreed by the Parties. All meetings will be conducted in English. The JDC may meet in person or by means of teleconference, Internet conference, videoconference, or other similar communication method. Each Party will be responsible for all of its own costs and expenses of participating in any JDC meeting.

3.3.2. **Membership of the JDC**. Each Party will designate up to three representatives with appropriate knowledge and expertise to serve as members of the JDC. The JDC will be co-chaired by one of the representatives of each Party. Each Party may replace its JDC representatives and co-chairpersons at any time upon written notice to the other Party. The Alliance Manager of each Party (or his or her designee) will attend each meeting of the JDC as a non-voting participant.

3.3.3. **JDC Roles and Responsibilities**. The responsibilities of the JDC will be to:

(a) serve as a forum of information exchange and coordinate for Continuing Know-How Transfer as described in Section 4.3 (Continuing Know-How Transfer);

(b) review, discuss, and submit to the JSC to further review, discuss, and determine whether to approve any updates to the Territory Development Plan, as described in Section 5.2.1 (Territory Clinical Development);

(c) review, discuss, and submit to the JSC to further review, discuss, and determine whether to approve each Territory Pre-Clinical Development Plan, as described in Section 5.2.2 (Territory Pre-Clinical Development);

(d) review, discuss, and submit to the JSC to further review, discuss, and determine whether to approve any updates to the Global Development Plan that include activities to be conducted by Partner in the Territory, including by participating in the conduct of any Global Clinical Trial, as described in Section 5.3 (Global Development Plan);

(e) update the Territory Development Plan to reflect the JSC's decision regarding the conduct of Territory-specific New Development Activities, as described in Section 5.4 (New Development by Partner);

(f) discuss and develop the regulatory strategy for receipt of approval from the NMPA with respect to the conduct of the applicable Clinical Trials in the Territory, and submit the same to the JSC to further review, discuss, and determine whether to approve, as described in Section 6.1 (Regulatory Strategy);

(g) review, discuss, and submit to the JSC to further review, discuss, and determine whether to approve Regulatory Submissions in each country or region in the Territory for the Licensed Product, as described in Section 6.2.3 (Review of Regulatory Submissions); and

(h) develop, review, and discuss an initial draft of the Medical Affairs Plans for the Licensed Product in the Territory and propose any update thereto, and submit the same to the JSC to further review, discuss, and determine whether to approve, as described in Section 8.1 (Medical Affairs Plan).

3.4. Joint Manufacturing Committee.

3.4.1. **Formation and Purpose of the JMC**. If the JSC determines that it will be advantageous for the Parties to have Partner Manufacture the Licensed Product in the Territory, as described in Section 4.2 (Manufacturing Technology Transfer), then promptly (and in any event, no later than [***] days) following such determination, the JSC will establish a Joint Manufacturing Committee ("**JMC**") to monitor, coordinate, and facilitate cooperation and information exchange of the Manufacture of the Licensed Product (or any component thereof) that the JSC has so determined that Partner will Manufacture. The JMC will be a subcommittee of the JSC and will have the responsibilities set forth in this Article 3 (Governance). The JMC will dissolve upon completion of all Manufacturing activities by Partner with respect to the Licensed Product (or any component thereof) for the Territory. The JMC will hold meetings at such times as it elects to do so, but will meet no less frequently than quarterly, unless otherwise agreed by the Parties. All meetings will be conducted in English. The JMC may meet in person or by means of teleconference, Internet conference, videoconference, or other similar communication method. Each Party will be responsible for all of its own costs and expenses of participating in any JMC meeting.

3.4.2. **Membership of the JMC**. Each Party will designate up to three representatives with appropriate knowledge and expertise to serve as members of the JMC. The JMC will be co-chaired by one of the representatives of each Party. Each Party may replace its JMC representatives and co-chairpersons at any time upon written notice to the other Party. The Alliance Manager of each Party (or his or her designee) will attend each meeting of the JMC as a non-voting participant.

3.4.3. **JMC Roles and Responsibilities**. The responsibilities of the JMC will be to:

(a) review and discuss the Manufacturing Technology Transfer Plan for the Licensed Product, and submit the same to the JSC to further review, discuss, and determine whether to approve, as described in Section 4.2 (Manufacturing Technology Transfer); and

(b) perform such other functions expressly allocated to the JMC in this Agreement or by the written agreement of the Parties.

3.5. Non-Member Attendance. Each Party may from time to time invite a reasonable number of participants, in addition to its representatives (which may include legal counsel), to attend a meeting of the JSC, the JDC, and the JMC (in a non-voting capacity), if such participants have expertise that is relevant to the planned agenda for such JSC, JDC, or JMC meeting; *provided* that if either Party intends to have any Third Party (including any consultant) attend such a meeting, then such Party will provide prior written notice to the other Party reasonably in advance of such meeting and will ensure that such Third Party is bound by obligations of confidentiality and non-use at least as stringent as those set forth in Article 11 (Confidentiality; Publication). Notwithstanding any provision to the contrary set forth in this Agreement, if the other Party objects in good faith to the participation of such Third Party in such meeting due to a *bona fide* concern regarding

competitively sensitive information that is reasonably likely to be discussed at such meeting *(i.e.*, a consultant that also provides services to a Third Party with a Competitive Product), then such Third Party will not be permitted to participate in such meeting (or the portion thereof during which such competitively sensitive information is reasonably likely to be discussed).

3.6. Decision-Making.

3.6.1. **General Process**. The JSC, the JDC, and the JMC will have only the powers expressly assigned to it in this Article 3 (Governance) and elsewhere in this Agreement and will not have the authority to: (a) modify or amend the terms of this Agreement; or (b) waive either Party's compliance with the terms of this Agreement. All decisions of the JSC, the JDC, and the JMC will be made by unanimous vote, with each Party's representatives having one vote (*i.e.*, one vote per Party). No action taken at any meeting of the JSC, the JDC, or the JMC will be effective unless there is a quorum at such meeting, and at all such meetings, a quorum will be reached if two voting representatives of each Party are present or participating in such meeting and no Party will unreasonably fail to cause a quorum of its representatives to attend any meeting of the JSC, JDC, and JMC. Except as otherwise expressly set forth in this Agreement, the phrases "determine," "designate," "confirm," "approve," or "determine whether to approve" by the JSC, the JDC, or the JMC and similar phrases used in this Agreement will mean approval in accordance with this Section 3.6 (Decision-Making), including the escalation and tie-breaking provisions herein. For the avoidance of doubt, matters that are specified in Section 3.2.4 (JSC Roles and Responsibilities), Section 3.3.3 (JDC Roles and Responsibilities), and Section 3.4.3 (JMC Roles and Responsibilities) to be reviewed and discussed (as opposed to reviewed, discussed, and approved) do not require any agreement or decision by either Party and are not subject to the voting and decision-making procedures set forth in this Section 3.6 (Decision-Making) or in Section 3.7 (Resolution of JSC Disputes).

3.6.2. **Resolution of JDC and JMC Disputes**. The JSC will use good faith efforts to resolve all disputes that arise within the JDC or JMC within [***] days after any such matter is brought to the JSC for resolution.

3.6.3. **Decisions of the JSC**. The JSC will use good faith efforts, in compliance with this Section 3.6.3 (Decisions of the JSC), to promptly resolve any such matter for which it has authority. If, after the use of good faith efforts, the JSC is unable to resolve any such matter referred to it by the JDC or JMC or any matter that is within the scope of the JSC's authority or any other disagreement between the Parties that may be referred to the JSC, in each case, within a period of [***] days, then a Party may refer such matter for resolution in accordance with 3.7.1 (Referral to Executive Officers) to the Chief Executive Officer of Kiniksa (or an executive officer of Kiniksa designated by the Chief Executive Officer of Kiniksa who has the power and authority to resolve such matter) and the Chief Executive Officer of Partner (or an executive officer of Partner designated by the Chief Executive Officer of Partner who has the power and authority to resolve such matter) (collectively, the "**Executive Officers**").

3.7. Resolution of JSC Disputes.

3.7.1. **Referral to Executive Officers**. If a Party makes an election under Section 3.6.3 (Decisions of the JSC) to refer a matter on which the JSC cannot reach a consensus decision for resolution by the Executive Officers, then the JSC will submit in writing the respective positions of the Parties to their respective Executive Officers. The Executive Officers will

use good faith efforts to resolve any such matter so referred to them as soon as practicable, and any final decision that the Executive Officers agree to in writing will be conclusive and binding on the Parties.

3.7.2. **Final Decision-Making Authority**. If the Executive Officers are unable to reach agreement on any such matter referred to them within [***] days after such matter is so referred (or such longer period as the Executive Officers may agree upon), then:

(a) **No Change; Status Quo**. Neither Party will have final decision-making authority over (i) [***], (ii) [***], (iii) [***], (iv) [***], (v) [***], (vi) [***], or (vii) [***], (each, a "**Status Quo Item**") and all such matters must be decided by unanimous agreement in order to take any action or adopt any change from the then-current status quo.

(b) **Partner Final Decision-Making Authority**. Partner will have final decision-making authority over matters that are not Status Quo Items and that are (i) [***], (ii) [***], and (iii) [***].

(c) **Kiniksa Final Decision-Making Authority**. Kiniksa will have final decision-making authority with respect to all matters related to (i) [***], (ii) [***], (iii) [***], (iv) [***], and (v) [***].

3.7.3. **Limitations on Decision-Making**. Notwithstanding any provision to the contrary set forth in this Agreement, without the other Party's prior written consent, neither Party (in the exercise of a Party's final decision-making authority), the JSC, the JDC, the JMC, nor a Party's Executive Officer, in each case, may make a decision that could reasonably be expected to (a) require the other Party to take any action that such other Party reasonably believes would (i) require such other Party to violate any Applicable Law, the requirements of any Regulatory Authority, or any agreement with any Third Party entered into by such other Party (including any Third Party IP Agreement) or (ii) require such other Party to infringe or misappropriate any intellectual property rights of any Third Party or (b) conflict with, amend, interpret, modify, or waive compliance under this Agreement, the Clinical Supply Agreement, the Commercial Supply Agreement, the Safety Agreement, or any other agreement between the Parties related to the subject matter set forth herein. Following a determination by the JSC (A) that Partner should itself assume responsibility for the Manufacture of the Licensed Product (or any component thereof) in the Territory, or (B) the time at which to conduct the Manufacturing Technology Transfer for the Licensed Product to those CMOs selected by Partner (or, if agreed by the JSC to Partner), the JSC will not have the authority to reverse or revoke such determination unless otherwise agreed in writing by the Parties.

3.8. Discontinuation of JSC. The JSC will continue to exist until the first to occur of (a) the Parties agreeing to disband the JSC, or (b) Kiniksa providing written notice to Partner of its intention to disband and no longer participate in the JSC. Once the JSC is disbanded, the JSC will have no further obligations under this Agreement and, thereafter, the Alliance Managers will be the points of contact for the exchange of information between the Parties under this Agreement and any references in this Agreement to performance of the obligations of each Party's representatives to the JSC, the exercise of each Party's representatives rights as members of the JSC, and to the decisions of the JSC, in each case, will automatically become references to the performance of each Party's obligations, exercise of rights, and decisions by and between the Parties in writing, subject

to the other terms of this Agreement and consistent with the terms of Section 3.7 (Resolution of JSC Disputes).

ARTICLE 4
TECHNOLOGY TRANSFERS

4.1. **Initial Know-How Transfer**. Within a reasonable period of time after the Effective Date as agreed by the Parties (but in no event more than [***] days after the Effective Date unless otherwise agreed by the Parties), Kiniksa will provide and transfer to Partner copies of Kiniksa Know-How (other than Kiniksa Manufacturing Know-How, the transfer of which will be performed pursuant to Section 4.2 (Manufacturing Technology Transfer)), that exists on the Effective Date to the extent not previously provided to Partner and is [***] for Partner's performance of Clinical Development or Medical Affairs, or Commercialization of Licensed Product in the Territory in accordance with this Agreement, which Kiniksa Know-How will include information regarding the characterization of Licensed Product, other than CMC process characterization and process and specifications relating to the packaging and labeling of Licensed Product ("**Kiniksa P&L Process and Specifications**"), U.S. INDs with respect to Licensed Product, clinical studies data and results related to Licensed Product, and existing IND-enabling Data (the "**Initial Know-How Transfer**"). Kiniksa or its Affiliate may make such Kiniksa Know-How available in the form it is currently constituted or such other reasonable form as Kiniksa reasonably determines following consultation with Partner.

4.2. **Manufacturing Technology Transfer**.

4.2.1. **Timing of Transfer**. At a time to be agreed by the JSC, which will in any event be conducted with sufficient time so that Partner can be the Marketing Authorization Holder for the Licensed Product throughout the Territory Kiniksa will perform (or cause one or more applicable Third Parties (including any CMO engaged by Kiniksa to Manufacture the Licensed Product) to perform) a Manufacturing Technology Transfer for the Licensed Product to those CMOs selected by Partner or, if agreed by the JSC, to Partner, which transfer, if to Partner and not to a CMO, will be conducted in accordance with the Manufacturing Technology Transfer Plan for the Licensed Product. Notwithstanding the foregoing, if a Manufacturing Technology Transfer is not required for Partner to be the Marketing Authorization Holder for the Licensed Product throughout the Territory, then at Partner's election, Kiniksa will supply Licensed Product to Partner under the terms of the Commercial Supply Agreement until such time as the Commercial Supply Agreement expires or is otherwise earlier terminated by the Parties.

4.2.2. **Transferred Steps**. Unless otherwise agreed by the JSC, the Manufacturing Technology Transfer for the Licensed Product will contemplate the transfer to the applicable CMOs, or, if approved by the JSC, to Partner, of all activities necessary to Manufacture the Licensed Product (or components thereof) for use in the Field in the Territory in accordance with this Agreement.

4.2.3. **Transfer to Partner**. If the JSC determines that Partner will itself (and not through one or more CMOs) Manufacture the Licensed Product, then, in addition to the Kiniksa Know-How provided to Partner pursuant to the Initial Know-How Transfer, the Parties will develop a draft Manufacturing Technology Transfer Plan for the Licensed Product that contemplates the transfer to Partner of the relevant Kiniksa Manufacturing Know-How for the Licensed Product in the Territory in accordance with Section 6.2.1(a) (Local Manufacturing). In such case, the Parties will develop a draft Manufacturing Technology

Transfer Plan at a time to be agreed by the JSC, which will in any event be with sufficient time so that Partner can be the Marketing Authorization Holder for the Licensed Product throughout the Territory or, if a Manufacturing Technology Transfer is not required for Partner to be the Marketing Authorization Holder for the Licensed Product throughout the Territory, no later than the date of submission of the first MAA for the Licensed Product in the PRC. The Parties will provide such initial draft of the Manufacturing Technology Transfer Plan to the JMC for review and discussion, and the JMC will provide such draft to the JSC to review, discuss, and determine whether to approve, which the JSC will do no later than [***] days following the JMC's provision of such draft to the JSC. If the JSC determines that Partner will itself Manufacture the Licensed Product, then following the approval of the Manufacturing Technology Transfer Plan for the Licensed Product, the Parties will use reasonable efforts to complete the Manufacturing Technology Transfer for the Licensed Product on a timely basis and in accordance with the terms of such Manufacturing Technology Transfer Plan.

4.2.4. **Manufacturing Technology Transfer Costs**. Subject to Section 4.4 (Technology Transfer Costs), Partner will be solely responsible for any and all costs and expenses relating to the Manufacturing Technology Transfer for the Licensed Product, whether to those CMOs selected by Partner or, if agreed by the JSC, to Partner, including any costs imposed by any CMO engaged by Kiniksa for the Manufacture of the Licensed Product relating to the transfer to those CMOs selected by Partner to Manufacture the Licensed Product for use by Partner in the Territory (or to Partner, if approved by the JSC).

4.3. **Continuing Know-How Transfer**. Following the Initial Know-How Transfer for the Licensed Product, Kiniksa will provide to the JDC in advance of the last JDC meeting each Calendar Quarter or more frequently as agreed by the Parties, a summary of any additional Kiniksa Know-How that is [***] for Partner's performance of Clinical Development, Pre-Clinical Development (to the extent permitted in accordance with Section 5.2.2 (Territory Pre-Clinical Development)) Medical Affairs, or Commercialization of the Licensed Product in the Field in the Territory in accordance with this Agreement, in each case, developed by or that comes into the Control of Kiniksa or its Affiliates since the previous quarterly disclosure. Following the completion of the Manufacturing Technology Transfer, Kiniksa will provide to the JDC in advance of the last JDC meeting each Calendar Quarter or more frequently as agreed by the Parties, a summary of any additional Kiniksa Manufacturing Know-How that is [***] for Partner's performance of Manufacturing of the Licensed Product in the Field in the Territory in accordance with this Agreement, in each case, developed by or that comes into the Control of Kiniksa or its Affiliates since the previous quarterly disclosure. Upon Partner's reasonable request (a) during the Term (and no later than [***] days after any such reasonable request), Kiniksa will make available to Partner all such Kiniksa Know-How in Kiniksa's or its Affiliates' possession and not previously provided to Partner hereunder and (b) following completion of the Manufacturing Technology Transfer (and no later than [***] days after any such reasonable request), Kiniksa will make available to Partner all such Kiniksa Manufacturing Know-How in Kiniksa's or its Affiliates' possession and not previously provided to Partner hereunder (the "**Continuing Know-How Transfer**," and together with the Initial Know-How Transfer and the Manufacturing Technology Transfer, the "**Technology Transfer**").

4.4. **Technology Transfer Costs**. Kiniksa will provide consultation and assistance with qualified personnel in connection with the Technology Transfer for the Licensed Product as reasonably requested by Partner and as reasonably necessary to accomplish each of the Initial Know-How Transfer and the Manufacturing Technology Transfer, in each case, in accordance with the terms of this Agreement. Except for the internal costs associated with the first [***] FTE hours incurred by Kiniksa in connection with the Initial Know-How Transfer, Partner will reimburse Kiniksa for

(a) internal costs (at the FTE Rate) of such consultation and assistance for the Licensed Product and (b) all out-of-pocket costs, in each case ((a) and (b)), reasonably incurred by or on behalf of Kiniksa in connection with such assistance for the Initial Know-How Transfer, and the Manufacturing Technology Transfer, and the Continuing Know-How Transfer within [***] days after receiving Kiniksa's invoice therefor.

ARTICLE 5
DEVELOPMENT PROGRAM

5.1. Development Diligence and Responsibilities. Subject to the terms of this Agreement, Partner will be responsible for and will use Commercially Reasonable Efforts to Clinically Develop and seek, obtain, and maintain Regulatory Approval for the Licensed Product in each Indication included in the Territory Development Plan in each country or region in the Territory ("**Territory Development**"). Without limiting the generality of the foregoing, Partner will use Commercially Reasonable Efforts (a) to perform the activities set forth in, and perform Territory Development of the Licensed Product in accordance with, the Territory Development Plan for the Licensed Product and achieve the objectives set forth therein, and (b) solely to the extent Partner has agreed, following review and discussion by the JSC, to serve as the Territory Sponsor for a given Global Clinical Trial under the Global Development Plan, conduct the tasks assigned to Partner in the Global Development Plan in accordance with Section 5.3 (Global Development Plan).

5.2. Territory Development Plan.

5.2.1. **Territory Clinical Development**. Except for the activities assigned to Partner under a Global Development Plan for the Licensed Product pursuant to Section 5.3 (Global Development Plan), all Clinical Development of the Licensed Product in the Territory by or on behalf of Partner will be conducted pursuant to a written development plan agreed by the JDC and approved by the JSC (as updated from time to time in accordance with this Section 5.2.1 (Territory Clinical Development) and Section 3.2 (Joint Steering Committee), the "**Territory Development Plan**"), and Partner will be primarily responsible for all Clinical Trials for the Licensed Product that are conducted only at clinical trial sites in the Territory. The initial Territory Development Plan for the Licensed Product is set forth on Schedule 5.2 (Territory Development Plan) attached hereto. The Territory Development Plan and all updates thereto will contain in reasonable detail (a) [***], (b) [***], (c) [***], and (d) [***]. In addition, at least annually during the Term or more frequently as may be necessary to include any New Territory-Specific Development Activities, the JDC will propose updates to each Territory Development Plan and submit such proposed updated Territory Development Plan to the JSC. The JSC will review, discuss, and determine whether to approve any and all such updates to the Territory Development Plan. Once approved by the JSC, each update to the Territory Development Plan will become effective and supersede the then-current Territory Development Plan. Notwithstanding any provision to the contrary set forth in this Agreement, including Partner's final decision-making authority under Section 3.7.2(b) (Partner Final Decision-Making Authority), the Territory Development Plan and all updates thereto must be consistent with the Global Development Plan for the Licensed Product, except as provided in Section 5.4 (New Development by Partner). In the event of any conflict or inconsistency between the Territory Development Plan and the Global Development Plan, the Global Development Plan will control and take precedence.

5.2.2. **Territory Pre-Clinical Development**. In connection with the Clinical Development of the Licensed Product pursuant to a given Territory Development Plan, Partner may

identify, on a country-by-country or region-by-region basis, certain Pre-Clinical Development that is required in order to obtain Regulatory Approval of the Licensed Product in such country or region ("**Required Pre-Clinical Development**"). [***] If the JSC approves a Pre-Clinical Development Plan, then Kiniksa will have [***] days following the date of such approval by the JSC to determine whether it will either perform or permit Partner to perform such Required Pre-Clinical Development in accordance with the Pre-Clinical Development Plan. If Kiniksa elects to perform such Required Pre-Clinical Development, then Kiniksa will (a) provide to Partner a budget for such Pre-Clinical Development, to be included under the Pre-Clinical Development Plan, (b) use reasonable efforts to perform the Required Pre-Clinical Development in accordance with the applicable Pre-Clinical Development Plan (including the budget therein), and (c) deliver all results therefrom to Partner in accordance with Section 4.3 (Continuing Know-How Transfer) or as otherwise specified in the Pre-Clinical Development Plan. Partner will reimburse Kiniksa for its documented costs and expenses incurred performing such Required Pre-Clinical Development. If Kiniksa elects not to perform the Required Pre-Clinical Development as set forth in the applicable Pre-Clinical Development Plan, or fails to notify Partner of its decision within such [***] day time period, then (i) Partner will have the right to perform, at its cost and expense, the Required Pre-Clinical Development in accordance with the applicable Pre-Clinical Development Plan, and (ii) only in such case, will Partner have the right to practice under the non-exclusive license under the Kiniksa Technology granted pursuant to Section 2.1 (Licenses Granted to Partner) solely with respect to the performance of the Pre-Clinical Development in accordance with the applicable Pre-Clinical Development Plan.

5.3. **Global Development Plan**. The Parties' global Development of the Licensed Product inside and outside of the Territory will be conducted pursuant to a written plan (as updated from time to time in accordance with this Section 5.3 (Global Development Plan), the "**Global Development Plan**"). The initial Global Development Plan for the Licensed Product is set forth on Schedule 5.3 (Global Development Plan) attached hereto. Other than any Clinical Development for the Licensed Product to be performed by Partner under the Global Development Plan (if Partner either requests or is requested to serve as Territory Sponsor, and agrees, following review and discussion by the JSC, to serve as the Territory Sponsor for such trials in accordance with this Agreement), Kiniksa will have the right to conduct all Development activities for the Licensed Product, including all non-clinical and preclinical studies for the Licensed Product worldwide, pursuant to the Global Development Plan (and solely pursuant to the Global Development Plan as it relates to the Territory) and will have the exclusive right to conduct Development activities for the Licensed Product outside the Territory. In addition to Partner's exclusive right to conduct Territory Development activities for the Licensed Product included in the Territory Development Plan, Partner will have the right to request (or to consent, if Kiniksa so requests of Partner), in each case, following review and discussion by the JSC, and permitted under Applicable Law (and subject to Partner agreeing to bear its share of costs for such Global Clinical Trial in accordance with Section 5.7.2 (Global Development Costs)), to support the global Development of the Licensed Product by serving as Territory Sponsor for and otherwise participating in the conduct of certain Global Clinical Trials, including, to the extent practicable, any Ongoing Global Clinical Trial, and other Clinical Development activities in the Territory as set forth in, and in accordance with, the Global Development Plan. Following any determination that Partner will serve as Territory Sponsor for a given Global Clinical Trial:

(a) the JSC will discuss and determine whether to add any additional countries or regions in the Territory to those countries and regions in the Territory first proposed by Kiniksa in the Global Development Plan as countries in which such

Global Clinical Trial will be conducted (the countries in the Territory in which the Global Clinical Trial will be conducted, the "**Selected Territory GCT Countries**") and, unless Applicable Law prevents the conduct of such Global Clinical Trial in the PRC, the Selected Territory GCT Countries will include the PRC,

(b) if the PRC is a Selected Territory GCT Country, then the protocol for such Global Clinical Trial will contemplate the enrollment of a sufficient number of patients in the PRC to support the submission of an MAA for the Licensed Product in the applicable Indication in the PRC, and

(c) unless otherwise agreed by the JSC, the Global Development Plan will not require Partner to enroll more than [***]% of the total number of patients contemplated in the applicable protocol for such Global Clinical Trial (and nothing set forth herein will require Kiniksa to otherwise increase the total number of patients contemplated in the applicable protocol for such Global Clinical Trial).

Kiniksa will not approach any other Third Party to serve as the Territory Sponsor for any Global Clinical Trial in the Territory without first offering such opportunity to Partner. The Global Development Plan and each update thereto will include: (i) an outline of all major Development activities for the Licensed Product to be conducted worldwide by Kiniksa, and (ii) for those Global Clinical Trials in which Partner agrees to participate and serve as Territory Sponsor in accordance with the terms set forth in this Agreement, details and estimated timelines of the Clinical Development activities to be conducted in the Selected Territory GCT Countries and assigned to Partner to support Global Clinical Trials or other global Development for the Licensed Product, which activities will, unless otherwise agreed to by Partner, be designed to support the filing of the Marketing Authorization Applications within the Territory for the Licensed Product. From time to time, Kiniksa may make and implement updates to the then-current Global Development Plan for the Licensed Product, including to contemplate the conduct of the Development of the Licensed Product for a New Development. Solely to the extent such amendments (A) are material (in cost, time, and scope), and (B) include activities to be conducted by Partner in the Territory, Kiniksa or the JDC (as applicable) will submit such proposed updates to the JSC to review, discuss, and determine whether to approve.

5.4. **New Development by Partner**. Notwithstanding Partner's final decision-making authority with respect to Development activities for the Licensed Product that are Territory-specific as set forth in Section 3.7.2(b) (Partner Final Decision-Making Authority), if Partner proposes to perform any Clinical Trials for or otherwise Develop (a) a new formulation of the Licensed Product, (b) any new combination regimen or fixed dose combination for the Licensed Product and another agent, or (c) the Licensed Product in a new Indication, in each case ((a), (b), and (c)) that is not already the subject of the Global Development Plan or Territory Development Plan ("**New Development**") for the Territory, then Partner will present to the JSC to review, discuss, and determine whether to approve a proposal to add such Development activities for such New Development to the Territory Development Plan for the Licensed Product, including the countries or regions in the Territory in which such activities would be conducted (a "**New Development Proposal**"). Each New Development Proposal will describe in reasonable detail the applicable Clinical Trials that Partner desires to conduct with respect to such New Development, including a synopsis of the trial or activities, the proposed enrollment criteria, the number of patients to be included, the endpoints to

be measured, and the statistical design and powering (the "**New Development Activities**"), as well as a proposed timeline and budget and an analysis of the business opportunity and revenue potential anticipated to result from such New Development Activities. The JSC will review, discuss, and determine whether to approve a New Development Proposal within [***] days after receipt thereof from Partner. Upon such an approval, (a) the New Development Activities set forth in such New Development Proposal will be "**New Territory-Specific Development Activities**" for purposes of this Agreement, and (b) the JDC will update the Territory Development Plan for the Licensed Product to include such New Territory-Specific Development Activities for those countries or regions in the Territory agreed by the JSC, including the proposed timelines, in each case, for such New Development Activities set forth in such New Development Proposal (as may be amended by the JSC upon such approval). Any New Territory-Specific Development Activities included in a Territory Development Plan pursuant to this 5.4 (New Development by Partner) will be Development activities for all purposes under this Agreement.

5.5. **New Development by Kiniksa**. If Kiniksa proposes any Global Clinical Trials for the Licensed Product for any New Development, then:

5.5.1. **Right to Develop**. Subject to the terms of Section 5.3 (Global Development Plan), if Partner (either itself or through its Affiliate) does not elect to serve as the Territory Sponsor or regulatory agent for any such Global Clinical Trials for such New Development in all countries or regions in the Territory in which Kiniksa proposes to perform such Global Clinical Trials pursuant to Section 5.3(a) (Global Development Plan), then:

(a) Partner will not be obligated to implement such Global Clinical Trials in any such country or region in the Territory or perform any activities in connection therewith, and

(b) notwithstanding any provision to the contrary set forth in this Agreement (including the terms of Section 2.1 (License Grants to Partner)), unless Partner subsequently elects to (and does) reimburse Kiniksa for the costs and expenses of such Global Clinical Trials for the Licensed Product in accordance with Section 5.5.3(b) (Reimbursement at a Premium), Partner will not have any rights with respect to any data or results generated in such Global Clinical Trials for such New Development, including pursuant to Section 5.11 (Data Exchange and Use) or Section 6.5 (Right of Reference) except as necessary for Partner to comply with Applicable Law or safety reporting requirements to applicable Regulatory Authorities in the Territory, and

(c) Kiniksa will have the right to conduct such Global Clinical Trials for the Licensed Product for such New Development globally (including in the Territory), at Kiniksa's cost and expense.

Notwithstanding any provision to the contrary set forth in this Agreement, if Partner agrees to act as Territory Sponsor or regulatory agent throughout the Selected Territory GCT Countries for a given Global Clinical Trial, but is prevented by Applicable Law from participating in such Global Clinical Trial for such New Development in the PRC and instead conducts a Pivotal Clinical Trial within the PRC with respect to such New Development for the submission of a MAA for the PRC with respect to such New Development, then (i) the foregoing restriction on access to data or results generated in such Global Clinical Trials for such New Development, including pursuant to Section 5.11 (Data Exchange and

Use), and (ii) the obligation to reimburse a percentage of the costs and expenses of such Global Clinical Trial in order to obtain access to such data and results, pursuant to Section 5.5.3 (Partner Sharing of Development Costs and Data Access), will not apply and such data and results will be included within Partner's right of reference pursuant to Section 6.5 (Right of Reference).

5.5.2. **Partner Assistance**. If Partner (either itself or through its Affiliate) elects to serve as the Territory Sponsor or regulatory agent in the Territory for, and enroll and treat patients in, any such Global Clinical Trials for a New Development, then such Partner activities will be added to the Global Development Plan and submitted to the JSC for approval in accordance with Section 5.3 (Global Development Plan).

5.5.3. **Partner Sharing of Development Costs and Data Access**.

(a) **Ongoing Reimbursement**. If Partner (either itself or through its Affiliate) elects to serve as the Territory Sponsor or regulatory agent in all Selected Territory GCT Countries for a New Development, then Partner will be granted rights with respect to any and all data or results generated in such Global Clinical Trials for the Licensed Product pursuant to Section 5.11 (Data Exchange and Use) and under Section 6.5 (Right of Reference), if, prior to the Initiation of such Global Clinical Trial for the Licensed Product (or, as of the Effective Date with respect to any Ongoing Global Clinical Trials), Partner agrees in writing to bear [***]% of the documented costs and expenses that are incurred by or on behalf of the Parties to conduct such Global Clinical Trial in the Selected Territory GCT Countries (including for all clinical sites in the Selected Territory GCT Countries and enrollment of the patients in the Selected Territory GCT Countries, as set forth in the Global Development Plan), any other Development costs or expenses associated therewith, and the Fully Burdened Manufacturing Cost of the Licensed Product used in the Selected Territory GCT Countries in such Global Clinical Trial.

(b) **Reimbursement at a Premium**. If Partner (either itself or through its Affiliate) either:

(i) elects to serve as the Territory Sponsor or regulatory agent in all Selected Territory GCT Countries, but does not bear [***]% of the costs and expenses incurred by or on behalf of the Parties in the conduct of such Global Clinical Trial in all such Selected Territory GCT Countries, any other Development costs or expenses associated therewith, and the Fully Burdened Manufacturing Cost of the Licensed Product used for such Global Clinical Trial as set forth above in Section 5.5.3(a) (Ongoing Reimbursement) or

(ii) does not elect to serve as the Territory Sponsor or regulatory agent in all Selected Territory GCT Countries for any such Global Clinical Trials and to bear [***]% of the costs and expenses incurred by or on behalf of the Parties in the conduct of such Global Clinical Trials in all such Selected Territory GCT Countries, any other Development costs or expenses associated therewith, and the Fully Burdened Manufacturing Cost of the Licensed Product used for such Global Clinical Trial as set forth above in Section 5.5.3(a) (Ongoing Reimbursement), then, in each case ((i) and (ii)), if Partner wishes to be granted rights with respect to any data or

results generated in such Global Clinical Trial for the Licensed Product for such New Development for the Territory, including pursuant to Section 5.11 (Data Exchange and Use) or Section 6.5 (Right of Reference), then unless otherwise agreed by the Parties, upon the receipt of the first Regulatory Approval for the Licensed Product for such New Development in the U.S. or any country or region in the Territory, Partner must:

(A) reimburse Kiniksa, in case (ii), for [***]% of all costs and expenses incurred by or on behalf of Kiniksa in the conduct of such Global Clinical Trial for the Licensed Product, including the Fully Burdened Manufacturing Cost of the Licensed Product used for such Global Clinical Trial, and reimburse Kiniksa, in case (i), for [***]% of all costs and expenses of such Global Clinical Trial solely in the Selected Territory GCT Countries for the Licensed Product and any other Development costs or expenses associated therewith, including the Fully Burdened Manufacturing Cost of the Licensed Product used for such Global Clinical Trial and other Development activities for the Selected Territory GCT Countries, which costs and expenses are incurred by or on behalf of Kiniksa as a result of Partner's failure to bear such costs in accordance with Section 5.5.3(a) (Ongoing Reimbursement), *plus*, in each case ((i) and (ii)), a [***]% mark-up with respect to all such costs and expenses, and

(B) pay to Kiniksa any Development Milestone Payment that would have been payable with respect to such Global Clinical Trial pursuant to Section 10.2.1 (Development Milestone Events and Payments) had Partner participated in such Global Clinical Trial.

(c) Notwithstanding any provision to the contrary in this Section 5.5.3 (Partner Sharing of Development Costs and Data Access), if Partner has elected to serve as the Territory Sponsor for a given Global Clinical Trial but Partner is prevented from selecting certain country(ies) in the Territory as Selected Territory GCT Countries in one or more Indications pursuant to Section 3.7.2(b)(iii)(A) or Section 3.7.2(b)(iii)(B) (Partner Final Decision-Making Authority), then, if Partner is required to perform a Territory-Specific Clinical Trial in order to obtain Regulatory Approval of the Licensed Product and does perform such Territory-Specific Clinical Trial in such country(ies) in such Indications, Partner will be granted rights with respect to any and all data or results generated in such Global Clinical Trials for the Licensed Product in such indications pursuant to Section 5.11 (Data Exchange and Use) and under Section 6.5 (Right of Reference) and will not be obligated to pay to Kiniksa the amounts due under this Section 5.5.3 (Partner Sharing of Development Costs and Data Access) with respect to such indications.

5.6. Standard of Conduct.

5.6.1. **General Obligations**. Partner will perform, and will cause its Affiliates, Sublicensees, and Subcontractors to perform, all Development activities for the Licensed Product in a timely and professional manner, and in compliance with the Territory Development Plan, Global Development Plan, or Pre-Clinical Development Plan, as applicable, and all

Applicable Law, including as applicable cGLP, cGCP, and cGMP. In addition, each Party will conduct its obligations with respect to any Global Clinical Trial under a Global Development Plan, Pre-Clinical Development Plan, or (with respect to Partner) Territory-Specific Clinical Trial under a Territory Development Plan (as applicable) in strict adherence with the study design set forth in the applicable protocol therefor and as set forth in such Global Development Plan or such Territory Development Plan, each as may be amended from time to time, and will comply with each statistical analysis plan implemented by the other Party (as applicable) in connection therewith.

5.6.2. **Global Development**. Kiniksa agrees that if Kiniksa or its Affiliates fail to perform one or more Global Clinical Trials as set forth in any Global Development Plan in accordance with the study design set forth in the protocol(s) therefor, then, to the extent that, as a direct result of such failure, Partner is unable to complete its obligations under the Global Development Plan (if Partner is participating as Territory Sponsor) or any Territory Development Plan, Partner will not be in breach of its diligence obligations under Section 5.1 (Development Diligence and Responsibilities) with respect to such failure to perform its obligations under the Global Development Plan or Territory Development Plan, as applicable, as a result of Kiniksa's failure to perform.

5.7. Responsibility for Development Costs.

5.7.1. **Territory-Specific Development Costs**. Except as otherwise set forth in this Agreement, and otherwise subject to Section 5.3 (Global Development Plan) and Section 5.5 (New Development by Kiniksa), Partner will be solely responsible for all costs and expenses incurred by or on behalf of Partner in connection with the Territory Development of the Licensed Product, including the performance of Territory Development activities for the Licensed Product under each Territory Development Plan, including all local studies necessary for Regulatory Approval of the Licensed Product in the Territory. In addition, Partner will be responsible for all costs arising from any compassionate use or open protocols arising from the Territory Development of the Licensed Product to the extent required by applicable Regulatory Authority in any country or region in the Territory.

5.7.2. **Global Development Costs**. Except as provided in this Section 5.7.2 (Global Development Costs), Kiniksa will be solely responsible for all costs and expenses incurred in connection with the Development of Licensed Product pursuant to the Global Development Plan and for the purpose of obtaining Regulatory Approvals and Reimbursement Approvals outside the Territory. Notwithstanding the foregoing, except as otherwise set forth in this Agreement, and only if Partner elects to serve as the Territory Sponsor in accordance with Section 5.3 (Global Development Plan) and Section 5.5 (New Development by Kiniksa), Partner will be responsible for and will pay (a) for all costs and expenses incurred in the furtherance of the conduct of any Global Clinical Trial in the Selected Territory GCT Countries and any other Clinical Development activities in the Selected Territory GCT Countries, to the extent assigned to Partner under the Global Development Plan, and (b) all other costs and expenses incurred by or on behalf of Partner in connection with the performance of any Clinical Development activities in the Selected Territory GCT Countries assigned to Partner under any Global Development Plan. Kiniksa will invoice Partner quarterly for the foregoing costs incurred by or on behalf of Kiniksa in such Calendar Quarter, and Partner will pay the undisputed invoiced amounts within [***] days after the date of any such invoice.

5.8. Clinical Trial Audit Rights.

5.8.1. **Conduct of Audits**. Upon at least [***] days' prior notice by Kiniksa and no more frequently than [***] in each Calendar Year, at Kiniksa's cost and expense, Kiniksa or its representatives may conduct an audit of Partner, its Affiliates, or any Sublicensees, Subcontractors, and all Clinical Trial sites engaged by Partner or its Affiliates or Sublicensees to perform Partner's obligations under the Global Development Plan or Territory Development Plan, in each case, to determine whether the applicable Global Clinical Trials and Territory-Specific Clinical Trials are being conducted in compliance with the terms of the Third Party IP Agreements, this Agreement, the Global Development Plan (if Partner is serving as the Territory Sponsor) or Territory Development Plan, cGLP, cGMP, cGCP, and Applicable Law and meet Kiniksa's Global Clinical Trial standards provided by Kiniksa from time to time during the Term (which standards will be made known to Partner or included in the Global Development Plan or Territory Development Plan as applicable). Notwithstanding any provision to the contrary set forth in this Agreement, there will be no limit on the number of "for cause" audits that Kiniksa may conduct of Partner, its Affiliates, or any Sublicensees, Subcontractors, and all Clinical Trial sites engaged by Partner or its Affiliates or Sublicensees to perform Partner's obligations under the Global Development Plan or Territory Development Plan, and Kiniksa will use reasonable efforts to notify Partner in writing of any "for cause" audit at least [***] Business Days in advance thereof. After preparing or receiving an audit report, Kiniksa will provide Partner with a written summary of Kiniksa's findings of any material deficiencies from such standards or other areas of remediation that Kiniksa identifies during any such audit. Partner will remediate any such undisputed deficiencies no later than [***] days after Partner's receipt of such report, at Partner's cost and expense or, if such remediation is anticipated to take longer than [***] days, then Partner will promptly implement a plan to complete such remediation as soon as practicable. If any material undisputed deficiencies or areas of remediation are identified in the course of such audit, then Partner will reimburse Kiniksa for Kiniksa's costs and expenses relating to the conduct of such audit within [***] days after receiving Kiniksa's invoice therefor. If Partner disputes any of Kiniksa's findings of deficiencies, then either Party may refer the issue to an independent Third Party regulatory compliance consultant expert agreed by both Parties for resolution. The decision of such independent expert will be final and binding and all fees and expenses of such independent expert will be borne by the Party against which the decision is rendered by the independent Third Party expert.

5.8.2. **Deficient Sublicensees or Sites and Replacement**. With respect to any Global Clinical Trial or Territory-Specific Clinical Trial, if any audit of a Clinical Trial site conducted pursuant to Section 5.8.1 (Conduct of Audits) identifies any non-compliance by such Clinical Trial site with the Third Party IP Agreements, this Agreement, the Global Development Plan (only if Partner has elected to serve as the Territory Sponsor) or Territory Development Plan, cGLP, cGMP, cGCP, Applicable Law, or Kiniksa's Global Clinical Trial standards provided by Kiniksa in accordance with Section 5.8.1 (Conduct of Audits) (each, a "**Deficient Site**") that may reasonably cause a Regulatory Authority to reject or otherwise deem deficient the Clinical Trial data from Partner's conduct of any such Global Clinical Trial or Territory-Specific Clinical Trial (as applicable) at such Deficient Site, then subject to Partner's right to remediate under Section 5.8.1 (Conduct of Audits), if Partner is unable to successfully remediate the situation in a timely manner and reasonably eliminate the condition causing the Clinical Trial site to be a Deficient Site, then Partner will promptly remove such Deficient Site from the applicable Global Clinical Trial or Territory-Specific Clinical Trial and replace such Deficient Site with a new Clinical Trial site (a "**Replacement Site**") within the Territory at Partner's sole cost and expense (unless not permitted by Applicable Law or for ethical reasons). Any such

Replacement Site will be compliant in all respects with Applicable Law and Kiniksa's Global Clinical Trial standards provided by Kiniksa from time to time during the Term. In addition, if any audit of any Sublicensee conducted pursuant to Section 5.8.1 (Conduct of Audits) identifies that any Sublicensee (including any contract research organizations or other subcontractors engaged to perform activities under the Global Development Plan or Territory Development Plan) is not performing its activities in accordance with the terms of the Third Party IP Agreements, this Agreement, the Global Development Plan or Territory Development Plan, cGLP, cGMP, or cGCP, as applicable, and Applicable Law or do not meet Kiniksa's Global Clinical Trial standards provided by Kiniksa in accordance with Section 5.8.1 (Conduct of Audits), or that any deficiencies identified as a result of any such audit related to any such Sublicensee's performance may cause a Regulatory Authority to reject or otherwise deem deficient the Clinical Trial data from Partner's conduct of any such Global Clinical Trial or Territory-Specific Clinical Trial (as applicable) (each, a "**Deficient Sublicensee**"), then Partner will promptly (a) require such Deficient Sublicensee to remediate such deficiencies in a timely manner or (b) remove such Deficient Sublicensee from performing further activities under the Global Development Plan or Territory Development Plan and replace such Deficient Sublicensee with a new Sublicensee engaged in accordance with Section 2.2 (Sublicensing and Subcontractors) to perform the applicable Development activities at Partner's sole cost and expense unless such deficiencies can be promptly remedied to Kiniksa's reasonable satisfaction in a timely manner. If the Deficient Sublicensee is unable to mitigate the deficiencies in a timely manner or Partner is unable to mitigate the deficiencies or replace any Deficient Site with a Replacement Site or Deficient Sublicensee with a replacement Sublicensee (as applicable), as applicable, or, in Kiniksa's reasonable discretion, the Deficient Sublicensee or Partner, as applicable, is unable to mitigate the deficiencies or replace any Deficient Site or Deficient Sublicensee, as applicable, in a timely manner so as not to jeopardize the Parties' ability to meet the timelines for Regulatory Submissions set forth in the Territory Development Plan, then, in each case, Kiniksa may (i) replace such Deficient Site with one or more Replacement Sites outside of the Territory, or (ii) with respect to a Deficient Sublicensee, perform itself or have performed by any Third Party engaged by Kiniksa in its sole discretion, the applicable Development activities, and in each case ((i) and (ii)), Partner will be responsible for all costs and expenses incurred by or on behalf of Kiniksa in connection with the engagement of any such Replacement Site or replacement Sublicensee. Kiniksa will invoice Partner quarterly for the foregoing costs incurred by or on behalf of Kiniksa in such Calendar Quarter, and Partner will pay the amount invoiced within [***] days after the date of any such invoice.

5.8.3. **Partner Audits**. Partner will provide Kiniksa with copies of all quality oversight or audit reports prepared in connection with any audit that Partner or its Affiliates or Sublicensees conduct of any Sublicensee, Subcontractor, or Clinical Trial site that Partner or its Affiliates or Sublicensees have engaged or are evaluating to potentially engage to fulfill Partner's obligations under a Global Development Plan or a Territory Development Plan no later than [***] days after receiving or preparing any such report (as applicable), and Kiniksa may provide any such reports to any counterparty to any Third Party IP Agreement if required by the terms of any such Third Party IP Agreement. If Kiniksa believes in good faith that it is required to submit any such quality oversight or audit report to any Regulatory Authority outside of the Territory in connection with obtaining, supporting, or maintaining one or more Regulatory Approvals for the Licensed Product or for other communications with Regulatory Authorities for the Licensed Product outside of the Territory, then upon Kiniksa's request, Partner will provide a copy of any such quality oversight or audit report to Kiniksa and Partner will reimburse Kiniksa for any translation

expenses reasonably incurred by Kiniksa to obtain translation thereof by translators selected by Kiniksa.

5.9. **Development Records**. Partner will, and will cause its Affiliates, Sublicensees, and Subcontractors to, maintain reasonably complete, current, and accurate records of all Development activities conducted by or on behalf of Partner, and its Affiliates, Sublicensees, and Subcontractors, respectively, pursuant to this Agreement and all data and other information resulting from such activities consistent with its usual practices, in validated computer systems that are compliant with 21 C.F.R. §11 and in accordance with Applicable Law of both the United States and the Territory. Partner will maintain all such records for a period of [***] years after the end of the Term. Such records will fully and properly reflect all work done and results achieved in the performance of the Development activities for the Licensed Product in good scientific manner appropriate for regulatory and patent purposes and may record only activities performed under this Agreement and not include or be comingled with records of activities not conducted under this Agreement. Partner will document all non-clinical and preclinical studies and Clinical Trials in formal written study reports in accordance with cGLP, cGMP, and cGCP, as applicable, and in compliance with Applicable Law. Upon Kiniksa's reasonable request, not more frequently than once each Calendar Quarter during which Partner or its Affiliates, Sublicensees, or Subcontractors are performing or having performed Development activities for the Licensed Product, Partner will, and will cause its Affiliates, Sublicensees, and Subcontractors to, allow Kiniksa to access, review, and copy such records (including access to relevant databases). Kiniksa and its Affiliates, licensees, licensors, and Sublicensees will have the right to use the data and results generated by or on behalf of Partner and its Affiliates, Sublicensees, and Subcontractors hereunder to Exploit the Licensed Product outside of the Territory and to perform Development activities under a Global Development Plan. Partner will transmit all records or other documents to Kiniksa electronically under this Agreement over secure systems that include adequate encryption safeguards to prevent unauthorized access and maintain data security.

5.10. **Development Reports**. No later than the end of each Calendar Quarter during which Partner is performing, or having performed, Development activities for the Licensed Product, and solely to the extent Partner has not already made a report to the JDC concerning its Development activities, Partner will provide Kiniksa, at Partner's sole cost and expense, with reasonably detailed written reports summarizing the Development activities performed during the period since the preceding report, the Development activities in process, and the future activities that Partner or its Sublicensees or Subcontractors expect to initiate, including a summary of the data, timelines, and results of such Development activities. Such reports will be in English. Partner will also establish a secure link that includes adequate encryption safeguards to provide solely to Kiniksa electronic access to such information. Without limiting the foregoing, such reports will contain sufficient detail to enable Kiniksa to assess Partner's compliance with its Development diligence obligations set forth in Section 5.1 (Development Diligence and Responsibilities) and progress towards obtaining Regulatory Approval for the Licensed Product, including under the then-current Territory Development Plan. Partner will promptly respond to Kiniksa's reasonable requests from time to time for additional information regarding significant Development activities for the Licensed Product performed by or on behalf of Partner or its Affiliates, Sublicensees, or Subcontractors. The Parties will discuss the status, progress, and results of all Development activities at each JDC and JSC meeting. Such reports will be the Confidential Information of each Party and subject to the terms of Article 11 (Confidentiality; Publication).

5.11. **Data Exchange and Use**. In addition to its adverse event and safety data reporting obligations set forth in Section 6.6 (Adverse Events Reporting), each Party will promptly provide the other Party, through the JDC, with copies of all data and results and all supporting documentation (*e.g.*,

protocols, Investigator's Brochures, case report forms, and analysis plans, all in English language) Controlled by such Party that are generated by or on behalf of such Party or its Affiliates, Sublicensees, or Subcontractors, if applicable, in the Development of the Licensed Product, including all data and results (or on whose behalf such data and results are generated) in the course of conducting such non-clinical or preclinical studies or Clinical Trials for the Licensed Product. Such data, results, and supporting documentation provided by a Party pursuant to this Section 5.11 (Data Exchange and Use) will be the Confidential Information of such Party, and such Party will be the Disclosing Party with respect thereto, in each case, subject to the terms of Article 11 (Confidentiality; Publication). Partner will not have the right to use or reference such data and results provided by Kiniksa or any data that constitutes Assigned Collaboration Know-How, unless and until Partner bears its applicable share of the costs and expenses in accordance with Section 5.5 (New Development by Kiniksa), in which case, Partner will have the exclusive right to use and reference such data and results for the purpose of performing Development activities in accordance with this Agreement (including under any Global Development Plan and Territory Development Plan), and obtaining, supporting, and maintaining Local Manufacturing Approvals, Regulatory Approvals, and any Reimbursement Approval, as applicable, of the Licensed Product in the Territory without additional consideration. Kiniksa and its designees will have the exclusive right to use and reference such data and results provided by Partner, for the purpose of Developing the Licensed Product, and obtaining, supporting, or maintaining Regulatory Approval or any Reimbursement Approval, as applicable, of the Licensed Product outside the Territory, without additional consideration.

ARTICLE 6
REGULATORY

6.1. **Regulatory Strategy**. The JDC will discuss and develop a regulatory strategy for the Licensed Product in each country or region in the Territory (which, strategy will include the estimated timeline for submission of MAAs for the Licensed Product in each country and region in the Territory) to be included in the Territory Development Plan and will submit the same to the JSC to review, discuss, and determine whether to approve. From time to time the JDC may update the regulatory strategy for the Licensed Product and submit the same to the JSC to review, discuss, and determine whether to approve. Once approved by the JSC, each update to a regulatory strategy for such the Licensed Product will become effective and supersede the then-current regulatory strategy for the Licensed Product.

6.2. **Partner's Responsibilities**.

6.2.1. **Obtaining and Maintaining Regulatory Approvals**. Through its reports submitted to the JDC, Partner will keep Kiniksa informed of regulatory developments related to the Licensed Product in each country and region in the Territory and will promptly notify Kiniksa in writing of any decision by any Regulatory Authority in the Territory regarding the Licensed Product.

(a) **Local Manufacturing**. At a time to be agreed by the JSC, which in all cases will be no later than [***] years after the commencement of the Manufacturing Technology Transfer for the Licensed Product, Partner, through one or more CMOs selected by Partner (or by Partner itself, if agreed by the JSC), will Manufacture the Licensed Product in the Territory for use in the Territory and Kiniksa will have no further obligations to supply to Partner Licensed Product. Upon such agreement by the JSC and following completion of the Manufacturing Technology Transfer for the Licensed Product and receipt of all approvals and

authorizations necessary for the applicable CMOs (or Partner, if agreed by the JSC) to Manufacture the Licensed Product (or any component thereof) in the Territory (including after validation and qualification of such CMOs' applicable facilities in the Territory) ("**Local Manufacturing Approval**"), Partner or one of its Affiliates will be responsible for all regulatory activities and interactions with Regulatory Authorities in the Territory leading up to and including obtaining (to the extent not already obtained) and thereafter maintaining Local Manufacturing Approvals for such locally-Manufactured Licensed Product (or any component thereof) in the Territory in Partner's or its Affiliate's own name in accordance with the applicable regulatory strategy approved by the JSC. Prior to undertaking any such activities and interactions relating to obtaining and maintaining Local Manufacturing Approvals in the Territory, whether prior to or after the date of receipt of such Local Manufacturing Approvals for the Licensed Product (or any component thereof), Partner will submit a reasonably detailed plan for undertaking the same to the JSC to review, discuss, and determine whether to approve.

(b) **Other Regulatory Approvals**. Subject to this Section 6.2.1(b) (Other Regulatory Approvals), for each Indication that is included in the Territory Development Plan or Global Development Plan for the Licensed Product, Partner will be the marketing authorization holder and will be responsible for all regulatory activities leading up to and including obtaining, and thereafter maintaining, Regulatory Approvals and any Reimbursement Approvals in all countries and regions of the Territory, in its own name or in the name of its Affiliate, Sublicensee, or Third Party Distributor. If it is not feasible for Partner to own any such Regulatory Submissions, Regulatory Approvals, or Reimbursement Approvals in its own name according to the relevant Applicable Laws in the Territory, then (i) Kiniksa will hold such Regulatory Submissions, Regulatory Approvals, or Reimbursement Approvals in its own name for the benefit of and on behalf of Partner (in such case, Kiniksa will be the "**Marketing Authorization Holder**", which means the Party in whose name the Regulatory Approvals and Reimbursement Approvals for the Licensed Product in the Territory are held) and will appoint Partner as its legal agent in the Territory; (ii) without the prior written consent of Kiniksa, Partner will not conduct any activities or initiate any procedures that would affect the validity or change the information of such Regulatory Submissions, Regulatory Approvals, or Reimbursement Approvals; (iii) Kiniksa will reasonably cooperate with Partner and execute such documents and make such submissions on behalf of Partner as may be reasonably necessary or to the extent Kiniksa is required to do so as owner of such Regulatory Submissions, Regulatory Approvals, or Reimbursement Approvals under Applicable Law in the Territory; *provided* that Kiniksa will assume no liability as a result of being the Marketing Authorization Holder or otherwise holding such Regulatory Submissions (unless Kiniksa is grossly negligent or willfully breaches its obligations as the Marketing Authorization Holder), Regulatory Approvals, or Reimbursement Approvals on behalf of Partner; (iv) Partner will reimburse Kiniksa for Kiniksa's costs and expenses incurred in its acting as Marketing Authorization Holder within [***] days after the date of any invoice from Kiniksa for any such costs or expenses; and (v) when feasible pursuant to Applicable Law, Kiniksa will conduct activities and execute documents that are necessary for transferring such Regulatory Submissions, Regulatory Approvals, or Reimbursement Approvals to Partner upon Partner's written request.

6.2.2. **Partner Assistance outside the Territory**. Partner will reasonably cooperate to assist Kiniksa in its efforts to prepare and submit any Regulatory Submissions to obtain, support, or maintain Regulatory Approvals for the Licensed Product outside the Territory, including by providing to Kiniksa all data and documentation related to the Licensed Product generated by Partner or its Affiliates (which assistance and data generation must be in accordance with Applicable Law and all requirements and standards of the FDA) as well as any necessary samples and materials. Partner will invoice Kiniksa quarterly for the costs (at the FTE Rate) and expenses incurred by or on behalf of Partner in the performance of such activities during such Calendar Quarter, and Kiniksa will pay the undisputed invoiced amounts within [***] days after the date of any such invoice.

6.2.3. **Review of Regulatory Submissions**. Partner will provide to Kiniksa (through the JDC) for each of [***] (each a "**Key Country**"), and for each other country and region in the Territory upon Kiniksa's request, in each case, for review and comment, drafts of all Regulatory Submissions for which Partner is responsible and all proposed Approved Labeling in the Territory for the Licensed Product, including all INDs and MAAs for the Licensed Product in each Indication in each Key Country and, to the extent requested by Kiniksa for each other country or region in the Territory, and Partner will incorporate any reasonable comments received from Kiniksa on such drafts. The JDC will review any changes in regulatory strategy and, to the extent requested by Kiniksa, will discuss any Regulatory Submission for which Partner is responsible and all proposed Approved Labeling for the Licensed Product in each Key Country and, to the extent requested by Kiniksa for each other country or region in the Territory. Partner will incorporate any reasonable comments received from Kiniksa on such proposed Approved Labeling. Notwithstanding the foregoing, if any regulatory activities are conducted, or any Regulatory Submissions filed, in each case, in Kiniksa's name, then (a) Kiniksa will have final decision-making authority regarding all such regulatory activities, including the content of Regulatory Submissions for the Licensed Product in the Field in the Territory; *provided* that Kiniksa will reasonably consider any comments Partner may have regarding such regulatory activities; and (b) Partner will, and will ensure that its relevant Affiliates and Sublicensees will, conduct all regulatory activities in compliance with Kiniksa's final decisions. In addition, each Party will notify the other Party of any substantive Regulatory Submissions in the U.S. or in any country or region the Territory and proposed Approved Labeling for the Licensed Product and any comments or other substantive correspondences related thereto submitted to or received from any Regulatory Authority in the U.S. or in any country or region in the Territory and will provide the other Party with copies thereof as soon as reasonably practicable, but in all events within [***] days after submission or receipt thereof (or such longer time period as may be necessary to obtain translations thereof). If any such Regulatory Submission or proposed Approved Labeling, comment, or correspondence is not in English, then Kiniksa may obtain English translation thereof by translators selected by Kiniksa, at Kiniksa's sole cost and expense, unless Kiniksa is the Marketing Authorization Holder or any such Regulatory Submission or proposed Approved Labeling is otherwise in Kiniksa's name, in each of which cases Kiniksa will invoice Partner for translation expenses with respect thereto and Partner will reimburse such undisputed invoiced amounts within [***] days after the date of any such invoice.

6.2.4. **Notice of Meetings**. Partner will provide Kiniksa with notice of any meeting or discussion with any Regulatory Authority in the Territory related to the Licensed Product no later than [***] Business Days after receiving notice thereof or in any event with as much advanced notice as is possible prior to such meeting or discussion if Partner receives notice thereof less than [***] Business Days in advance of the applicable meeting or discussion. Partner

(or its designee) will lead any such meeting or discussion and Kiniksa or its designee will have the right, but not the obligation, to attend and participate in any such meeting or discussion unless prohibited or restricted by Applicable Law or Regulatory Authority. Notwithstanding the foregoing, if any such meeting or discussion with a Regulatory Authority concerns the Licensed Product for which Kiniksa is the Marketing Authorization Holder from such Regulatory Authority at such time, then Kiniksa or its designee will have the further right, but not obligation, to lead such meeting or discussion. At Kiniksa's request, Kiniksa may participate in any preparations of Partner or its Affiliates or Sublicensees for any such meeting or discussion. If Kiniksa elects not to attend such meeting or discussion, then Partner will provide to Kiniksa a written summary thereof in English promptly following such meeting or discussion, as well as any minutes prepared by Partner or, to the extent available, formal minutes generated by the Regulatory Authority.

6.2.5. **Partner Responsibility for Costs and Expenses**. Irrespective of which Party is the Marketing Authorization Holder for the Licensed Product in the Territory, Partner will be responsible for all costs and expenses incurred in connection with the performance of all regulatory activities leading up to and including obtaining and thereafter maintaining, Local Manufacturing Approvals, Regulatory Approvals, and any Reimbursement Approvals, as applicable, for the Licensed Product from Regulatory Authorities in the Territory.

6.3. **Communications with Regulatory Authorities**. Unless otherwise agreed by the Parties (or unless otherwise set forth in this Agreement or in the applicable Global Development Plan), Partner will not, and will ensure that its Affiliates and its Sublicensees do not, communicate with any Regulatory Authority having jurisdiction outside of the Territory with respect to the Licensed Product, unless so ordered by such Regulatory Authority, in which case, Partner will immediately notify Kiniksa of such order.

6.4. **Kiniksa's Responsibilities**. Except with respect to the New Development of the Licensed Product for a Global Clinical Trial for which Partner does not agree to bear its share of costs and expenses as set forth under Section 5.5.3 (Partner Sharing of Development Costs and Data Access), Kiniksa will reasonably cooperate with Partner in obtaining any Regulatory Approvals and any Reimbursement Approvals, as applicable, for the Licensed Product in the Territory by providing access to Regulatory Approvals, Regulatory Submissions, other information, documentation, samples and materials for the Licensed Product, both inside and outside of the Territory, in each case, to the extent (a) Controlled by Kiniksa, (b) not previously provided to Partner, and (c) reasonably necessary for or requested by Partner to obtain Regulatory Approvals. Partner will reimburse Kiniksa's out-of-pocket costs reasonably incurred in connection with providing any such access or further assistance to Partner. Accordingly, Kiniksa will invoice Partner quarterly for the foregoing costs incurred by or on behalf of Kiniksa in such Calendar Quarter, and Partner will pay the undisputed invoiced amounts within [***] days after the date of any such invoice.

6.5. **Right of Reference**. Except with respect to the New Development of the Licensed Product for a Global Clinical Trial for which Partner does not agree to bear its share of costs and expenses as set forth under Section 5.5.3 (Partner Sharing of Development Costs and Data Access) each Party will grant, and hereby does grant, to the other Party a right of reference to all Regulatory Submissions pertaining to the Licensed Product in the Field submitted by or on behalf of such Party or its Affiliates, which right of reference (a) to Regulatory Submissions submitted by or on behalf of Kiniksa is exclusive to Partner in the Territory, and (b) to Regulatory Submissions submitted by or on behalf of Partner is exclusive to Kiniksa outside of the Territory. Partner may use such right of reference to Kiniksa's Regulatory Submissions solely to seek, obtain, support, and maintain

Regulatory Approvals and any Reimbursement Approvals, as applicable, for the Licensed Product in the Field in the Territory. Kiniksa may use such right of reference to Partner's Regulatory Submissions, if any, solely to seek, obtain, support, and maintain Regulatory Approval and any Reimbursement Approvals for the Licensed Product outside of the Territory. Each Party will bear its own costs and expenses associated with providing the other Party with the right of reference pursuant to this Section 6.5 (Right of Reference). Each Party will take such actions as may be reasonably requested by the other Party to give effect to the intent of this Section 6.5 (Right of Reference) and to give the other Party the benefit of the granting Party's Regulatory Submissions in the other Party's territory as provided herein. Such actions may include providing to the other Party copies of correspondence and communications received from the applicable Regulatory Authorities related to such Party's application for Regulatory Approval of the Licensed Product in the Territory (if Partner is the Party seeking Regulatory Approval) and of the Licensed Product outside of the Territory (if Kiniksa is the Party seeking Regulatory Approval).

6.6. Adverse Events Reporting.

6.6.1. **Safety Agreement**. Prior to the commencement of the first Clinical Trial of the Licensed Product conducted by or on behalf of Partner or its Affiliates, the Parties will enter into a written agreement setting forth worldwide safety and pharmacovigilance procedures for the Parties with respect to the Licensed Product (the "**Safety Agreement**"). The Safety Agreement will describe the obligations of both Parties with respect to the coordination of collection, investigation, reporting, and exchange of information between the Parties concerning any adverse event experienced by a subject, and the seriousness thereof, whether or not determined to be attributable to the Licensed Product, including any such information received by either Party from a Third Party (subject to receipt of any required consents from such Third Party) and will be sufficient to permit each Party and its Affiliates, licensees, or Sublicensees (as applicable) to comply with its legal obligations with respect thereto, including each Party's obligations as the owner or holder of Regulatory Submissions, Regulatory Approvals, and Reimbursement Approvals for the Licensed Product in the Territory, as applicable. The Safety Agreement will also detail each Party's responsibilities with respect to recalls and withdrawals of the Licensed Product inside and outside of the Territory. If required by changes in Applicable Law, the Parties will make appropriate updates to the Safety Agreement. Each Party will comply with its respective obligations under the Safety Agreement and cause its Affiliates, licensees, and Sublicensees to comply with such obligations. Each time the JSC approves a new planned Clinical Trials for the Licensed Product, the Parties will update the Safety Agreement to the extent necessary to comply with any applicable requirements set forth under Applicable Law or of any Regulatory Authorities related to adverse event reporting, drug safety, patient safety, pharmacovigilance, and risk management. Notwithstanding any provision to the contrary in this Agreement or the Safety Agreement, each Party and its Affiliates, licensees, and Sublicensees will have the right to disclose information related to the safety of the Licensed Product to the extent that such disclosure is required for such Party to comply with its obligations under Applicable Law or the safety requirements of the applicable Regulatory Authorities. The Parties will cooperate with each other to address any safety-related inquiries or requests for safety assessment by any Regulatory Authority, including providing any necessary data or information in a timely manner. To the extent that there is a conflict between the terms of this Agreement and the terms of the Safety Agreement, the terms of the Safety Agreement will govern with respect to the subject matter set forth therein.

6.6.2. **Safety Databases**. Partner will maintain a safety database in English for Clinical Trials for the Licensed Product conducted in the Territory under a Territory Development Plan, at its sole cost and expense. Partner will be responsible for: (a) reporting to the applicable Regulatory Authorities in the Territory all quality complaints, adverse events, and safety data related to the Licensed Product for all Territory-Specific Clinical Trials or Global Clinical Trials conducted in the Territory; and (b) responding to safety issues and to all requests of Regulatory Authorities related to the Licensed Product in the Territory. Partner will provide Kiniksa (i) real-time access to Partner's safety database for the Licensed Product in the Territory, and (ii) upon Kiniksa's request, query results from Partner's safety database for the Licensed Product. As between the Parties, Kiniksa will maintain a global safety database for Global Clinical Trials for the Licensed Product conducted under each Global Development Plan at Kiniksa's cost and expense.

6.7. **Regulatory Audits**. In addition to its rights to conduct audits pursuant to Section 5.8 (Clinical Trial Audit Rights), upon reasonable notification and no more frequently than [***] in each Calendar Year (unless Kiniksa is the Marketing Authorization Holder for the Licensed Product for a country or region in the Territory, in which case there will be no such limitation on the number of inspections or audits that may be conducted in such country or region in a given Calendar Year), Kiniksa or its representatives will be entitled to conduct audits of safety and regulatory systems, procedures, or practices of Partner or its Affiliates or Sublicensees (including Clinical Trial sites) relating to the Licensed Product. Notwithstanding any provision to the contrary set forth in this Agreement, there will be no limit on the number of "for cause" audits that Kiniksa may conduct of safety and regulatory systems, procedures, or practices of Partner or its Affiliates or Sublicensees (including Clinical Trial sites) related to the Licensed Product, and Kiniksa will use reasonable efforts to notify Partner in writing of any "for cause" audit at least [***] Business Days in advance thereof. Kiniksa or its representatives will conduct all such audits in accordance with Applicable Law. With respect to any inspection of Partner or its Affiliates or Sublicensees (including Clinical Trial sites) by any Governmental Authority relating to the Licensed Product, Partner will notify Kiniksa of such inspection (a) no later than [***] Business Days after Partner receives notice of such inspection (or in any event with as much advanced notice as is possible prior to such inspection if Partner receives notice thereof less than [***] Business Days in advance of the applicable inspection) or (b) within [***] Business Days after the completion of any such inspection of which Partner did not receive prior notice. Partner will promptly provide Kiniksa with all available information related to any such inspection (unless prohibited by Applicable Law), and Kiniksa may provide any such reports to any counterparty to any Third Party IP Agreement if required by the terms of such Third Party IP Agreement. Partner will also permit Governmental Authorities outside of the Territory to conduct inspections of Partner or its Affiliates or Sublicensees (including Clinical Trial sites) relating to the Licensed Product, and will ensure that all such Affiliates or Sublicensees permit such inspections. Kiniksa or its designee will have the right, but not the obligation (unless required by Applicable Law or any Governmental Authority), to be present at any such inspection at its sole cost and expense. Following any such regulatory inspection related to the Licensed Product, Partner will provide Kiniksa with (i) an unredacted copy of any findings, notice, or report provided by any Governmental Authority related to such inspection (to the extent related to the Licensed Product) within [***] Business Days of Partner receiving the same, and (ii) a written summary in English of any findings, notice, or report of a Governmental Authority related to such inspection (to the extent related to the Licensed Product) no later than [***] Business Days after receiving the same.

6.8. **Notice of Regulatory Action**. If any Regulatory Authority takes or gives notice of its intent to take any regulatory action with respect to any activity of Partner relating to the Licensed Product, then Partner will notify Kiniksa of such contact, inspection, or notice or action within [***]

Business Days after receipt of such notice (or, if action is taken without notice, within [***] Business Days of Partner becoming aware of such action). Partner will have the final decision-making authority with respect to such responses and will incorporate Kiniksa's reasonable comments to any such responses, *provided* that if Kiniksa is then the Marketing Authorization Holder for the Licensed Product, then Kiniksa will have final decision-making authority with respect to such responses. The costs and expenses of any regulatory action in the Territory [***]. Each Party will keep the other Party informed, as soon as possible, but no later than [***] after notification of any action by, or notification or other information that it receives (directly or indirectly) from, any Regulatory Authority, Third Party, or other Governmental Authority that:

6.8.1. raises any material concerns regarding the safety or efficacy of the Licensed Product;

6.8.2. indicates or suggests a potential investigation or formal inquiry by any Regulatory Authority in connection with the Exploitation of the Licensed Product; or

6.8.3. is reasonably likely to lead to a recall or market withdrawal of the Licensed Product anywhere in the Territory.

ARTICLE 7
MANUFACTURING

7.1. Supply by Kiniksa.

7.1.1. **Development Supply**. Promptly after the Effective Date and in no event later than [***] days prior to the anticipated commencement of the first Clinical Trial to be conducted by Partner in the Territory, the Parties will use reasonable efforts to negotiate in good faith to enter into a clinical supply agreement for the supply to Partner of the Licensed Product (for the Licensed Product, together with the corresponding quality agreement, the "**Clinical Supply Agreement**") pursuant to which Partner will purchase from Kiniksa or its Affiliate all of its requirements of drug product for the Licensed Product as necessary for Partner to fulfill its obligations under this Agreement related to the Clinical Development of the Licensed Product in the Territory, which drug product will be labeled or unlabeled as applicable depending on whether such Licensed Product is to be used in the performance of a Global Clinical Trial or a Territory-Specific Clinical Trial and as to be further specified in the Clinical Supply Agreement. The terms of the Clinical Supply Agreement will include product warranties and terms related to labeling, audit, delivery, acceptance and rejection, limitations of liability, and other customary terms, which, in each case, are consistent with the terms of any agreement between Kiniksa and its CMOs engaged for the Manufacture of the Licensed Product. Pursuant to and in accordance with the Clinical Supply Agreement, unless otherwise agreed by the Parties, for a period of [***] years after the Effective Date, Kiniksa will use reasonable efforts to supply unlabeled drug product to Partner pursuant to this Section 7.1.1 (Development Supply) at a transfer price equal to [***]. Upon its receipt of a purchase order from Partner for the Licensed Product under the Clinical Supply Agreement, Kiniksa will invoice Partner for the Licensed Product and, subject to the terms of the Clinical Supply Agreement, Partner will pay the undisputed invoiced amounts within [***] days after the date of the invoice.

7.1.2. **Commercial Supply**. No later than [***] [***] prior to the anticipated First Commercial Sale of the Licensed Product in the Territory, the Parties will use reasonable efforts to negotiate in good faith to agree on the terms of, and enter into, a commercial supply agreement for the Licensed Product (together with the corresponding quality agreement,

the "**Commercial Supply Agreement**"), for the supply to Partner of the Licensed Product pursuant to which Partner will purchase from Kiniksa all of its requirements of drug product for the Licensed Product necessary for Partner to fulfill its obligations under this Agreement related to the Commercialization of the Licensed Product in the Territory. The terms of the Commercial Supply Agreement will include product warranties and terms related to labeling, safety stock provisions, failure to supply, audit, shortage allocation, delivery, acceptance and rejection, limitations of liability, and other customary terms, that, in each case, are consistent with the terms of any agreement between Kiniksa and any Third Party Manufacturing the Licensed Product. Notwithstanding any provision to the contrary set forth in this Agreement, the term of the Commercial Supply Agreement will expire no later than [***] years after the commencement of the Manufacturing Technology Transfer for the Licensed Product and following expiration of the Commercial Supply Agreement, Kiniksa will have no obligation to supply to Partner drug product for the Licensed Product for Partner to fulfill its obligations under this Agreement related to the Commercialization of the Licensed Product in the Territory. Pursuant to and in accordance with the Commercial Supply Agreement for the Licensed Product in the Territory, Kiniksa will use reasonable efforts to supply to Partner pursuant to this Section 7.1.2 (Commercial Supply) the Licensed Product at a transfer price equal to [***]. Upon its receipt of a purchase order from Partner for the Licensed Product under the Commercial Supply Agreement, Kiniksa will invoice Partner for the Licensed Product and, subject to the terms of the Commercial Supply Agreement, Partner will pay the undisputed invoiced amounts within [***] days after the date of the invoice.

7.1.3. **Shipment and Delivery**. Delivery of all Licensed Product supplied by Kiniksa under the Clinical Supply Agreement or Commercial Supply Agreement will take place [***] (Incoterms 2020) at the applicable port of import. Kiniksa will be responsible for obtaining all licenses or other authorizations for the exportation of Licensed Product. Partner will be responsible for obtaining all licenses or other authorizations for the importation of Licensed Product into the Territory, and Kiniksa will use reasonable efforts to provide to Partner any documentation in Kiniksa's Control that is required with respect to the importation of the Licensed Product into the Territory. Partner will also be responsible for all quality control and quality assurance, release, storage, customs clearance, and distribution of the Licensed Product in the Territory, at Partner's cost and expense.

7.2. Supply by Partner.

7.2.1. Packaging and Labeling. Partner will package and, to the extent applicable, label all Licensed Product solely for the Territory in accordance with the Kiniksa P&L Process and Specifications and all Applicable Law.

7.2.2. **Restriction on Manufacturing by Partner**. Notwithstanding any provision to the contrary set forth in this Agreement, other than Section 7.2.1 (Packaging and Labeling), Partner will not Manufacture or have Manufactured the Licensed Product (or any component thereof) other than in accordance with (a) the terms of this Agreement, including the Manufacturing License granted pursuant to Section 2.1.2 (Manufacturing License), unless otherwise agreed by the JSC for the Licensed Product, through only those CMOs selected by Partner to Manufacture the Licensed Product in the Territory for use in the Territory, and (b) the terms of the Manufacturing Technology Transfer for the Licensed Product as described in Section 4.2 (Manufacturing Technology Transfer), each of which Manufacturing Technology Transfers, if to Partner and not a CMO, will be completed pursuant to the Manufacturing Technology Transfer Plan.

7.2.3. **Supply of Licensed Product**. Subject to Section 7.2.2 (Restriction on Manufacturing by Partner), following the date of receipt of Local Manufacturing Approvals for the Licensed Product (or any component thereof) pursuant to Section 4.2 (Manufacturing Technology Transfer), Partner will, solely through those CMOs selected by Partner to Manufacture the Licensed Product in the Territory for use by Partner in the Territory (or, if approved by the JSC, by Partner itself), Manufacture Licensed Product (or any component thereof) in the Territory solely for clinical or commercial use in the Territory by or on behalf of Partner or its Affiliates and, if Partner is to itself Manufacture the Licensed Product, as set forth in the Manufacturing Technology Transfer Plan for the Licensed Product approved by the JSC, except with respect to any supply of Licensed Product (or any component thereof) for use by Kiniksa, at Partner's sole cost and expense. Partner will ensure that the Manufacturing process with respect to all locally-Manufactured Licensed Product (or any component thereof) will at all times be in accordance with the Partner Process and Specifications for the Licensed Product approved by Kiniksa pursuant to Section 7.2.4 (Process and Specifications) and cGMP and cGCP guidelines, and in compliance with Applicable Law. In addition, following the date of receipt of Local Manufacturing Approvals, at Kiniksa's request, those CMOs selected by Partner (or, if the JSC determines that Partner will have the right to Manufacture the Licensed Product, Partner) will serve as a second source of supply of the Licensed Product (or any component thereof) for use by Kiniksa. Following any such request by Kiniksa, the Parties will enter into a separate written agreement pursuant to which Partner (through its CMOs, or, if the JSC determines that Partner will have the right to Manufacture the Licensed Product, Partner itself) would supply such locally-Manufactured Licensed Product to Kiniksa at a price equal to Partner's Fully Burdened Manufacturing Cost and upon such other customary terms to be agreed to by the Parties, including product warranties and terms related to labeling, safety stock provisions, failure to supply, audit, shortage allocation, delivery, acceptance and rejection, limitations of liability, and other customary terms, that, in each case, are consistent with the terms of any agreement between Partner and any Third Party Manufacturing the Licensed Product.

7.2.4. **Process and Specifications**. As part of the Manufacturing Technology Transfer for the Licensed Product, Kiniksa will provide those CMOs selected by Partner to Manufacture the Licensed Product in the Territory for use by Partner in the Territory (or, if the JSC determines that Partner will have the right to Manufacture the Licensed Product, Partner) with Kiniksa's written process and quality specifications for the Manufacturing of the Licensed Product in the Territory, other than for the performance of any step in the Manufacturing process for the Licensed Product that Kiniksa determines, in its sole discretion, cannot be transferred to such CMOs (or, if agreed by the JSC, to Partner) due to restrictions in any agreement between Kiniksa and any Third Party (the "**Kiniksa Process and Specifications**"). Partner will cause those CMOs selected by Partner to Manufacture the Licensed Product in the Territory for use by Partner in the Territory to (or, if approved by the JSC, Partner will itself) prepare written process and quality specifications for the Manufacture of the Licensed Product applicable to such CMOs' (or Partner's, if applicable) Manufacturing facilities, systems, processes, and capabilities, including how the foregoing relate to drug substance, drug product, in-process intermediates, raw materials, and reference material (the "**Partner Process and Specifications**"), which Partner Process and Specifications will be consistent in all respects with the Kiniksa Process and Specifications for the Licensed Product, subject to Applicable Law. Partner will cause the applicable CMOs to, or, if the JSC determines that Partner will itself Manufacture the Licensed Product, then Partner will itself, provide to Kiniksa all such Partner Process and Specifications (and any subsequent changes thereto) for Kiniksa

review and approval. In addition, Partner will cause the applicable CMOs to, or, if the JSC determines that Partner will itself Manufacture the Licensed Product, then Partner will itself, promptly provide to Kiniksa for Kiniksa's review, comment, and approval any proposed changes to the Partner Process and Specifications for the Licensed Product together with an explanation for such change. No later than [***] days after Kiniksa's receipt of such Partner Process and Specifications for the Licensed Product (or any changes thereto), Kiniksa may either (a) approve the Partner Process and Specifications for the Licensed Product (or any changes thereto), or (b) provide Partner with a written response to the Partner Process and Specifications for the Licensed Product (or such changes thereto) that includes a description of any deficiencies or limitations that Kiniksa has identified with respect thereto, in which case the JSC (or JMC, if applicable) will cooperate to develop a plan for remediation with respect to any such deficiencies or limitations within a reasonable period of time thereafter. Following the applicable CMO's or Partner's, as applicable, remediation of all deficiencies, Partner will cause the applicable CMOs to, or, if the JSC determines that Partner will itself Manufacture the Licensed Product, then Partner will itself, provide Kiniksa with a revised draft of the Partner Process and Specifications for the Licensed Product (or any subsequent changes to any Partner Process and Specifications) for Kiniksa's review and approval. Thereafter, and on a continuing basis for so long as the CMOs selected by Partner (or, if approved by the JSC, Partner) Manufacture the Licensed Product, Partner will require the applicable CMOs to, or, if the JSC determines that Partner will itself Manufacture the Licensed Product, then Partner will itself, (i) Manufacture the Licensed Product at all times in accordance with the Kiniksa-approved Partner Process and Specifications for the Licensed Product and cGMP guidelines, and (ii) complete any additional studies or testing required to maintain any qualifications and Regulatory Approvals (including manufacturing licenses) from any Regulatory Authorities or other Governmental Authorities necessary to continue to Manufacture the Licensed Product in the Territory and provide to Kiniksa copies of reports from any such additional studies or testing in English, at Partner's sole cost and expense.

7.2.5. **Manufacturing by Partner**. Subject to the terms of this Agreement, including Section 7.2.4 (Process and Specifications), following completion of the Manufacturing Technology Transfer to the applicable CMOs to, or, if the JSC determines that Partner will itself Manufacture the Licensed Product, to Partner, Partner will have the right to make day-to-day operational decisions solely relating to the Manufacture by such CMOs (or, if approved by the JSC, Partner) of the Licensed Product in the Territory.

7.3. Product Tracking in the Territory. Partner will, and will ensure that its Affiliates and Sublicensees, maintain adequate records to permit the Parties to trace the distribution, sale, and use of all Licensed Product in the Territory. At Kiniksa's request, Partner will provide such records to Kiniksa.

ARTICLE 8
MEDICAL AFFAIRS

8.1. Medical Affairs Plan. No later than [***] days prior to the anticipated date of performance of the Medical Affairs activities for the Licensed Product in the Territory, and in no event later than [***] days prior to the anticipated commercial launch of the Licensed Product in the Territory, the JDC will develop, review, and discuss an initial draft of the Medical Affairs Plan for the Licensed Product and provide such initial draft to the JSC to review, discuss, and determine whether to approve. The Medical Affairs Plan will contain a high level summary of the major Medical Affairs activities to be undertaken for the Licensed Product in the Territory and the estimated timelines for

performing such activities. Thereafter, from time to time, but at least annually, the JDC will propose updates to the Medical Affairs Plan for the Licensed Product to reflect changes in such plans, including to account for relevant factors that may influence such plan and the Medical Affairs activities set forth therein and provide each such update to the JSC to review, discuss, and determine whether to approve. To the extent relevant to the conduct of Medical Affairs activities for the Licensed Product in the Territory by Partner in accordance with the Medical Affairs Plan, the Parties will discuss, through the JSC, Kiniksa's Medical Affairs activities outside of the Territory, including medical publications, real world study data, symposium, and conference presentations.

8.2. **Medical Affairs Reports**. For each Calendar Quarter in which any Medical Affairs are conducted by or on behalf of Partner or its Affiliates or Sublicensees for the Licensed Product in the Territory no later than the end of such Calendar Quarter, Partner will provide to Kiniksa a report (by means of a slide presentation or otherwise) summarizing the Medical Affairs activities performed by or on behalf of Partner and its Affiliates and Sublicensees in the Territory for the Licensed Product in each country and region in the Territory since the prior report provided by Partner. Such reports will be the Confidential Information of each Party and subject to the terms of Article 11 (Confidentiality; Publication). Partner will provide updates to any such report at each meeting of the JSC and JDC.

8.3. **Coordination of Medical Affairs Activities**. The Parties recognize that each Party may benefit from the coordination of certain Medical Affairs activities for the Licensed Product inside and outside of the Territory. Accordingly, the Parties will coordinate such activities through the JDC where appropriate.

ARTICLE 9
COMMERCIALIZATION

9.1. **Commercialization Diligence Obligations**. Subject to the availability of commercial supply of Licensed Product and receipt of Regulatory Approval for the Licensed Product, Partner will be solely responsible for and will use Commercially Reasonable Efforts to Commercialize Licensed Product in each Indication for which Regulatory Approval is granted in each country or region in the Territory, including to seek and obtain Reimbursement Approval for the Licensed Product in each Indication in each such country or region (to the extent required therein). Partner will conduct all Commercialization of the Licensed Product in the Territory in accordance with the Commercialization Plan for the Licensed Product, at its sole cost and expense, and subject to the terms of this Agreement. Without limiting the foregoing, Partner will use Commercially Reasonable Efforts to achieve First Commercial Sale of the Licensed Product in each country or region in the Territory within [***] months after obtaining Regulatory Approval for the Licensed Product in such country or region, *provided* that Kiniksa supplies conforming Licensed Product in accordance with the Commercial Supply Agreement.

9.2. **Commercialization Plan**. No later than [***] months prior to the anticipated date of approval of the first filing of the first MAA for the Licensed Product in a country or region in the Territory, Partner will develop an initial draft of the Commercialization Plan for the Licensed Product and provide such initial draft to the JSC to review and discuss such initial draft. The Commercialization Plan for the Licensed Product will contain in reasonable detail the major Commercialization activities to be undertaken (including revenue targets) for the Licensed Product in the Territory and the estimated timelines for achieving such activities. Thereafter, from time to time, but at least annually (and in any event no later than [***] days prior to the anticipated date of the first filing of the first MAA for the Licensed Product in the Territory), Partner will propose updates to the Commercialization Plan for the Licensed Product to reflect changes in such plans, including those

in response to changes in the marketplace, relative commercial success of the Licensed Product, and other relevant factors that may influence such plan and the Commercialization activities set forth therein and provide each such update to the JSC to review, discuss, and determine whether to approve. The Commercialization Plan (including each update thereto) must be consistent with Kiniksa's global brand strategy and global key messaging for the Licensed Product (each, a "**Global Brand Strategy**"), as provided to Partner by Kiniksa from time to time during the Term.

9.3. **Commercialization Reports**. [***] Partner will provide to Kiniksa a written report that summarizes the Commercialization activities performed by or on behalf of Partner and its Affiliates and Sublicensees in the Territory for the Licensed Product in each country or region in the Territory since the prior report provided by Partner. Each such report will contain reasonably sufficient detail to enable Kiniksa to assess Partner's compliance with its Commercialization diligence obligations set forth in Section 9.1 (Commercialization Diligence Obligations) and will include at least the following information for each country or region in the Territory, as well as any other information as may be required by each Third Party IP Agreement: (a) [***], (b) [***], (c) [***], (d) [***], and (e) [***]. Such reports will be Confidential Information of each Party and subject to the terms of Article 11 (Confidentiality; Publication). Partner will, or will cause its Affiliates or Sublicensees to, provide updates to any such report at each meeting of the JSC.

9.4. **Coordination of Commercialization Activities**. The Parties recognize that each Party may benefit from the coordination of certain Commercialization activities for the Licensed Product inside and outside of the Territory (other than pricing for the Licensed Product inside and outside of the Territory, the responsibilities for which are set forth in Section 9.5 (Pricing; Reimbursement Approvals)). Accordingly, the Parties will coordinate such activities through the JSC where appropriate.

9.5. **Pricing; Reimbursement Approvals**. Each Party will have the right to determine the price of the Licensed Product sold in its respective territory and neither Party will have the right to direct, control, or approve the pricing of the Licensed Product in the other Party's territory. Partner will keep Kiniksa timely informed on the status of any application for Reimbursement Approval for the Licensed Product in the Territory, including any discussion with any Regulatory Authority with respect thereto.

9.6. **Diversion**. Each Party agrees that it will not, and will ensure that its Affiliates and Sublicensees and Subcontractors will not, either directly or indirectly, promote, market, distribute, import, sell, or have sold the Licensed Product to any Third Party or to any address or Internet Protocol address or the like in the other Party's territory, including via the Internet or mail order. Notwithstanding any provision to the contrary set forth in this Agreement, each Party will have the right to attend conferences and meetings of congresses in the other Party's territory and to promote and market the Licensed Product to Third Party attendees at such conferences and meetings, subject to this Section 9.6 (Diversion). Neither Party will engage, nor permit its Affiliates or Sublicensees to engage, in any advertising or promotional activities relating to the Licensed Product for use directed primarily to customers or other buyers or users of the Licensed Product located in any country or jurisdiction in the other Party's territory or solicit orders from any prospective purchaser located in any country or jurisdiction in the other Party's territory. If a Party or its Affiliates or Sublicensees receive any order for the Licensed Product from a prospective purchaser located in a country or jurisdiction in the other Party's territory, then such Party will immediately refer that order to such other Party and will not accept any such orders. Neither Party will, nor will either Party permit its Affiliates or Sublicensees to, deliver or tender (or cause to be delivered or tendered) the Licensed Product to Third Parties for use in the other Party's territory except in accordance with a Global

Development Plan or Territory Development Plan, or except in connection with a Manufacturing Technology Transfer pursuant to Article 7 (Manufacturing).

ARTICLE 10
PAYMENTS

10.1. Upfront Payment. No later than [***] days following the Effective Date, Partner will pay to Kiniksa, by wire transfer of immediately available funds, a non-refundable non-creditable upfront payment of $[***] in U.S. Dollars.

10.2. Milestone Payments.

10.2.1. **Development Milestone Events and Payments**. No later than [***] days after the earliest achievement of (a) each development milestone event set forth in Table 10.2.1 below for the Licensed Product, Partner will pay to Kiniksa the corresponding development milestone payment set forth in Table 10.2.1 (the development milestone events set forth in Table 10.2.1 below, the "**Development Milestone Events**," and the development milestone payments set forth in Table 10.2.1 below, the "**Development Milestone Payments**").

Table 10.2.1 Development Milestones

Development Milestone Events	***Development Milestone Payment (in U.S. Dollars)***
Initiation of first Territory-Specific Clinical Trial that is a Phase III Clinical Trial for each Indication for the Licensed Product	$[***]
Initiation of first Global Clinical Trial that is a Phase III Clinical Trial in each Indication for the Licensed Product in which Partner has agreed to participate in accordance with this Agreement	$[***]
Receipt of Regulatory Approval from the NMPA for the Licensed Product in the first Indication	$[***]
Receipt of Regulatory Approval from the NMPA for the Licensed Product in the second Indication	$[***]

10.2.2. **Sales Milestone Events and Payments**. No later than [***] days after the Calendar Quarter in which each sales milestone event set forth below is achieved as set forth in Table 10.2.2 below for the Licensed Product, Partner will pay to Kiniksa the corresponding sales milestone payment set forth in Table 10.2.2 (the sales milestone events set forth in Table 10.2.2, the "**Sales Milestone Events**" and the sales milestone payments set forth in Table 10.2.2, the "**Sales Milestone Payments**"). If in a given Calendar Quarter during the Term more than one Sales Milestone Event is achieved, then Partner will pay to Kiniksa a separate Sales Milestone Payment with respect to each such Sales Milestone Event that is achieved for the first time in such Calendar Quarter.

Table 10.2.2 Sales Milestones		
	Sales Milestone Event	***Sales Milestone Payment (in U.S. Dollars)***
1.	First Calendar Year in which annual Net Sales of the Licensed Product in the Territory equal or exceed $[***] USD	$[***]
2.	First Calendar Year in which annual Net Sales of the Licensed Product in the Territory equal or exceed $[***] USD	$[***]
3.	First Calendar Year in which annual Net Sales of the Licensed Product in the Territory equal or exceed $[***] USD	$[***]
4.	First Calendar Year in which annual Net Sales of the Licensed Product in the Territory equal or exceed $[***] USD	$[***]
5.	First Calendar Year in which annual Net Sales of the Licensed Product in the Territory equal or exceed $[***] USD	$[***]
6.	First Calendar Year in which annual Net Sales of the Licensed Product in the Territory equal or exceed $[***] USD	$[***]
7.	First Calendar Year in which annual Net Sales of the Licensed Product in the Territory equal or exceed $[***] USD	$[***]
8.	First Calendar Year in which annual Net Sales of the Licensed Product in the Territory equal or exceed $[***] USD	$[***]

10.2.3. **Milestone Conditions**.

(a) **Notification of Milestone Events**. Partner will promptly notify Kiniksa in writing, but in no event later than (i) [***] days after the achievement of each Development Milestone Event and (ii) [***] days after the end of the Calendar Quarter in which each Sales Milestone Event is achieved (together with the Development Milestone Events, the "**Milestone Events**"). However, in no event will a failure by Partner to deliver such notice of achievement of a Milestone Event relieve Partner of its obligation to pay Kiniksa the corresponding Development Milestone Payment or Sales Milestone Payment (collectively, the "**Milestone Payments**").

(b) **Skipped Milestone Events**. If Partner achieves any of the Development Milestone Events for the Licensed Product and a given Indication (if applicable) but without the prior achievement of any corresponding earlier listed Milestone Events for the Licensed Product and such same Indication (if applicable), then Partner will pay to Kiniksa the applicable Milestone Payment to be made with respect to such earlier Milestone Events for the Licensed Product and Indication at the same time as Partner pays the applicable Milestone Payment due upon achievement of such Development Milestone Event.

10.3. Royalty Payments to Kiniksa.

10.3.1. **Royalty Rates**. Subject to the remainder of this Section 10.3 (Royalty Payments to Kiniksa), Partner will pay to Kiniksa royalties in the amount of the marginal royalty rates set forth in Table 10.3.1 below based on the aggregate Net Sales resulting from the sale of the Licensed Product in the Territory during each Calendar Year of the Royalty Term for the Licensed Product in each country. The royalty payments due with respect to Net Sales of the Licensed Product pursuant to this Section 10.3 (Royalty Payments to Kiniksa), collectively the "**Royalty Payments**."

Table 10.3.1 Royalty Payments	
Portion of Aggregate Calendar Year Net Sales of the Licensed Product in the Territory (in U.S. Dollars)	***Royalty Rate***
Greater than $[***] and less than $[***]	[***]%
Greater than or equal to $[***] and less than $[***]	[***]%
Greater than or equal to $[***] and less than $[***]	[***]%
Greater than or equal to $[***]	[***]%

For example, [***]**Royalty Term**. Partner will pay to Kiniksa the Royalty Payments on a country-by-country or region-by-region basis, as applicable, until the later of: (a) the [***] anniversary of the date of the First Commercial Sale of the Licensed Product in such country or region in the Territory; (b) the date of expiration of the last-to-expire Valid Claim of a Royalty Patent Right Covering the Licensed Product in such country or region; and (c) the expiration of all Regulatory Exclusivity for the Licensed Product in such country or region ("**Royalty Term**").

10.3.2. **Royalty Reductions**.

(a) **Expiration of Valid Claims**. Subject to Section 10.3.3(d) (Cumulative Reductions Floor), on a country-by-country or region-by-region basis, as applicable, in the Territory, if during the Royalty Term for the Licensed Product in such country or region in the Territory, there is no Valid Claim of a Royalty Patent Right that Covers a composition of matter (including drug formulation), method of use, or method of Manufacturing of the Licensed Product in such country or region, then, commencing the first Calendar Quarter after the date on which this Section 10.3.3(a) (Expiration of Valid Claims) applies and for all Calendar Quarters thereafter during such Royalty Term in which this Section 10.3.3(a) (Expiration of Valid Claims) applies, then the royalty rates for the Licensed Product set forth in Table 10.3.1 in such country or region under Section 10.3 (Royalty Payments to Kiniksa) will be reduced by [***]%; *provided* that if a composition of matter, method of use, or method of Manufacturing of the Licensed Product subsequently becomes Covered by a Valid Claim of a Royalty Patent Right in such country or region prior to the expiration of the Royalty Term for the Licensed Product in such country or region, then the royalty rate of the Licensed Product in such country or region will no longer be subject to the aforementioned reduction beginning at the commencement of the first Calendar Quarter after the date on which the relevant patent issues.

(b) **Biosimilar Product Reduction**. Subject to Section 10.3.3(d) (Cumulative Reductions Floor), on a country-by-country or region-by-region basis, as

applicable, if during any Calendar Quarter, there is Biosimilar Competition for the Licensed Product in such country or region, then the Net Sales of the Licensed Product in such country or region in such Calendar Quarter will be reduced by the applicable percentage set forth in Table 10.3.3(b), in each Calendar Quarter in which the Biosimilar Competition continues during the Royalty Term for the Licensed Product in such country or region. Partner will promptly notify Kiniksa of the occurrence of Biosimilar Competition, which notice will specify the applicable Biosimilar Products, Indication, and country or region in the Territory.

Table 10.3.3(b) – BIOSIMILAR PRODUCT ROYALTY REDUCTION RATES	
Percentage Decline in Aggregate Calendar Year Net Sales of the Licensed Product in the Territory Due to Biosimilar Competition	***Net Sales Reduction***
Greater than [***]% but less than [***]%	[***]%
Greater than [***]%	[***]%

(c) **Third Party Patent Rights**. Subject to Section 10.3.3(d) (Cumulative Reductions Floor), on a country-by-country or region-by-region basis, as applicable, during any Calendar Quarter, Partner may credit against the Royalty Payments payable to Kiniksa pursuant to Section 10.3 (Royalty Payments to Kiniksa) with respect to the Licensed Product in such country or region in such Calendar Quarter up to [***]% of any royalty payments for which Partner is responsible (i) under any Third Party IP Agreement pursuant to Section 2.6.4 (Responsibility for Costs), or (ii) under any agreement with a Third Party entered into by Partner pursuant to Section 2.6.2 (Partner Identified Rights), but, in each case (i) and (ii), solely to the extent such royalty payments are made in consideration for the acquisition or license of Third Party Patent Rights that (in the opinion of counsel) would be infringed by the sale of the Licensed Product in such country or region.

(d) **Cumulative Reductions Floor**. In no event will the aggregate amount of Royalty Payments due to Kiniksa for the Licensed Product in a country or region in the Territory in any given Calendar Quarter during the Royalty Term for the Licensed Product in such country or region be reduced to less than [***]% of the amount that otherwise would have been due and payable to Kiniksa in such Calendar Quarter for the Licensed Product in such country or region but for the reductions set forth in Section 10.3.3(a) (Expiration of Valid Claims) and Section 10.3.3(b) (Biosimilar Product Reduction), and Section 10.3.3(c) (Third Party Patent Rights). Partner may carry forward to subsequent Calendar Quarters any amounts it could not deduct as a result of such floor.

(e) **No Duplicative Royalties**. In no event will the sale of the Licensed Product in a given country in the Territory give rise to more than one Royalty Payment due to Kiniksa, including any instance where the Licensed Product is Covered by more than one Royalty Patent Right in such country.

10.3.3. **Royalty Reports and Payments**. Within [***] days after the end of each Calendar Quarter, Partner will provide Kiniksa with a detailed report that contains the following information for the applicable Calendar Quarter, on a country-by-country or region-by-region basis, as applicable, (each, a "**Royalty Report**"): (a) [***], (b) [***], (c) [***], and

(d) [***]. If there are no sales of the Licensed Product in a given Calendar Quarter, then the Royalty Report will provide such information. Concurrent with the delivery of the applicable Royalty Report, but in any event within [***] days after each Calendar Quarter, Partner will pay such the amount of the Royalty Payments set forth in the applicable Royalty Report to Kiniksa in Dollars. If requested by Kiniksa, the Parties will seek to resolve any questions or issues related to a Royalty Report within [***] days following receipt by Kiniksa of each Royalty Report. If no Royalty Payments are due in a particular Calendar Quarter, then the applicable Royalty Report will state that no such payments are due.

10.4. Payments to Third Parties. Subject to Section 2.6 (Third Party In-Licenses), each Party will be solely responsible for any payments due to Third Parties under any agreement entered into by such Party prior to or after the Effective Date.

10.5. Other Amounts Payable. With respect to any amounts owed under this Agreement by one Party to the other for which no other invoicing and payment procedure is specified hereunder, within [***] days after the end of each Calendar Quarter, each Party will provide an invoice, together with reasonable supporting documentation, to the other Party for such amounts owed in respect of such Calendar Quarter. The owing Party will pay any undisputed amounts within [***] days after the receipt of the invoice, and any disputed amounts owed by a Party will be paid within [***] days after resolution of the dispute.

10.6. No Refunds. Except as expressly provided herein, all payments under this Agreement will be irrevocable, non-refundable, and non-creditable.

10.7. Accounting Standards. If a Party changes its general accounting principles from the then-current standard (*e.g.*, from GAAP to IFRS) at any time during the Term, then at least [***] days prior to adopting such change in principles, such Party will provide written notice to the other Party of such change.

10.8. Currency; Exchange Rate. All payments to be made by Partner to Kiniksa or Kiniksa to Partner under this Agreement will be made in Dollars by electronic funds transfer in immediately available funds to a bank account designated in writing by Kiniksa or Partner, as applicable. Net Sales will be recorded by Partner and its Affiliates and Sublicensees in the currency for the country or region in which the Net Sales occurred. Conversion of Net Sales recorded in local currencies will be converted to Dollars at the exchange rate set forth in Bloomberg or any successor thereto for the last day of the Calendar Quarter in which the applicable payment obligation became due and payable.

10.9. Blocked Payments. If by reason of Applicable Law in any country or region, it becomes impossible or illegal for a Party to transfer, or have transferred on its behalf, payments owed the other Party hereunder, then such Party will promptly notify the other Party of the conditions preventing such transfer and such payments will be deposited in local currency in the relevant country or region to the credit of the other Party in a recognized banking institution designated by the other Party or, if none is designated by the other Party within a period of [***] days, in a recognized banking institution selected by the transferring Party, as the case may be, and identified in a written notice given to the other Party. Payments that are blocked as set forth in, but otherwise made in accordance with the terms of, this Section 10.9 (Blocked Payments) will not be deemed a late payment subject to Section 10.10 (Late Payments) and will not be subject to the accrual of interest specified thereunder for so long as such payments are blocked.

10.10. Late Payments. Any payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement will bear interest at a rate equal to the lesser of: (a) [***] percentage points above the prime rate as published by *The Wall Street Journal* or any successor thereto on the first day of each Calendar Quarter in which such payments are overdue; or (b) the maximum rate permitted by Applicable Law; in each case, calculated on the number of days such payment is delinquent, compounded monthly.

10.11. Financial Records and Audits. Each Party will maintain complete and accurate records in sufficient detail to permit the other Party or its designee to confirm the accuracy of the amount of Royalty Payments and other amounts payable under this Agreement. Upon at least [***] days' prior written notice, such records will be open during regular business hours for a period of [***] years (or such longer period as may be required under any applicable statute of limitations for applicable Taxes or by Applicable Law) from the creation of individual records for examination by an independent "Big Four" (or equivalent) accounting firm selected by the examining Party and reasonably acceptable to the other Party or its designee for the sole purpose of verifying for the examining Party the accuracy of the financial reports furnished by the other Party (the "**Examined Party**") pursuant to this Agreement or of any payments made, or required to be made, by such Examined Party pursuant to this Agreement; *provided* that such independent accounting firm is subject to written obligations of confidentiality and non-use applicable to each Party's Confidential Information that are at least as stringent as those set forth in Article 11 (Confidentiality; Publication). Such audit will not be (a) performed more frequently than once per [***] during the Term or once during the [***] year period after the expiration or termination of this Agreement, (b) conducted for any Calendar Year more than [***] years after the end of such year, or (c) repeated for any Calendar Year or with respect to the same set of records (unless a material discrepancy with respect to such records is discovered during a prior audit). Such auditor will not disclose the Examined Party's Confidential Information to the examining Party or to any Third Party, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by the Examined Party or the amount of payments by the Examined Party under this Agreement. The Examined Party will pay any amounts shown to be owed to the examining Party but unpaid within [***] days after the accountant's report, *plus* interest (as set forth in Section 10.10 (Late Payments)) from the original due date. The examining Party will bear the full cost of such audit unless such audit reveals an underpayment by the Examined Party of more than [***]% of the amount actually due for the time period being audited, in which case the Examined Party will reimburse the examining Party for the reasonable audit fees for such examination. To the extent that an audit hereunder reveals an overpayment by the Examined Party to the examining Party, the Examined Party may credit such overpayment against amounts due to the examining Party under this Agreement.

10.12. Taxes.

10.12.1. **Taxes on Income; Payments Free of Taxes**. Except as set forth in this Section 10.12 (Taxes) or Section 10.13 (VAT Credits), each Party will be solely responsible for the payment of any and all income Taxes levied on account of all payments it receives under this Agreement. Any and all payments due to Kiniksa from Partner pursuant to this Agreement will be paid without deduction or withholding for any Taxes, except as required by Applicable Law. If any Applicable Law requires the deduction or withholding of any Tax from any such payment, then Partner (or its applicable withholding agent) will be entitled to make such deduction or withholding and Partner will increase the amount of such payment due to Kiniksa under this Agreement upon which such Tax is due as may be necessary so that the net amount Kiniksa receives after making any payments in respect of any such Tax is an amount equal to the sum that it would have received had (i) no such

deduction or withholding been required to be made on such amount and (ii) no other Taxes been imposed on any additional amounts payable to Kiniksa. Each Royalty Report will show the amounts of Taxes due and paid by Partner with respect to payments made by Partner to Kiniksa during such Calendar Quarter. The amount of the invoice provided by Kiniksa to Partner must include the withholding income tax amount paid by Partner and the amount actually received by Kiniksa, even if Kiniksa only receives the net amount payable in accordance with this Agreement.

10.12.2. **Tax Cooperation**. The Parties agree to cooperate with one another in accordance with Applicable Law and use reasonable efforts to minimize Tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by each Party to the other Party under this Agreement. To the extent either Party (the "**Paying Party**") is required to deduct and withhold Taxes on any payment to the other Party (the "**Recipient**"), the Paying Party will (a) pay the full amount of such Taxes to the proper Governmental Authority in a timely manner, and (b) promptly transmit to the Recipient an official tax certificate or other evidence of such payment sufficient to enable the Recipient to claim such payment of Taxes on the Recipient's applicable tax returns. The Paying Party will provide the Recipient with advance notice prior to withholding any Taxes from payments payable to the Recipient and will provide the Recipient with a commercially reasonable period of time to claim an exemption or reduction in otherwise applicable Taxes. The Recipient will provide the Paying Party any tax forms that may be reasonably necessary in order for the Paying Party to not withhold Tax or to withhold Tax at a reduced rate under an applicable bilateral income tax treaty, to the extent the Paying Party is legally able to do so. The Recipient will use reasonable efforts to provide any such tax forms to the Paying Party in advance of the due date. Each Party will provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Law, of withholding Taxes or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Paying Party if the Paying Party is the Party bearing such withholding Tax under this Section 10.12 (Taxes). To the extent that Kiniksa recovers any Taxes withheld by Partner or receives Tax credits that would otherwise have reduced the amount by which Partner had to increase the payment to Kiniksa under Section 10.12.1 (Taxes on Income; Payments Free of Taxes) if such withholding recovery or receipt of Tax credit been realized at the time of payment to Kiniksa, then Partner will receive a credit for such amount, which credit Partner may set off against future payments of amounts due to Kiniksa hereunder. In addition, the Parties will cooperate in accordance with Applicable Law to minimize indirect Taxes (such as VAT, sales tax, consumption tax, and other similar Taxes) in connection with this Agreement. In the event of any inconsistency between this Section 10.12 (Taxes) and Section 10.13 (VAT Credits), Section 10.13 (VAT Credits) will take precedence.

10.12.3. **Changes in Domicile**. Notwithstanding any provision to the contrary in this Agreement, if the Paying Party assigns, transfers or otherwise disposes of some or all of its rights and obligations to any Person and if, as a result of such action, the withholding or deduction of Tax required by Applicable Law with respect to payments under this Agreement is increased, then any amount payable to the Recipient under this Agreement will be increased to take into account such withheld Taxes as may be necessary so that, after making all required withholdings (including withholdings on the withheld amounts), the Recipient receives an amount equal to the sum it would have received had no such withholding been made.

10.12.4. **Returns**. All transfer, documentary, sales, use, stamp, registration, and other such Taxes, and any conveyance fees, recording charges, and other fees and charges (including any penalties and interest) incurred in connection with consummation of the transactions contemplated hereby, if any, will be borne and paid by the Paying Party. The Paying Party will prepare and timely file all tax returns required to be filed in respect of any such Taxes. The Parties will reasonably cooperate in accordance with Applicable Law to minimize transfer Taxes in connection with this Agreement.

10.13. VAT Credits. All payments due to Kiniksa from Partner pursuant to this Agreement will be paid without any deduction for any VAT that Partner may be required to collect or pay to any tax authorities in the Territory. Kiniksa will use reasonable efforts to assist Partner to minimize and obtain all available exemptions from such VAT, but if applicable, Partner will pay any such VAT to the proper taxing authorities upon receipt of a valid VAT invoice (where such invoice is required under local VAT laws). If Partner is required to pay or Kiniksa is required to report or pay any such VAT, then Partner will increase the amount of any and all payments under this Agreement upon which such VAT is due as may be necessary so that the net amount Kiniksa receives after making any payments in respect of any such VAT is an amount equal to the sum that it would have received had (i) no such VAT been required to be paid on such amount and (ii) no other Taxes been imposed on any additional amounts payable to Kiniksa. Partner will promptly provide to Kiniksa applicable receipts evidencing payment of such VAT and other documentation reasonably requested by Kiniksa. To the extent that Kiniksa recovers any VAT paid in connection with any payment made by Partner hereunder, then Partner will receive a credit for such refunded or recovered VAT amount, which credit Partner may set off against future payments of amounts due to Kiniksa hereunder.

ARTICLE 11
CONFIDENTIALITY; PUBLICATION

11.1. Duty of Confidence. Subject to the other provisions of this Article 11 (Confidentiality; Publication):

11.1.1. except to the extent expressly authorized by this Agreement, all Confidential Information of a Party (the "**Disclosing Party**") will be maintained in confidence and otherwise safeguarded, and not published or otherwise disclosed, by the other Party (the "**Receiving Party**") and its Affiliates for the Term and for [***] years thereafter;

11.1.2. the Receiving Party will treat all Confidential Information provided by the Disclosing Party at a minimum, with the same degree of care as the Receiving Party uses for its own similar information, but in no event less than a reasonable degree of care;

11.1.3. the Receiving Party may only use any Confidential Information of the Disclosing Party for the purposes of performing its obligations or exercising its rights under this Agreement;

11.1.4. a Receiving Party may disclose Confidential Information of the Disclosing Party to: (a) such Receiving Party's Affiliates, licensees and Sublicensees; and (b) employees, directors, officers, agents, contractors, consultants, attorneys, accountants, banks, investors, and advisors of the Receiving Party and its Affiliates, licensees, and Sublicensees, in each case ((a) and (b)), to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this Agreement; *provided* that such Persons are bound by legally enforceable obligations of confidentiality and non-use with respect to the Disclosing Party's Confidential Information no less stringent than the confidentiality and non-use

obligations set forth in this Agreement. Each Party will remain responsible for any failure by its Affiliates, licensees, and Sublicensees, and its and its Affiliates', licensees', and Sublicensees' respective employees, directors, officers, agents, contractors, consultants, attorneys, accountants, banks, investors, and advisors, in each case, to treat such Confidential Information as required under this Section 11.1 (Duty of Confidence) (as if such Affiliates, licensees, Sublicensees, employees, directors, officers, agents, contractors, consultants, attorneys, accountants, banks, investors, and advisors were Parties directly bound to the requirements of this Section 11.1 (Duty of Confidence)); and

11.1.5. each Party will promptly notify the other Party of any misuse or unauthorized disclosure of the other Party's Confidential Information.

11.2. Confidential Information. The Kiniksa Know-How will be the Confidential Information of Kiniksa notwithstanding the fact that such information may be developed or invented and disclosed to Kiniksa by Partner. The Partner Know-How will be the Confidential Information of Partner. The Joint Collaboration Know-How will be the Confidential Information of both Parties. Except as provided in Section 11.4 (Authorized Disclosures) and Section 11.7 (Publicity; Use of Names), neither Party nor its Affiliates may disclose the existence or the terms of this Agreement.

11.3. Exemptions. Information of a Disclosing Party will not be Confidential Information of such Disclosing Party to the extent that the Receiving Party can demonstrate through competent evidence that such information:

11.3.1. is known by the Receiving Party or any of its Affiliates without an obligation of confidentiality at the time of its receipt from the Disclosing Party, and not through a prior disclosure by or on behalf of the Disclosing Party, as documented by the Receiving Party's business records;

11.3.2. is generally available to the public before its receipt from the Disclosing Party;

11.3.3. became generally available to the public or otherwise part of the public domain after its disclosure by the Disclosing Party and other than through any act or omission of the Receiving Party or any of its Affiliates or disclosees in breach of this Agreement;

11.3.4. is subsequently disclosed to the Receiving Party or any of its Affiliates without obligation of confidentiality by a Third Party who may rightfully do so and is not under a conflicting obligation of confidentiality to the Disclosing Party; or

11.3.5. is developed by the Receiving Party or any of its Affiliates independently and without use of or reference to any Confidential Information received from the Disclosing Party, as documented by the Receiving Party's business records.

No combination of features or disclosures will be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party.

11.4. Authorized Disclosures.

11.4.1. **Permitted Circumstances**. Notwithstanding the obligations set forth in Section 11.1 (Duty of Confidence), a Party may disclose the other Party's Confidential Information

(including this Agreement and only the specifically relevant terms herein) to the extent such disclosure is reasonably necessary in the following situations:

(a) disclosure to comply with the terms of any Third Party IP Agreement;

(b) (i) the Patent Prosecution or enforcement of Kiniksa Patent Rights, Kiniksa Manufacturing Patent Rights, or Partner Collaboration Patent Rights, in each case, as contemplated by this Agreement; or (ii) in connection with regulatory filings and other filings with Governmental Authorities (including Regulatory Authorities), as necessary for the Exploitation of the Licensed Product;

(c) disclosure of this Agreement, its terms, and the status and results of Exploitation of the Licensed Product to actual or *bona fide* potential investors, acquirers, (sub)licensees, lenders, and other financial or commercial partners (including in connection with any royalty monetization transaction), and their respective attorneys, accountants, banks, investors, and advisors, solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, (sub)license, debt transaction, or collaboration; *provided* that, in each such case, on the condition that such Persons are bound by obligations of confidentiality and non-use at least as stringent as those set forth Article 11 (Confidentiality; Publication) or otherwise customary for such type and scope of disclosure any such disclosure is limited to the maximum extent practicable for the particular context in which it is being disclosed;

(d) such disclosure is required to comply with Applicable Law (whether generally or in pursuit of an application for listing of securities) including the United States Securities and Exchange Commission, or equivalent foreign agency or regulatory body, or otherwise required by judicial or administrative process, *provided* that in each such event, as promptly as reasonably practicable and to the extent not prohibited by Applicable Law or judicial or administrative process, such Party will notify the other Party, unless a shorter time period is required by Applicable Law, no later than [***] Business Days in advance of such required disclosure and provide a draft of the disclosure to the other Party reasonably in advance of such filing or disclosure for the other Party's review and comment. The non-disclosing Party will provide any comments as soon as practicable, and the disclosing Party will consider any reasonable, timely comments provided by the non-disclosing Party; *provided* that the disclosing Party may or may not accept such comments in its sole discretion. Confidential Information that is disclosed in order to comply with Applicable Law or by judicial or administrative process pursuant to this Section 11.4.1(d) (Permitted Circumstances), in each case, will remain otherwise subject to the confidentiality and non-use provisions of this Article 11 (Confidentiality; Publication) with respect to the Party disclosing such Confidential Information, and such Party will take all steps reasonably necessary, including seeking of confidential treatment or a protective order for a period of at least [***] years (to the extent permitted by Applicable Law or Governmental Authority), to ensure the continued confidential treatment of such Confidential Information, and each Party will be responsible for its own legal and other external costs in connection with any such filing or disclosure pursuant to this Section 11.4.1(d) (Permitted Circumstances); or

(e) disclosure pursuant to Section 6.8 (Notice of Regulatory Action), Section 11.6 (Publication and Listing of Clinical Trials), and Section 11.7 (Publicity; Use of Name).

11.4.2. **Confidential Treatment**. Notwithstanding any provision to the contrary set forth in this Agreement, in each case of a disclosure to be made pursuant to Section 11.4.1(d) (Permitted Circumstances), where some or all of the terms of this Agreement are to be disclosed, Kiniksa will, to the extent reasonably possible, provide to Partner a redacted version of this Agreement to be made in connection with any such disclosure, and Partner will not disclose or provide any other redacted version hereof, unless such version has been approved in writing by Kiniksa, not to be unreasonably withheld, conditioned, or delayed. Subject to the foregoing, but notwithstanding any other provision to the contrary set forth in this Agreement, if a Party is required or permitted to make a disclosure of the other Party's Confidential Information pursuant to Section 11.4.1 (Permitted Circumstances), then it will, to the extent not prohibited by Applicable Law or judicial or administrative process, except where impracticable, give reasonable advance notice to the other Party of such proposed disclosure and use reasonable efforts to secure confidential treatment of such information and will only disclose that portion of Confidential Information that is legally required to be disclosed as advised by its legal counsel. In any event, each Party agrees to take all reasonable action to avoid disclosure of Confidential Information of the other Party hereunder.

11.5. Publications. Partner will not publicly present or publish any Clinical Trial data, non-clinical or preclinical data, or any associated results or conclusions generated by or on behalf of Partner pursuant to this Agreement (each such proposed presentation or publication, a "**Publication**") without Kiniksa's prior written consent, not to be unreasonably withheld, and subject to the additional limitations set forth in this Section 11.5 (Publications) and Section 11.6 (Publication and Listing of Clinical Trials). If Partner desires to publicly present or publish a Publication in accordance with the foregoing sentence, then Partner will provide Kiniksa (including the Alliance Manager and all Kiniksa members of the JSC) with a copy of such proposed Publication to review, discuss, and determine whether to approve at least [***] days prior to the earlier of its presentation or intended submission for publication (such applicable period, the "**Review Period**"). Partner will not submit or present any Publication until (a) Kiniksa has approved such Publication or provided written comments thereon, in each case, during such Review Period, or (b) the applicable Review Period has elapsed without approval or written comments from Kiniksa, in which case Partner may proceed and the Publication will be considered approved in its entirety. If Partner receives written comments from Kiniksa on any Publication during the applicable Review Period, then it will incorporate such comments where appropriate. Notwithstanding any provision to contrary set forth in this Agreement, Partner will (i) delete any Confidential Information of Kiniksa that Kiniksa identifies for deletion in Kiniksa's written comments, (ii) delete any Clinical Trial data, results, conclusions, or other related information for the Licensed Product, the publication of which Kiniksa determines, in its sole discretion, could conflict with Kiniksa's global publication strategy with respect to the Licensed Product, and (iii) delay such Publication for a period of up to an additional [***] days after the end of the applicable Review Period to enable Kiniksa to draft and file one or more patent applications with respect to any subject matter to be made public in such Publication. Partner will provide Kiniksa a copy of the Publication at the time of the submission or presentation thereof. Partner agrees to acknowledge the contributions of Kiniksa and the employees of Kiniksa, in each case, in all Publications as scientifically appropriate. In addition, Kiniksa agrees to acknowledge the contributions of Partner and the employees of Partner, in each case, in all presentations and publications as scientifically appropriate to the extent related to any Global Clinical Trials in which Partner assists in the enrollment of patients from the Territory. Partner

will require its Affiliates and Sublicensees to comply with the obligations of this Section 11.5 (Publications) as if they were Partner, and Partner will be liable for any non-compliance of such Persons.

11.6. Publication and Listing of Clinical Trials. With respect to the listing of Clinical Trials or the publication of Clinical Trial results for the Licensed Product and to the extent applicable to a Party's activities conducted under this Agreement, each Party will comply with (a) the Pharmaceutical Research and Manufacturers of America (PhRMA) Guidelines on the listing of Clinical Trials and the Publication of Clinical Trial results, and (b) any Applicable Law or applicable court order, stipulations, consent agreements, and settlements entered into by such Party. The Parties agree that any such listings or publications made pursuant to this Section 11.6 (Publication and Listing of Clinical Trials) will be considered a Publication for purposes of this Agreement and will be subject to Section 11.5 (Publications).

11.7. Publicity; Use of Names.

11.7.1. **Press Release**. The Parties will each issue a press release announcing this Agreement, as set forth on Schedule 11.7.1(a) (Kiniksa Press Release) and Schedule 11.7.1(b) (Partner Press Release), to be issued by the Parties on such date and time as may be agreed by the Parties. Other than the press releases set forth on Schedule 11.7.1(a) (Kiniksa Press Release) and Schedule 11.7.1(b) (Partner Press Release) and the public disclosures permitted by this Section 11.7 (Publicity; Use of Names), and Section 11.4 (Authorized Disclosures), the Parties agree that except as permitted under Section 11.7.2 (Disclosures by the Parties), the portions of any other news release or other public announcement relating to this Agreement or the performance hereunder that would disclose information other than that already in the public domain will first be reviewed and approved by both Parties (with such approval not to be unreasonably withheld, conditioned, or delayed).

11.7.2. **Disclosures by the Parties**.

(a) Notwithstanding any provision to the contrary set forth in this Agreement, Kiniksa or its designees may publicly disclose (in written, oral, or other form): (a) the achievement of Milestone Events under this Agreement (including the amount, payment, and timing of any such Milestone Event); (b) the commencement, completion, material data, or key results of any Global Clinical Trials or Territory-Specific Clinical Trials for the Licensed Product conducted under this Agreement; (c) any information relating to any Global Clinical Trial, including the commencement, completion, material data, or key results; and (d) the receipt of Regulatory Approval or Reimbursement Approval for the Licensed Product.

(b) Notwithstanding any provision to the contrary set forth in this Agreement, Partner its designees may publicly disclose (in written, oral, or other form): (a) the achievement of Milestone Events under this Agreement (including the amount, payment, and timing of any such Milestone Event); (b) with Kiniksa's prior written approval, the commencement, completion, material data, or key results of any Global Clinical Trials as it relates to the Territory or Territory-Specific Clinical Trials for the Licensed Product conducted under this Agreement; (c) with Kiniksa's prior written approval, any other information relating to any Global Clinical Trial as it relates to the Territory, including the commencement, completion, material data, or key results; and (d) the receipt of Regulatory

Approval or Reimbursement Approval within the Territory for the Licensed Product.

11.7.3. **Use of Names**. Other than the press releases set forth on Schedule 11.7.1(a) (Kiniksa Press Release) and Schedule 11.7.1(b) (Partner Press Release) and the use of names in public disclosures permitted by Section 11.4 (Authorized Disclosures), the Parties agree that except as permitted under Section 11.7.2 (Disclosures by the Parties), each Party's use of other Party's name and logo in presentations, its website, collateral materials, and corporate overviews to describe the collaboration relationship, as well as in taglines of press releases issued pursuant to this Section 11.7 (Publicity; Use of Names) will first be reviewed and approved by both Parties (with such approval not to be unreasonably withheld, conditioned, or delayed). Except as permitted under this Section 11.7 (Publicity; Use of Names) or with the prior express written permission of the other Party, neither Party will use the name, trademark, trade name, or logo of the other Party or its Affiliates or their respective employees in any publicity, promotion, news release, or disclosure relating to this Agreement or its subject matter except as may be required by Applicable Law. Each Party will use the other Party's corporate name in all publicity relating to this Agreement, including the initial press release and all subsequent press releases. Partner will include explanatory text such as "*Licensed from Kiniksa*" in all publicity, promotion, news releases, or disclosures relating to the Licensed Product or such other similar text provided by Kiniksa and reasonably acceptable to Partner.

11.7.4. **Repeated Disclosures**. The Parties agree that after (a) the issuance of a disclosure or press release made in accordance with Section 11.7.1 (Press Release) or Section 11.4 (Authorized Disclosures), (b) the use of the other Party's name or logo by a Party in presentations, its website, collateral materials, or corporate overviews to describe the collaboration relationship in accordance with Section 11.7.3 (Use of Names), or (c) use of the other Party's name or logo by a Party in any taglines of press releases issued pursuant to Section 11.7.1 (Press Release) or Section 11.4 (Authorized Disclosures), in each case ((a) – (c)), the disclosing Party may make subsequent public disclosures reiterating such information without having to obtain the other Party's prior consent and approval so long as the information in such press release, other public announcement, or other materials remains true, correct, and the most current information with respect to the subject matters set forth therein. Similarly, after a Publication has been made available to the public, each Party may post such Publication or a link to it on its corporate website (or any website managed by such Party in connection with a Clinical Trial for the Licensed Product, as appropriate) without the prior written consent of the other Party, so long as the information in such Publication remains true, correct, and the most current information with respect to the subject matters set forth therein. Notwithstanding any provision to the contrary set forth in this Agreement, neither Party will use the other Party's corporate name in such manner that the distinctiveness, reputation, and validity of any trademarks and corporate or trade names of such other Party will not be impaired, and consistent with best practices used by such other Party for its other collaborators.

ARTICLE 12
REPRESENTATIONS, WARRANTIES, AND COVENANTS

12.1. Representations and Warranties of Each Party. Each Party represents and warrants to the other Party as of the Effective Date as follows:

12.1.1. It (a) is a corporation or limited company duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization; (b) has the full right, power and authority to enter into this Agreement and to perform its obligations hereunder, including the legal right to grant the licenses granted by it hereunder in accordance with the terms of this Agreement; and (c) has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder**.**

12.1.2. It has not been Debarred/Excluded and no proceeding that could result it in being Debarred/Excluded is pending, and neither it nor any of its Affiliates has used, in any capacity in the performance of obligations relating to the Licensed Product, any employee, Subcontractor, consultant, agent, representative, or other Person who has been Debarred/Excluded**.**

12.1.3. All consents, approvals, and authorizations from all Governmental Authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained**.**

12.1.4. This Agreement has been duly executed by it and is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any Applicable Law or regulation of any court, governmental body, or administrative or other agency having jurisdiction over it**.**

12.2. Representations and Warranties of Kiniksa. Kiniksa represents and warrants to Partner as of the Effective Date as follows:

12.2.1. It has the right under the Kiniksa Technology and Kiniksa Manufacturing Technology to grant to Partner the licenses set forth in this Agreement, and it has not granted any license or other right under the Kiniksa Technology that is inconsistent with the licenses granted to Partner hereunder**.**

12.2.2. With respect to any such Kiniksa Patent Right identified on Schedule 1.106 (Kiniksa Patent Rights) as being owned by Kiniksa, Kiniksa owns all rights, title, and interests in and to such Kiniksa Patent Rights**.**

12.2.3. Except as otherwise disclosed to Partner in writing, there is no pending or, to Kiniksa's Knowledge, threatened litigation, nor has Kiniksa received any written notice from any Third Party, asserting or alleging that the Exploitation of the Licensed Product infringes or misappropriates the intellectual property rights of such Third Party**.**

12.2.4. There are no pending or, to Kiniksa's Knowledge, threatened, adverse actions, suits, or proceedings against Kiniksa or any of its Affiliates or to Kiniksa's Knowledge, any of its licensees, sublicensees or licensors involving the Kiniksa Technology or Kiniksa Manufacturing Technology (including, to Kiniksa's Knowledge, any action to invalidate Kiniksa Patent Rights)**.**

12.2.5. To Kiniksa's Knowledge, Kiniksa has not withheld from Partner any information with respect to the Kiniksa Technology that, in Kiniksa's reasonable determination, would materially adversely affect the Development, Manufacture, or Commercialization of the Licensed Product in the Territory as contemplated under this Agreement. To Kiniksa's

Knowledge, (a) true, complete, and correct copies of all portions of Regulatory Documentation that is material for the Licensed Product in the Territory; and (b) all material adverse written information with respect to the safety of the Licensed Product have been provided or made available to Partner prior to the Effective Date. To Kiniksa's Knowledge, the information provided by Kiniksa to Partner regarding the Kiniksa Technology is accurate, true, and correct in all material respects.

12.2.6. To Kiniksa's Knowledge, neither Kiniksa nor any of its Affiliates have employed nor used a contractor or consultant that has employed any Person Debarred/Excluded, or any Person that is the subject of an investigation or proceeding that could result in such Person being Debarred/Excluded, in any capacity in connection with this Agreement**.**

12.2.7. There are no legal claims, judgments, or settlements against or owed by Kiniksa or any of its Affiliates, or pending or, to Kiniksa's Knowledge, threatened, legal claims or litigation, in each case, relating to antitrust, anti-competition, or Anti-Corruption Law violations**.**

12.2.8. Schedule 1.58 (Existing In-Licenses) sets forth all Existing In-Licenses as of the Effective Date, redacted copies of which have been provided to Partner prior to the date hereof**.** Except for the redactions in such copies, Kiniksa has provided Partner with true, complete and correct copies of all Existing In-Licenses. Other than the Existing In-Licenses, there are no agreements between Kiniksa and any Third Party pursuant to which Kiniksa Controls any Kiniksa Technology licensed to Partner under this Agreement.

12.2.9. Each Existing In-License is a valid binding agreement, enforceable in accordance with its terms and neither Kiniksa nor any counterparty to any Existing In-Licenses has in writing alleged or threatened that the other party has breached an Existing In-License (which has not been cured) or, to Kiniksa's Knowledge, threatened in writing to terminate an Existing In-License**.**

12.2.10. To its Knowledge, neither Kiniksa nor any of its Affiliates, or its or their directors, officers, employees, distributors, agents, representatives, sales intermediaries, or other Third Parties acting on behalf of Kiniksa or any of its Affiliates:

(a) has taken any action in violation of any applicable Anti-Corruption Laws; or

(b) has corruptly offered, paid, given, promised to pay or give, or authorized the payment or gift of anything of value, directly or indirectly, to any Public Official, for the purposes of:

(i) influencing any act or decision of any Public Official in his or her official capacity;

(ii) inducing such Public Official to do or omit to do any act in violation of his or her lawful duty;

(iii) securing any improper advantage; or

(iv) inducing such Public Official to use his or her influence with a government, governmental entity, or commercial enterprise owned or controlled by any government (including state-owned or controlled

veterinary, laboratory or medical facilities) in obtaining or retaining any business whatsoever.

12.3. Representations and Warranties of Partner. Partner represents and warrants to Kiniksa as of the Effective Date as follows:

12.3.1. No Partner Technology exists as of the Effective Date**.**

12.3.2. There are no Partner Patent Rights owned by or exclusively licensed to Partner or any of its Affiliates**.**

12.3.3. There are no legal claims, judgments, or settlements against or owed by Partner or any of its Affiliates, or pending or, to Partner's Knowledge, threatened, legal claims or litigation, in each case, relating to antitrust, anti-competition, or Anti-Corruption Law violations**.**

12.3.4. Partner has sufficient financial wherewithal to (a) perform all of its obligations set forth under this Agreement, and (b) meet all of its obligations that come due in the ordinary course of business**.**

12.3.5. Partner has, or can readily obtain, sufficient technical, clinical, and regulatory expertise to perform all of its obligations pursuant to this Agreement, including its obligations relating to Development, Manufacturing, performance of Medical Affairs, Commercialization, and obtaining Regulatory Approvals, in each case, of the Licensed Product as contemplated under this Agreement**.**

12.3.6. To its Knowledge, neither Partner nor any of its Affiliates, or its or their directors, officers, employees, distributors, agents, representatives, sales intermediaries, or other Third Parties acting on behalf of Partner or any of its Affiliates:

(a) has taken any action in violation of any applicable Anti-Corruption Laws; or

(b) has corruptly offered, paid, given, promised to pay or give, or authorized the payment or gift of anything of value, directly or indirectly, to any Public Official, for the purposes of:

(i) influencing any act or decision of any Public Official in his or her official capacity;

(ii) inducing such Public Official to do or omit to do any act in violation of his or her lawful duty;

(iii) securing any improper advantage; or

(iv) inducing such Public Official to use his or her influence with a government, governmental entity, or commercial enterprise owned or controlled by any government (including state-owned or controlled veterinary, laboratory or medical facilities) in obtaining or retaining any business whatsoever.

12.3.7. Except as otherwise disclosed on Schedule 12.3 (Partner Disclosures), none of the officers, directors, or employees of Partner or of any of its Affiliates or agents acting on behalf of

Partner or any of its Affiliates, in each case, that are employed or reside outside the United States, is a Public Official**.**

12.4. Covenants of Partner. Partner covenants to Kiniksa that:

12.4.1. Partner will conduct all Clinical Development activities for the Licensed Product solely in accordance with, and will not conduct any Clinical Development activities other than as set forth in, the applicable Territory Development Plan or Global Development Pla**n**. Partner will conduct all Medical Affairs and Commercialization activities for the Licensed Product solely in accordance with, and will not conduct any Medical Affairs or Commercialization activities other than as set forth in, the applicable Medical Affairs Plan or Commercialization Plan, respectively.

12.4.2. Partner will only engage Clinical Trial sites under a Global Development Plan or a Territory Development Plan that conduct all Clinical Trials in compliance with Applicable Law, including cGCP and the GCP guidelines and that are approved by the applicable Regulatory Authority in the country or region in the Territory in which such Clinical Trial site is located**.**

12.4.3. Partner will permit, or will cause any of its applicable Affiliates, Sublicensees, or Subcontractors to permit, Kiniksa, its Affiliates, or Representatives to visit and inspect, no more than [***] per Calendar Year any of Partner's or its Affiliates', Sublicensees', or Subcontractors' facilities that perform Pre-Clinical Development, Manufacturing, Medical Affairs, or Commercialization of the Licensed Product (or any component thereof) upon Kiniksa's request during normal business hours and upon no less than [***] days' prior notice and at Kiniksa's sole cost; provided that all such inspections will be conducted in accordance with Partner's and its Affiliates', Sublicensees' or Subcontractors confidentiality requirements and on-site policies (as applicable), in each, to the extent communicated to Kiniksa in writing in advance**.**

12.5. Covenants of Kiniksa and Partner.

12.5.1. **Compliance with Existing In-Licenses**. In the course of performing its obligations or exercising its rights under this Agreement, each Party will comply with all terms of each Existing In-License.

12.5.2. **Compliance with Applicable Law**. In the course of performing its obligations or exercising its rights under this Agreement, each Party will comply with all Applicable Law, including, as applicable, cGMP, cGCP, and cGLP, and will not employ or engage, and if so employed and engaged, will thereafter terminate any Person who has been Debarred/Excluded, or is the subject of any proceedings that could result in such Person being Debarred/Excluded.

12.5.3. **Compliance with Anti-Corruption Laws.** Notwithstanding any provision to the contrary set forth in this Agreement, each Party agrees as follows:

(a) It will not, in the performance of this Agreement, perform any actions that are prohibited by any Anti-Corruption Laws that may be applicable to one or both Parties.

(b) It will not, in the performance of this Agreement, directly or indirectly, make any payment, or offer or transfer anything of value, or agree or promise to make any payment or offer or transfer anything of value, to a government official or government employee, to any political party or any candidate for political office or to any other Third Party with the purpose of influencing decisions related to either Party or its business in a manner that would violate applicable Anti-Corruption Laws.

(c) It will not, directly or indirectly, solicit, receive, or agree to accept any payment of money or anything else of value in violation of the Anti-Corruption Laws.

(d) It will comply with the Anti-Corruption Laws and will not take any action that will, or would reasonably be expected to, cause the other Party or its Affiliates or licensors to be in violation of any such laws.

(e) It will, no later than [***] days following the end of each Calendar Year, verify in writing that to its Knowledge, there have been no violations of Anti-Corruption Laws by it or its Affiliates or Sublicensees, or persons employed by or Subcontractors used by it or its Affiliates or Sublicensees in the performance of this Agreement, or will provide details of any exception to the foregoing.

(f) It will maintain records (financial and otherwise) and supporting documentation related to the subject matter of this Section 12.5.3 (Compliance with Anti-Corruption Laws) in order to document or verify compliance with the provisions of this Section 12.5.3 (Compliance with Anti-Corruption Laws), and upon request of other Party upon reasonable advance notice, will provide the other Party or its representative with access to such records for purposes of verifying compliance with the provisions of this Section 12.5.3 (Compliance with Anti-Corruption Laws).

(g) It will promptly provide the other Party with written notice of the following events: (i) upon becoming aware of any breach or violation by the other Party of any covenant or undertaking set out in this Section 12.5.3 (Compliance with Anti-Corruption Laws); or (ii) upon receiving a formal notification that it is the target of a formal investigation by a Governmental Authority for a material Anti-Corruption Law violation or upon receipt of information from its Affiliates, agents, representatives, consultants, and Sublicensees, subcontractors hired in connection with the subject matter of this Agreement that any of them is the target of a formal investigation by a Governmental Authority for a material Anti-Corruption Law violation.

12.6. NO OTHER WARRANTIES. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 12 (REPRESENTATIONS, WARRANTIES, AND COVENANTS), (A) NO REPRESENTATION, CONDITION, OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF KINIKSA OR PARTNER; AND (B) ALL OTHER CONDITIONS AND WARRANTIES WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE ARE EXPRESSLY EXCLUDED, INCLUDING ANY CONDITIONS AND WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, OR NON-INFRINGEMENT. ANY INFORMATION PROVIDED BY KINIKSA OR ITS AFFILIATES IS MADE AVAILABLE ON AN "AS IS" BASIS WITHOUT WARRANTY WITH RESPECT TO COMPLETENESS, COMPLIANCE WITH REGULATORY STANDARDS OR

REGULATIONS, OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER KIND OF WARRANTY WHETHER EXPRESS OR IMPLIED.

12.7. **Time for Claims**. Except in the case of any fraud or intentional misrepresentation by a Party: (a) the representations and warranties of the Parties contained in Section 12.1 (Representations and Warranties of Each Party), Section 12.2 (Representations and Warranties of Kiniksa), and Section 12.3 (Representations and Warranties of Partner) will survive until the date that is [***] months after the Effective Date, (b) no claim may be made or suit instituted alleging breach or seeking indemnification pursuant to Article 12 (Representations, Warranties, and Covenants) for any breach of, or inaccuracy in, any representation or warranty contained in Section 12.1 (Representations and Warranties of Each Party), Section 12.2 (Representations and Warranties of Kiniksa), and Section 12.3 (Representations and Warranties of Partner) unless a written notice is provided to the Indemnifying Party at any time prior to the date that is [***] months following the Effective date, and (c) after such [***] month period, no Party may bring any claim against the other Party arising from or relating to such other Party's breach of such representations and warranties.

ARTICLE 13
INDEMNIFICATION

13.1. **By Partner**. Partner will indemnify and hold harmless Kiniksa and its Affiliates, and their respective directors, officers, employees, successors, heirs and assigns, and agents (individually and collectively, the "**Kiniksa Indemnitees**") from and against all Losses incurred in connection with any Third Party Claims to the extent arising from or relating to (a) the Exploitation of the Licensed Product by or on behalf of Partner or any of its Affiliates, Sublicensees, or Subcontractors, including product liability and intellectual property claims arising from such Exploitation, (b) the negligence or willful misconduct of Partner or any of its Affiliates, Sublicensees, or Subcontractors, (c) breach by Partner or any of its Affiliates, Sublicensees, or Subcontractors of any of Partner's representations, warranties, covenants, or obligations set forth in or entered into pursuant to this Agreement, (d) the failure of Partner or any of its Affiliates, Sublicensees, or Subcontractors to abide by any Applicable Law, (e) any claim or demand from any employee or contractor of Partner or its Affiliate who is an inventor of any Assigned Collaboration Technology, or Joint Collaboration Technology with respect to the ownership thereof under Applicable Law in the Territory, or (f) the holding by Kiniksa of, or action by Kiniksa related to, any Regulatory Submissions, Regulatory Approvals, or Reimbursement Approvals on behalf of Partner, in each case of clauses (a) through (f) above, except to the extent such Third Party Claims arise out of a Kiniksa Indemnitee's negligence or willful misconduct, breach of this Agreement, or failure to abide by any Applicable Law or to the extent otherwise indemnifiable by Kiniksa under Section 13.2 (Indemnification; By Kiniksa).

13.2. **By Kiniksa**. Kiniksa will indemnify and hold harmless Partner, its Affiliates, and their directors, officers, employees, successors, heirs and assigns, and agents (individually and collectively, the "**Partner Indemnitees**") from and against all Losses incurred in connection with any Third Party Claims to the extent from or relating to (a) the Exploitation of the Licensed Product, by or on behalf of Kiniksa or any of its Affiliates, licensees (not including Partner or its Affiliates, Sublicensees, or its Subcontractors), including product liability and intellectual property claims arising from such Exploitation, and including such Exploitation after the effective date of termination of this Agreement, (b) the negligence or willful misconduct of Kiniksa or any of its Affiliates, licensees (not including Partner or its Affiliates, Sublicensees, or its Subcontractors), Sublicensees (not including Partner or its Affiliates, Sublicensees, or Subcontractors), or Subcontractors, (c) breach by Kiniksa or any of its Affiliates, licensees (not including Partner or its Affiliates, Sublicensees,

or Subcontractors), Sublicensees (not including Partner or its Affiliates, Sublicensees, or Subcontractors), or Subcontractors of any of Kiniksa's representations, warranties, covenants, or obligations set forth in or entered into pursuant to this Agreement, or (d) the failure of Kiniksa or any of its Affiliates, licensees (not including Partner or its Affiliates, Sublicensees, or Subcontractors), Sublicensees (not including Partner or its Affiliates, Sublicensees, or Subcontractors), or Subcontractors to abide by any Applicable Law, in each case of clauses (a) through (d) above, except to the extent such Third Party Claims arise out of any of a Partner Indemnitee's negligence or willful misconduct, breach of this Agreement or failure to abide by any Applicable Law or to the extent otherwise indemnifiable by Partner under Section 13.1 (Indemnification; By Partner).

13.3. **Indemnification Procedure**. If either Party is seeking indemnification under Section 13.1 (Indemnification; By Partner) or Section 13.2 (Indemnification; By Kiniksa) (the "**Indemnified Party**"), then it will inform the other Party (the "**Indemnifying Party**") of the Third Party Claim giving rise to such indemnification obligations within [***] days after receiving written notice of the Third Party Claim (it being understood and agreed, however, that the failure or delay by an Indemnified Party to give such notice of a Third Party Claim will not affect the Indemnifying Party's indemnification obligations hereunder except to the extent the Indemnifying Party will have been actually and materially prejudiced as a result of such failure or delay to give notice). The Indemnifying Party will have the right to assume the defense of any such Third Party Claim for which it is obligated to indemnify the Indemnified Party. The Indemnified Party will cooperate with the Indemnifying Party and the Indemnifying Party's insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party's cost and expense. The Indemnified Party will have the right to participate, at its own expense and with counsel of its choice, in the defense of any Third Party Claim that has been assumed by the Indemnifying Party. Neither Party will have the obligation to indemnify the other Party in connection with any settlement made without the Indemnifying Party's written consent, which consent will not be unreasonably withheld, conditioned, or delayed. The Indemnifying Party will not admit liability of the Indemnified Party without the Indemnified Party's prior written consent, which consent will not be unreasonably withheld, conditioned, or delayed. If the Parties cannot agree as to the application of Section 13.1 (Indemnification; By Partner) or Section 13.2 (Indemnification; By Kiniksa) as to any Third Party Claim, pending resolution of the Dispute pursuant to Article 16 (Dispute Resolution), then the Parties may conduct separate defenses of such Third Party Claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 13.1 (Indemnification; By Partner) or Section 13.2 (Indemnification; By Kiniksa), as applicable, upon resolution of the underlying Third Party Claim.

13.4. **Insurance**. Each of Kiniksa and Partner will procure and maintain during the Term of this Agreement and until the later of: (a) [***] years after termination or expiration of this Agreement, or (b) the date that all statutes of limitation covering claims or suits that may be instituted for personal injury based on the sale or use of the Licensed Product have expired, commercial general liability insurance from a minimum of "A-" AM Bests rated insurance company or insurer reasonably acceptable to the other Party, including contractual liability and product liability or clinical trials, if applicable, with coverage limits of not less than $[***] per occurrence and $[***] in the aggregate. Such policies will name the other Party and its Affiliates as additional insureds and provide a waiver of subrogation in favor of Kiniksa and its Affiliates or Partner and its Affiliates (as the case may be). Such insurance policies will be primary and non-contributing with respect to any other similar insurance policies available to Kiniksa or its Affiliates or Partner and its Affiliates (as the case may be). Each of Kiniksa and Partner will provide the other Party with evidence of such insurance promptly following execution by both Parties of this Agreement, upon a Party's request, and prior to expiration of any one coverage. Each of Kiniksa and Partner will

provide the other Party with reasonable advanced written notice prior to the cancellation or non-renewal of, or material changes in, such insurance. Such insurance will not be construed to create a limit of Kiniksa's or Partner's liability with respect to its indemnification obligations under this Article 13 (Indemnification).

ARTICLE 14
INTELLECTUAL PROPERTY

14.1. Inventions.

14.1.1. **Ownership**. As between the Parties, (a) Kiniksa will solely own all (i) Assigned Collaboration Technology, and (ii) Kiniksa Collaboration Technology, (b) Partner will solely own all Partner Collaboration Technology, and (c) the Parties will jointly own all Joint Collaboration Technology.

14.1.2. **Disclosure**. Partner will promptly disclose to Kiniksa all inventions within the Collaboration Know-How that it develops or invents, whether solely or jointly with others (in any event, prior to the filing of any patent application with respect to such inventions), including all invention disclosures or other similar documents submitted to Partner by its or its Affiliates' employees, agents, or independent contractors relating thereto. Partner will also promptly respond to reasonable requests from Kiniksa for additional information relating thereto.

14.1.3. **Assignment by Partner**. Partner will and hereby does assign to Kiniksa all of its rights, title, and interests in and to all Assigned Collaboration Technology, and Kiniksa hereby accepts such assignment. Partner will take (and cause its Affiliates and Sublicensees, and their respective employees, agents, and contractors to take) such further actions reasonably requested by Kiniksa to evidence such assignment and to assist Kiniksa in obtaining patent and other intellectual property rights protection for inventions within the Assigned Collaboration Know-How, including executing further assignments, consents, releases, and other commercially reasonable documentation and providing good faith testimony by affidavit, declaration, in-person, or other proper means in support of any effort by Kiniksa to establish, perfect, defend, or enforce its rights in any Assigned Collaboration Technology through prosecution of governmental filings, regulatory proceedings, litigation, and other means, including through the filing, prosecution, maintenance, and enforcement of the Assigned Collaboration Technology. Partner will obligate its Affiliates, Sublicensees, and Subcontractors to assign all Assigned Collaboration Technology to Partner (or directly to Kiniksa) so that Partner can comply with its obligations under this Section 14.1.3 (Assignment by Partner), and Partner will promptly obtain such assignment. Without limitation, Partner will cooperate with Kiniksa if Kiniksa applies for U.S. or ex-U.S. patent protection for such Assigned Collaboration Technology and will obtain the cooperation of the individual inventors of any such Collaboration Technology. If Partner is unable to assign to Kiniksa any Assigned Collaboration Technology, then Partner hereby grants and agrees to grant to Kiniksa a royalty-free, fully paid-up, exclusive (even as to Partner, subject to the terms of this Agreement, including the licenses granted to Partner pursuant to Section 2.1 (License Grants to Partner)), perpetual, irrevocable license (with the right to grant sublicenses through multiple tiers) under such Assigned Collaboration Technology, as applicable, for any and all purposes.

14.1.4. **Practice Under and other Use of Joint Collaboration Technology**. Subject to the rights granted under and the restrictions set forth in this Agreement (including Section 2.7

(Exclusivity Covenants)), neither Party will have any obligation to account to the other Party for profits, or to obtain any approval of the other Party to license, assign, or otherwise exploit any Joint Collaboration Technology by reason of joint ownership thereof, and each Party hereby waives any right it may have under the Applicable Law of any jurisdiction to require any such approval or accounting. To the extent any further consent is required to enable a Party to so license or exploit its interest in the Joint Collaboration Technology, the other Party hereby grants such consent.

14.1.5. **Employee Assignment**. Partner and its Affiliates and Sublicensees performing activities or exercising rights under this Agreement will enter into with each of their respective employees legally binding and sufficient agreements or employment policies providing for the payment by Partner or its Affiliate of any reward or remuneration required under Applicable Law in a particular country or region in the Territory in consideration for the development of inventions by such employees. Without limiting the generality of the foregoing, Partner and its Affiliates will, and will cause its Sublicensees to, enter into an agreement or employment policy with each of its employees performing activities under this Agreement that (a) compels prompt disclosure to Partner (or its Sublicensee, as applicable) of all Collaboration Technology discovered or developed, invented, or filed by such employee during any performance under this Agreement; (b) automatically assigns to Partner (or its Sublicensee, as applicable) all rights, title, and interests in and to all Collaboration Technology, and requires each employee to execute all documents and take such other actions as may be necessary to effectuate such assignment; (c) includes an invention and patent reward and remuneration policy providing for the payment by Partner of any reward or remuneration required under Applicable Law in such country or region in consideration for the development of inventions by such employees that is legally sufficient under Applicable Law in the applicable country or region in the Territory; and (d) includes a waiver of pre-emption rights under any Applicable Law in such country or region, including in the case of an employee in the PRC, Article 326 of the Contract Law of the PRC to the effect that the employee will confirm that he/she will not have any right or claim with respect to any Collaboration Technology derived from his/her work, except for the reward and remuneration he/she is entitled to under the invention and patent reward and remuneration policy.

14.1.6. **Payments in Consideration of Assignments of Intellectual Property**.

(a) **Payment by Kiniksa**. In consideration of the assignment by Partner to Kiniksa of all Assigned Collaboration Technology, Kiniksa will pay to Partner a one-time payment of $[***] [***], which payment will be payment in-full for the assignment of all Assigned Collaboration Technology hereunder, regardless of how many patent applications are filed or patents are issued Covering the Assigned Collaboration Know-How. Kiniksa will notify Partner of Kiniksa's filing of the first patent application claiming any Assigned Collaboration Know-How with respect to which an employee of Partner is an inventor. Promptly thereafter, Partner will invoice Kiniksa for the foregoing amount, and Kiniksa will pay the undisputed invoiced amounts within [***] days after the date of such invoice. The Parties expressly acknowledge that the foregoing amount is reasonable compensation paid in consideration of the assignments of Assigned Collaboration Technology contemplated under this Agreement and is sufficient to satisfy the requirements under Applicable Law in the Territory regarding amounts to be paid in consideration of the assignment of intellectual property rights by Persons domiciled in the PRC to Persons domiciled outside of the PRC.

(b) **Reward and Remuneration Payments to Partner Employees**. As between the Parties, Partner will be solely responsible for the payment of, and Partner will pay, any rewards and remuneration for inventions and technical achievements required by Applicable Law to be paid to its employees for the development or invention of any Collaboration Technology, regardless of the form of such payment (including, for example, as a royalty). Notwithstanding any provision to the contrary in this Agreement, no payment made by Partner pursuant to Section 14.1.3 (Assignment by Partner) as reward or remuneration for any employee invention may be used as a credit against, or may otherwise reduce, any payment owed by Partner to Kiniksa under this Agreement.

14.2. CREATE Act. Notwithstanding any provision to the contrary set forth in this Agreement, Partner may not invoke the Cooperative Research and Technology Enhancement Act, 35 U.S.C. § 102(c) (the "**CREATE Act**") when exercising its rights under this Agreement without the prior written approval of Kiniksa. If Partner intends to invoke the CREATE Act, then it will notify Kiniksa and if agreed by the Parties, Kiniksa will cooperate and coordinate its activities with Partner with respect to any filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in the CREATE Act.

14.3. Patent Prosecution.

14.3.1. **Kiniksa Patent Rights and Kiniksa Manufacturing Patent Rights**.

(a) **Right to Prosecute**. As between the Parties, Kiniksa or its Affiliate will have the first right, in its sole discretion, to control the Patent Prosecution of all Kiniksa Patent Rights throughout the world. Partner will obtain any necessary assignment documents for Kiniksa with respect to the Patent Prosecution of such Patent Rights, will render all signatures that will be necessary for such patent filings, and will assist Kiniksa or its Affiliate in all other reasonable ways that are necessary for the issuance of such Patent Rights as well as for the Patent Prosecution of such Patent Rights. Partner will be responsible for [***]% of the reasonable out-of-pocket costs incurred by or on behalf of Kiniksa or its Affiliate with respect to the Patent Prosecution of such Patent Rights in the Territory, and will reimburse Kiniksa for such costs within [***] days after receiving an invoice with reasonable supporting documentation for such costs.

(b) **Review and Consult**. Kiniksa will consult with Partner and keep Partner reasonably informed regarding the Patent Prosecution of the Kiniksa Patent Rights in the Territory and will provide Partner with substantive correspondence received from any patent authority in the Territory in connection therewith no later than [***] days after Kiniksa's receipt thereof. In addition, Kiniksa will provide Partner with drafts (in English) of proposed substantive filings in the Territory and correspondence to any patent authority in the Territory in connection with the Patent Prosecution of the Kiniksa Patent Rights in the Territory for Partner's review and comment prior to the submission of such proposed filings and correspondence, which comments (if any) Partner must provide no later than [***] Business Days after receipt of the applicable filing or correspondence. Further, Kiniksa will notify Partner of any decision to cease Patent Prosecution of any Kiniksa Patent Rights in the Territory. Kiniksa will consider Partner's reasonable comments on Patent Prosecution, but will have final decision-making authority under this Section 14.3.1(b) (Review and Consult). The Parties, through their

respective IP counsels, will discuss the strategy for the portfolio of Patent Rights Covering the Licensed Product in the Territory.

(c) **Abandonment**. If Kiniksa or its Affiliate decides that it is no longer interested in the Patent Prosecution of a particular Kiniksa Patent Right in the Territory during the Term, then, unless Kiniksa or its Affiliate has a strategic rationale for ceasing such Patent Prosecution or such Patent Prosecution is otherwise inconsistent with any Third Party IP Agreement, it will provide written notice to Partner of such decision at least [***] days prior to the date that such the applicable Patent Right will become abandoned. To the extent consistent with the rights granted to Kiniksa or its Affiliate under any Third Party IP Agreement, Partner may, upon written notice to Kiniksa, cause Kiniksa or its Affiliate not to cease the Patent Prosecution of any such Patent Right with respect to which Kiniksa or its Affiliate does not have a strategic rationale for the abandonment thereof.

(d) **Manufacturing Patent Rights**. Notwithstanding any provision to the contrary set forth in this Agreement, Kiniksa or its Affiliate will have the sole right to control the Patent Prosecution of the Kiniksa Manufacturing Patent Rights worldwide, including in the Territory at Kiniksa's sole cost and expense.

14.3.2. **Partner Collaboration Patent Rights**.

(a) **Right to Prosecute**. As between the Parties, Partner will have the right to control the Patent Prosecution of all Partner Collaboration Patent Rights throughout the world. Partner will be responsible for [***]% of the costs and expenses incurred with respect to the Patent Prosecution of such Patent Rights throughout the world.

(b) **Review and Consult**. Partner will consult with Kiniksa and keep Kiniksa reasonably informed regarding the Patent Prosecution of the Partner Collaboration Patent Rights and will provide Kiniksa with all substantive correspondence received from any patent authority in connection therewith. In addition, Partner will provide Kiniksa with drafts of all proposed substantive filings and correspondence to any patent authority in connection with the Patent Prosecution of the Partner Collaboration Patent Rights for Kiniksa's review and comment at least [***] days prior to the submission of such proposed filings and correspondence, which comments (if any) Kiniksa must provide no later than [***] Business Days after receipt of the applicable filing or correspondence. Further, Partner will notify Kiniksa of any decision to cease Patent Prosecution of any Partner Collaboration Patent Rights. Partner will consider Kiniksa's reasonable comments on Patent Prosecution and will incorporate such comments where appropriate.

(c) **Abandonment**. If Partner decides that it is no longer interested in continuing the Patent Prosecution of a particular Partner Collaboration Patent Right during the Term, then, unless Partner has a strategic rationale for ceasing such Patent Prosecution, it will provide written notice to Kiniksa of such decision at least [***] days prior to the date on which such Patent Right will become abandoned. Kiniksa or its Affiliate may, upon written notice to Partner, cause Partner not to cease such Patent Prosecution of such Partner Collaboration Patent Right with respect to which Partner does not have a strategic rationale for the abandonment thereof. In

such event, Kiniksa will be responsible for [***]% of the costs and expenses of the Patent Prosecution of such Patent Right.

14.3.3. **Joint Collaboration Patent Rights**. During the Term, the Parties and their respective patent counsel will jointly determine the strategy for the Patent Prosecution of any Joint Collaboration Patent Right. Each Party will conduct its activities with respect to Patent Prosecution of any Joint Collaboration Patent Right in a reasonable manner that does not unduly prejudice the rights of the other Party in the other Party's territory, and each Party will provide all assistance reasonably requested by the other Party in relation to the Patent Prosecution of the Joint Collaboration Patent Rights in the other Party's territory.

14.4. Patent Enforcement.

14.4.1. **Notice**. Each Party will notify the other within [***] days after becoming aware of any suspected or actual infringement by a Third Party product in the Territory of any of the (a) Kiniksa Patent Rights in the Territory, (b) Kiniksa Manufacturing Patent Rights in the Territory, or (c) Partner Collaboration Patent Rights in the Territory, and, in each case, any related declaratory judgment or equivalent action alleging the invalidity, unenforceability, or non-infringement of such Patent Rights (collectively "**Kiniksa Patent Right Infringement**"). Each Party will also notify the other Party within [***] days after becoming aware of any alleged or threatened infringement by a Third Party of any Kiniksa Patent Right, Kiniksa Manufacturing Patent Right, or Partner Collaboration Patent Right that adversely affects or is expected to adversely affect the Licensed Product outside of the Territory, including any related declaratory judgment or equivalent action alleging the invalidity, unenforceability or non-infringement of any such Patent Rights (an "**Ex-Territory Infringement**"). For clarity, Kiniksa Patent Right Infringement and Ex-Territory Infringement each exclude any adversarial Patent Prosecution proceedings.

14.4.2. **Enforcement Rights**.

(a) **First Right and Step-In for Kiniksa Patent Right Infringement**.

(i) **Kiniksa Sole Right**. Except as expressly provided in this Section 14.4.2 (Enforcement Rights), Kiniksa or its Affiliate will have the sole right, in its discretion, to bring and control any legal action to enforce Kiniksa Patent Rights and Kiniksa Manufacturing Patent Rights.

(ii) **Kiniksa First Right**. Kiniksa or its Affiliate will have the first right, in its discretion, to bring and control any legal action to enforce a Kiniksa Patent Rights against any Kiniksa Patent Right Infringement related a product of a Third Party that is competitive with the Licensed Product in the Territory (a "**Competitive Infringement**") as it reasonably determines appropriate, and Kiniksa will consider the interests of Partner in such enforcement of such Kiniksa Patent Right against any Competitive Infringement in the Territory.

(iii) **Partner First Right**. Partner will have the first right to bring and control any legal action to enforce the Partner Collaboration Patent Rights against any Competitive Infringement in the Territory as it reasonably determines appropriate, and Partner will consider the interests of Kiniksa in such

enforcement of the Partner Collaboration Patent Rights against such Competitive Infringement.

(iv) **Joint Collaboration Patent Rights**. The Parties and their respective patent counsel will jointly determine which Party will have the first right to bring and control any legal action to enforce the Joint Collaboration Patent Rights against any Competitive Infringement in the Territory.

(v) **Step-In Rights**. The Party with the first right to bring and control any legal action to enforce the Kiniksa Patent Rights or Partner Collaboration Patent Rights, as applicable, pursuant to Section 14.4.2(a)(ii) (Kiniksa First Right) or Section 14.4.2(a)(iii) (Partner First Right) will be referred to herein as the "**Controlling Party**." If the Controlling Party or its designee fails to abate such Competitive Infringement in the Territory or to file an action to abate such Competitive Infringement in the Territory within [***] months after a written request from the other Party to do so, or if the Controlling Party discontinues the prosecution of any such action after filing without abating such infringement, then, in either case, to the extent consistent with the rights granted to Kiniksa or its Affiliate under any Third Party IP Agreement, the other Party will have the right to enforce the applicable Patent Rights against such Competitive Infringement (A) with respect to Kiniksa as the non-Controlling Party, both in and outside of the Territory, or (B) with respect to Partner as the non-Controlling Party, only in the Territory, in each case ((A) and (B)) as such non-Controlling Party reasonably determines appropriate, *provided* that (1) the Controlling Party does not provide reasonable rationale for not doing so or continuing to do so (including a substantive concern regarding counter-claims by the infringing Third Party), and (2) the other Party will not enter into any settlement admitting the invalidity of, or otherwise impairing, any such Patent Rights without the prior written consent of the Controlling Party.

14.4.3. **Cooperation**. At the request of the Party bringing an action related to infringement of any Kiniksa Patent Right, Kiniksa Manufacturing Patent Right, or Partner Collaboration Patent Right in accordance with this Section 14.4 (Patent Enforcement) either inside or outside the Territory, the other Party will provide reasonable assistance reasonably requested by the enforcing Party in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery, and joining as a party to the action if required by Applicable Law to pursue such action.

14.4.4. **Recoveries**. Any recoveries resulting from an enforcement action relating to a Competitive Infringement in the Territory will be first applied against payment of each Party's costs and expenses in connection therewith. Any such recoveries in excess of such costs and expenses will be split as follows: (a) [***]% will be paid to the Party initiating such suit, action, or proceeding and (b) [***]% will be paid to the non-initiating Party.

14.5. Infringement of Third Party Rights.

14.5.1. **Notice**. If the Licensed Product used or sold by Partner or its Affiliates or Sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent Right or other rights in the Territory that are owned or controlled by such Third Party, then

Partner will promptly notify Kiniksa within [***] Business Days after receipt of such claim or assertion and will include in such notice a copy of any summons or complaint (or the equivalent thereof) received regarding the foregoing. Thereafter, the Parties will promptly meet to consider the claim or assertion and the appropriate course of action and may, if appropriate, agree on and enter into a "common interest agreement" wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute. The Parties will assert and not waive the joint defense privilege with respect to any communications between the Parties in connection with the defense of such claim or assertion.

14.5.2. **Defense**. Partner will be solely responsible for the defense of any such infringement claims brought against Partner, at Partner's cost and expense; *provided* that Partner will not agree to any settlement, consent to judgment, or other voluntary final disposition in connection with such defense action without Kiniksa's prior written consent if such settlement, consent to judgment, or other voluntary final disposition would (a) result in the admission of any liability or fault on behalf of Kiniksa or any of its Affiliates, (b) result in or impose any payment obligations upon Kiniksa or any of its Affiliates, or (c) subject Kiniksa or any of its Affiliates to an injunction or otherwise limit Kiniksa's or any of its Affiliates' ability to take any actions or refrain from taking any actions under this Agreement or with respect to the Licensed Product or the Third Party's Patent Rights or other rights. Partner will keep Kiniksa informed on the status of such defense action, and Kiniksa or its Affiliate will have the right, but not the obligation, to participate and be separately represented in such defense action at its sole option and at its own expense.

14.6. Patent Listings. With respect to patent listings in any patent listing system established by any applicable Regulatory Authority in a region in the Territory or under Applicable Law, including, (a) in the PRC, under Article 76 of the Patent Law of the PRC and its implementing measures and interpretations promulgated by relevant PRC Governmental Authorities, including the National Medical Products Administration (NMPA), the China National Intellectual Property Administration (CNIPA), and the Supreme People's Court, and (b) other equivalents thereof in the Territory, for Kiniksa Patent Rights, Kiniksa Manufacturing Patent Rights, or Collaboration Patent Rights Covering the Licensed Product, the Parties will discuss and agree which Patent Rights to list in such patent listing in such region (the "**Listing Patent Rights**") (i) prior to the submission of the first and any subsequent MAA for the Licensed Product in such region to such applicable Regulatory Authority, (ii) within [***] days, but in any event reasonably in advance of the deadline for listing under Applicable Laws, after the receipt of the first and any subsequent Regulatory Approval in such region for the Licensed Product from such Regulatory Authority, including any additional Indication for the Licensed Product, (iii) within [***] days, but in any event reasonably in advance of the deadline for listing under Applicable Laws, after the issuance in such region of a patent included in the Listing Patent Rights, and (iv) within [***] days following the submission of a new patent application in such region Covering the Licensed Product included in the Kiniksa Patent Rights, Kiniksa Manufacturing Patent Rights, or Collaboration Patent Rights that has not been previously considered in any prior discussion and agreement of the Parties regarding Listing Patent Rights; *provided* that, except as otherwise permitted under Applicable Laws, the Party holding the MAA for the Licensed Product in the Territory will not list, and will not be obligated to list, as of the date of listing, (A) any unissued patent, (B) any Patent Right that does not Cover the Licensed Product, (C) any patent that is of a type or that contains patent claims that are of a type not permitted to be listed under Applicable Law, or (D) any patent that such Party knows or has a reasonable basis to know is reasonably likely to be declared invalid by a competent Governmental Authority in such region. In furtherance of the foregoing clause (D), if either Party has such knowledge or reasonable basis, such Party will promptly notify and inform the Party of all facts and circumstances it is aware of underlying such knowledge or reasonable basis. If the

Parties are unable to agree on which Patent Rights to list by the time required as provided under clause (i) to (iv) above, subject to the above proviso, then Kiniksa will have the final decision-making right over whether the Party holding the MAA for the Licensed Product in the Territory will list any Kiniksa Patent Rights, Kiniksa Manufacturing Patent Rights, or Joint Collaboration Patent Rights, and Partner will have the final decision-making right over whether the Party holding the MAA for the Licensed Product in the Territory will list any issued patents included in the Partner Collaboration Patent Rights. The Party holding the MAA for the Licensed Product in the Territory will promptly, and in any event at least [***] days prior to the applicable deadline for listing under Applicable Laws, list the Listing Patent Rights in the applicable patent listing system in the applicable regions in the Territory *provided*, that, without limiting the foregoing, if the Party holding the MAA for the Licensed Product in the Territory has not listed the Listing Patent Rights in the patent listing system of an applicable region before [***] days prior to the deadline for listing in the applicable region, then the other Party may list the Listing Patent Rights at anytime when permitted by Applicable Laws by providing prior written notice to the Party holding the MAA for the Licensed Product in the Territory. The Party holding the MAA for the Licensed Product in the Territory will provide copies of all documentation to be filed in connection with any such listing of Listing Patent Rights to the other Party prior to filing thereof and will consider the other Party's comments with respect to such documentation. The Party holding the MAA for the Licensed Product in the Territory will cooperate with the other Party to the extent reasonably requested by the other Party to effectuate the intent of this Section 14.6 (Patent Listings), including providing all documentation, certifications, and consents necessary to effectuate the foregoing and setting up an account to list patents on the applicable patent listing system, and granting the other Party access to and a right to use such account as reasonably necessary to effectuate the intent of this Section 14.6 (Patent Listings). Neither Party will list any patent in any patent listing system in a region in the Territory for the Licensed Product, except in accordance with this Section 14.6 (Patent Listings).

14.7. Patent Term Extensions. With respect to any system for extending the term of Patent Rights in the Territory or supplementary protection certificates and any other extensions that are now or become available in the future under Applicable Laws in any country or region in the Territory, in each case, due to the time needed to obtain Regulatory Approval of a pharmaceutical product established by any applicable Regulatory Authority or other Governmental Authority in any region in the Territory (a "**Patent Term Extension**"), or adjusting the term of Patent Rights in the Territory due to the time needed to prosecute and obtain a grant of a Patent Right under Applicable Laws in any region in the Territory (a "**Patent Term Adjustment**"), (a) Kiniksa will have the right, but not the obligation, and will be solely responsible for making all decisions regarding Patent Term Extensions or Patent Term Adjustments in the Territory that are applicable to Kiniksa Patent Rights, Kiniksa Manufacturing Patent Rights, or Joint Collaboration Patent Rights and that become available for a patent included in the Kiniksa Patent Rights, Kiniksa Manufacturing Patent Rights, or Joint Collaboration Patent Rights *provided* that Kiniksa will consult with Partner with respect to such decisions and consider the reasonable comments and concerns raised by Partner; and (b) Partner will have the right, but not the obligation, and will be solely responsible for making all decisions regarding Patent Term Extensions, and Patent Term Adjustments in the Territory that are applicable to Partner Collaboration Patent Rights and that become available for the Licensed Product in the Territory or following issuance of a patent included in the Partner Collaboration Patent Rights; *provided* that Partner will consult with Kiniksa with respect to such decisions and consider the reasonable comments and concerns raised by Kiniksa. The Party holding the MAA for the Licensed Product in the Territory will make the appropriate filings and applications in the Territory in order to effectuate each Party's decisions regarding Patent Term Extensions, or Patent Term Adjustments in the Territory in accordance with the foregoing sentence. Each Party will cooperate with the other Party to the extent reasonably required by the other Party to effectuate the intent of this Section 14.7 (Patent Term Extensions), including providing to the other Party all

documentation, certifications, and consents necessary to make and prosecute such application and obtain such Patent Term Extension or Patent Term Adjustment.

14.8. Filing of Agreement with CNIPA. The Parties will file a redacted copy of this Agreement with the CNIPA as required by Applicable Law in the Territory no later than the date required under such Applicable Law.

14.9. Product Trademarks.

14.9.1. **Global Brand Elements**. Partner acknowledges that Kiniksa or its Affiliate may decide to develop and adopt certain distinctive colors, logos, images, symbols, and trademarks to be used in connection with the Commercialization of the Licensed Product on a global basis (such branding elements, collectively, the "**Global Brand Elements**").

14.9.2. **Product Marks in the Territory**. Partner will have the right to brand the Licensed Product in the Territory using trademarks, logos, and trade names that it determines appropriate for the Licensed Product, which may vary by region or within a country or region in the Territory, and that are consistent with Kiniksa's Global Brand Elements (the "**Product Marks**"); *provided*, *however*, that Partner will provide Kiniksa with a reasonable opportunity to review and provide comments on each proposed Product Mark, and Partner will consider and incorporate Kiniksa's reasonable comments before selecting any Product Mark. Partner will not use any trademarks of Kiniksa (including Kiniksa's corporate name) or any trademark confusingly similar thereto except as expressly permitted hereunder without Kiniksa's prior written consent.

14.9.3. **Ownership**. Kiniksa will be the sole and exclusive owner of all Product Marks and Global Brand Elements, including all trademark registrations and applications therefor inside and outside of the Territory and all goodwill associated therewith. To the extent Partner acquires any rights, title, or interests in or to any Product Mark or Global Brand Element (including any trademark registration or application therefor or goodwill associated with any Product Mark), Partner will, and hereby does, assign the same to Kiniksa. Kiniksa will and hereby does grant Partner the exclusive right to use the Product Marks and the Global Brand Elements solely to Commercialize the Licensed Product in the Territory. Kiniksa will have the sole right to register, prosecute, and maintain the Product Marks in the Territory that it determines reasonably necessary in Kiniksa's name, at Partner's cost and expense, and Partner will reimburse Kiniksa within [***] days after receiving Kiniksa's invoice therefor.

14.9.4. **Use and Quality**. Partner agrees that it and its Affiliates and Sublicensees will Commercialize the Licensed Product in the Territory in a manner consistent with the Global Brand Elements and will: (a) ensure that all Licensed Product that are sold bearing the Product Marks and Global Brand Elements are of a high quality consistent with industry standards for global pharmaceutical and biologic therapeutic products; (b) ensure that each use of the Global Brand Elements and Product Marks by Partner and its Affiliates and Sublicensees is accompanied by an acknowledgment that such Global Brand Elements and Product Marks are owned by Kiniksa; (c) not use such Global Brand Elements or Product Marks in a way that might materially prejudice their distinctiveness or validity or the goodwill of Kiniksa therein and includes the trademark registration symbol ® or ™ as appropriate; (d) not use any trademarks or trade names so resembling any of such Global Brand Elements or Product Marks as to be likely to cause confusion or deception; and (e) place and display the Global Brand Elements and the Product Marks on and in connection

with the Licensed Product in a way that acknowledges Kiniksa's role in discovering the Licensed Product and that the Licensed Product is under license from Kiniksa. To the extent permitted by Applicable Law, Partner will include the words "*Licensed from Kiniksa*." on all packaging and labeling for the Licensed Product and in relevant scientific, medical, and other Licensed Product-related communications to the extent such communications address the Development, Manufacture, performance of Medical Affairs, or Commercialization of such the Licensed Product, or such other similar text provided by Kiniksa and reasonably acceptable to Partner.

14.10. Patent Marking. Partner will mark all Licensed Product in accordance with the applicable patent marking laws, and will require all of its Affiliates and Sublicensees to do the same. To the extent permitted by Applicable Law, Partner will indicate on the product packaging, advertisement and promotional materials that the Licensed Product is in-licensed from Kiniksa.

ARTICLE 15
TERM AND TERMINATION

15.1. Term. This Agreement will be effective as of the Effective Date and, if not otherwise terminated earlier pursuant to this Article 15 (Term and Termination), will continue, as applicable, on a country-by-country or region-by-region basis until the expiration of the Royalty Term in such country or region (the "**Term**"); *provided however*, that Partner will be obligated to pay to Kiniksa any Milestone Payment achieved during the [***] year period after the expiration of the Term. As applicable, on a country-by-country or region-by-region basis upon the natural expiration of this Agreement as contemplated in this Section 15.1 (Term) (but not termination), (a) so long as Partner (i) is not at such time in material breach of any obligation under this Agreement based on receipt on or prior to such date of written notification from Kiniksa as required under Section 15.2.2 (Termination for Material Breach) or (ii) if Partner is so in material breach of any obligation under this Agreement, then only if such breach is timely cured in accordance with Section 15.2.2 (Termination for Material Breach) prior to the expiration of the Agreement, the license granted to Partner under Section 2.1.1 (License Grants to Partner; In the Territory) will become fully paid-up, perpetual, and exclusive for a period of [***] years after the effective date of expiration of this Agreement and non-exclusive thereafter; and (b) the license granted to Kiniksa under Section 2.3 (License Grant to Kiniksa) will become fully paid-up, perpetual, and irrevocable.

15.2. Termination.

15.2.1. **Termination by Partner for Convenience**. Partner may terminate this Agreement in its entirety by providing a written notice of termination to Kiniksa that includes an effective date of termination of at least [***] months after the date of such notice.

15.2.2. **Termination for Material Breach**. If either Party believes that the other is in material breach of any of its obligations hereunder, then the non-breaching Party may deliver notice of such breach to the other Party stating the cause and proposed remedy ("**Breach Notification**"). For any breach arising from a failure to make a payment set forth in this Agreement, the allegedly breaching Party will have [***] Business Days from the receipt of the applicable Breach Notice to dispute or cure such breach. For all breaches other than a failure to make a payment as set forth in this Agreement, the allegedly breaching Party will have [***] days from the date of the Breach Notification to dispute or cure such breach. If the Party receiving notice of breach fails to cure, or fails to dispute, that breach within the applicable period set forth above, then the Party originally delivering the Breach Notification may terminate this Agreement effective on written notice of termination to the

other Party. The Parties stipulate and agree that a breach of a Party's obligations set forth under Section 2.7 (Exclusivity Covenant), the restrictions on Partner's Manufacture of the Licensed Product or use of Kiniksa Manufacturing Technology in Section 7.2 (Supply by Partner), or of Partner's payment obligations set forth under Article 10 (Payments), will each be considered a material breach of a material obligation under this Agreement for purposes of this Section 15.2.2 (Termination for Material Breach).

15.2.3. **Termination for Patent Challenge**. Except to the extent unenforceable under Applicable Law, Kiniksa may terminate this Agreement by providing written notice of termination to Partner if Partner or its Affiliates or Sublicensees (individually or in association with any Person) contests or assists a Third Party in contesting the scope, validity, or enforceability of any Kiniksa Patent Right or any foreign counterpart thereof anywhere in the world in any court, tribunal, arbitration proceeding, or other proceeding, including the U.S. Patent and Trademark Office and the U.S. International Trade Commission (a "**Patent Challenge**"). In the event of such a Patent Challenge, Kiniksa will provide prompt written notice of such Patent Challenge to Partner, and Kiniksa may terminate this Agreement by providing written notice of such termination to Partner. If Kiniksa reasonably believes that termination of this Agreement pursuant to this Section 15.2.3 (Termination for Patent Challenge) is not an available remedy under Applicable Law, then in lieu of such termination, Kiniksa may instead increase the amount of all yet unpaid (as of the date of such election). Milestone Payments and Royalty Payments payable under this Agreement by [***]% by providing written notice of such election to Partner. If Kiniksa elects the foregoing [***]% increase in the Milestone Payments and Royalty Payments as liquidated damages, then such increase would be Kiniksa's sole and exclusive remedy for such Patent Challenge. The Parties hereby stipulate and agree that the damages that Kiniksa would suffer as a result of such a Patent Challenge would be uncertain in amount and difficult to prove, and therefore the foregoing [***]% increase in Milestone Payments and Royalty Payments is a reasonable liquidated damages remedy and not a penalty. As used herein, a Patent Challenge includes: (a) filing an action under 28 U.S.C. §§ 2201-2202 seeking a declaration of invalidity or unenforceability of any such Patent Right; (b) filing, or joining in, a petition under 35 U.S.C. § 311 to institute *inter partes* review of any such Patent Right; (c) filing, or joining in, a petition under 35 U.S.C. § 321 to institute post-grant review of any such Patent Right or any portion thereof; (d) filing or commencing any opposition, nullity, or similar proceedings challenging the validity of any such Patent Right in any country or region; or (e) any foreign equivalent of clauses (a), (b), (c), or (d).

15.2.4. **Termination in** [***]. If Partner does not (a) file an MAA for the Licensed Product or (b) Initiate a Clinical Trial for the Licensed Product, in each case ((a) and (b)) in at least [***] within [***] years after receipt of Regulatory Approval for the Licensed Product in the U.S., then, unless otherwise agreed in writing by Kiniksa in its sole discretion, (i) all licenses and rights granted to Partner in each of [***] will terminate, (ii) if Partner has conducted any Clinical Development or Commercialization activities in any such country, then the applicable effects of Section 15.3 (Effects of Termination) will apply to such country(ies), and (iii) the definition of Territory will no longer include [***] for purposes of this Agreement.

15.2.5. **Cessation of Development and Commercialization in the PRC**. If Partner and its Affiliates do not conduct any material Development or Commercialization activities with respect to the Licensed Product in the PRC for a continuous period of longer than [***] months, and such suspension of activity is not: (a) contemplated in the Territory Development Plan (except to the extent such inactivity was approved by Partner through

exercise of its final decision-making authority over the Territory Development Plan pursuant to Section 3.7.2(b) (Partner Final Decision-Making Authority)) or Global Development Plan or otherwise by written agreement of the Parties, (b) a result of Partner's reasonable response to written guidance from or action by a Regulatory Authority in the Territory (such as a clinical hold, or a recall or withdrawal), (c) a Force Majeure event pursuant to Section 17.4 (Force Majeure), or (d) due to Kiniksa's failure to supply the Licensed Product in accordance with the terms of the Clinical Supply Agreement or, if applicable, the Commercial Supply Agreement, then Kiniksa may, at its election, terminate this Agreement upon [***] days' prior written notice to Partner with respect to the Licensed Product, if Partner has not performed any material Development or Commercialization activities with respect to the Licensed Product in the PRC during such [***] day period. For the avoidance of doubt, any activities that Partner conducts in furtherance of making alternative arrangements for Development of the Licensed Product in the PRC in response to Kiniksa's material failure to perform its obligations under the Global Development Plan with respect to the Licensed Product will be deemed material Development activities for purposes of this Section 15.2.5 (Cessation of Development and Commercialization in the PRC).

15.2.6. **Termination for Insolvency**. Each Party will have the right to terminate this Agreement upon delivery of written notice to the other Party if (a) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (b) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within [***] days of its filing, or (c) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors.

15.2.7. **Full Force and Effect During Notice Period**. This Agreement will remain in full force and effect until the expiration of the applicable termination notice period.

15.3. Effects of Termination. Upon the termination of this Agreement:

15.3.1. **Partial Termination**. In the event that this Agreement is terminated pursuant to Section 15.2.4 (Termination in [***]) with respect to only certain countries or regions in the Territory, then Section 15.3 (Effects of Termination), Section 15.4 (Survival), and Section 15.5 (Cumulative Remedies; Termination Not Sole Remedy) will apply solely with respect to the terminated countries or regions, and all other rights and obligations of the Parties under this Agreement will otherwise remain in full force and effect.

15.3.2. **Licenses**. As of the effective date of termination of this Agreement, all licenses and all other rights granted by Kiniksa to Partner under the Kiniksa Technology and Kiniksa Manufacturing Technology will terminate and all sublicenses granted and Subcontractors engaged by Partner will also terminate. In addition, upon the termination of this Agreement, Kiniksa will have, and Partner hereby grants to Kiniksa, effective upon such termination, a worldwide, fully-paid, perpetual, irrevocable, and sublicensable (through multiple tiers) license under the Partner Technology Controlled by Partner as of the effective date of such termination solely to Exploit the Licensed Product. If this Agreement is terminated by Partner pursuant to Section 15.2.2 (Termination for Material Breach), then Kiniksa will have the right to elect whether the license will be either non-exclusive, royalty-free, and fully paid-up, or exclusive, and if Kiniksa elects an exclusive license, then the

license granted to Kiniksa will be royalty-bearing at a royalty rate to be agreed by the Parties upon termination of this Agreement. In addition, Partner will assign to Kiniksa any Third Party IP Agreement pursuant to which Partner then Controls any Partner Technology, if permitted under such Third Party IP Agreement (and will use reasonable efforts to seek any consent required from the applicable Third Party in connection with such an assignment). If such Third Party IP Agreement cannot be assigned to Kiniksa, then upon Kiniksa's reasonable request, Partner will maintain such Third Party IP Agreement and Kiniksa will pay to Partner [***]% of all payments due to the applicable Third Party under any such Third Party IP Agreement in consideration of the sublicense to Kiniksa and Kiniksa's Exploitation of such Partner Identified Rights. If Partner is unable to assign the Third Party IP Agreement pursuant to which Partner acquired rights to any Partner Identified Rights and is unable to sublicense any Partner Identified Rights to Kiniksa pursuant to this Section 15.3.2 (Effects of Termination; Licenses) without the consent of the Third Party, then Partner will, on request from Kiniksa (and at Kiniksa's cost and expense), use reasonable efforts to procure such licenses with respect to Licensed Product on behalf of Kiniksa to the extent that it is able to do so, and Kiniksa will pay such fees and agree to be bound by the terms agreed between Partner and the Third Party licensor.

15.3.3. **Appointment as Exclusive Distributor**. If Partner is Commercializing the Licensed Product in any country or region in the Territory as of the effective date of termination, then, at Kiniksa's election (in its sole discretion) on a country-by-country or region-by-region basis, as applicable, in the Territory, until such time as all Regulatory Approvals with respect to the Licensed Product in such country or region have been assigned and transferred to Kiniksa, either (a) Partner will appoint Kiniksa or its designee as its exclusive distributor of the Licensed Product in such country or region and grant Kiniksa or its designee the right to appoint sub-distributors, to the extent not prohibited by any written agreement between Partner or any of its Affiliates and a Third Party; *provided* that Kiniksa will purchase any and all salable inventory of the Licensed Product held by Partner or its Affiliates as of the effective date of termination with respect to the Licensed Product at a price equal to the price paid by Partner to Kiniksa for such inventory (if Manufactured by Kiniksa) or at Partner's Fully Burdened Manufacturing Cost (if Manufactured by Partner), or (b) Partner will have the continued right to sell the Licensed Product in such country or region from its inventory; *provided*, *however*, that Partner's obligations under this Agreement with respect to all Licensed Product that Partner sells, including the obligation to remit Royalty Payments to Kiniksa hereunder, will continue in full force and effect during such period.

15.3.4. **Regulatory Submissions and Regulatory Approvals**. Partner will and hereby does, and will cause its Affiliates and Sublicensees to, (a) no later than [***] days after the effective date of termination of this Agreement (or such longer period as may be required under Applicable Law), assign and transfer to Kiniksa or its designee all of Partner's rights, title, and interests in and to all Regulatory Submissions and Regulatory Approvals for the Licensed Product then owned or Controlled by Partner or any of its Affiliates or Sublicensees, and (b) to the extent assignment pursuant to clause (a) is delayed or is not permitted by the applicable Regulatory Authority, permit Kiniksa to cross-reference and rely upon any Regulatory Submissions and Regulatory Approvals filed by Partner or any of its Affiliates or Sublicensees with respect to the Licensed Product. Partner will take all steps necessary to transfer ownership of all such assigned Regulatory Submissions and Regulatory Approvals to Kiniksa, including submitting to each applicable Regulatory Authority a letter or other necessary documentation (with a copy to Kiniksa) notifying such Regulatory Authority of the transfer of such ownership of each Regulatory Submission and

Regulatory Approval. In addition, upon Kiniksa's written request, Partner will, at its cost and expense, provide to Kiniksa copies of all substantive related documentation, including non-clinical, preclinical, and clinical data that are held by or reasonably available to Partner or its Affiliates or Sublicensees. The Parties will discuss and establish appropriate arrangements with respect to safety data exchange, *provided* that Kiniksa will assume all safety and safety database activities with respect to the Licensed Product no later than [***] days after the effective date of termination of this Agreement.

15.3.5. **Assignment and Disclosure**. To the extent requested by Kiniksa following the date that a Party provides notice of termination of this Agreement, Partner will promptly upon request (and in any event within [***] days after the effective date of termination):

(a) subject to Partner's confidentiality obligations to Third Parties, provide to Kiniksa for its review unredacted copies of all clinical trial agreements, manufacturing and supply agreements, distribution agreements (to the extent assignable and not cancelled), and confidentiality and other agreements, in each case, relating to the Licensed Product and that are [***] for the Exploitation of the Licensed Product, and, following such review, upon Kiniksa's request and solely to the extent permitted under the terms of such agreements, assign and transfer to Kiniksa or its designee all of Partner's rights, title, and interests in and to any such agreements. If such agreement is not assignable, then Partner will cooperate with Kiniksa in all reasonable respects to secure the consent of the applicable Third Party to such assignment or to cause such Third Party to enter into a separate agreement with Kiniksa on terms substantially similar to those granted to Partner;

(b) disclose to Kiniksa or its designee all data, information, documents, records, and materials related to the Licensed Product that are controlled by Partner or that Partner is able to obtain using reasonable efforts, and that embody the foregoing; and

(c) assign and transfer to Kiniksa or its designee all of Partner's rights, title, and interests in and to any promotional materials, training materials, medical education materials, packaging and labeling, and all other literature or other information related to the Licensed Product and copyrights and any registrations for the foregoing.

Unless this Agreement is terminated by Partner pursuant to Section 15.2.2 (Termination for Material Breach) or Section 15.2.6 (Termination for Insolvency), Partner will bear the costs and expenses associated with the assignments set forth in this Section 15.3.5 (Assignment and Disclosure). To the extent that any agreement or other asset described in this Section 15.3.5 (Assignment and Disclosure) is not assignable by Partner, then such agreement or other asset will not be assigned, and upon the request of Kiniksa, Partner will take such steps as may be necessary to allow Kiniksa to obtain and to enjoy the benefits of such agreement or other asset, without additional payment therefor, in the form of a license or other right to the extent Partner has the right and ability to do so. For clarity, Kiniksa will have the right to request that Partner take any or all of the foregoing actions in whole or in part, or with respect to all or any portion of the assets set forth in this Section 15.3.5 (Assignment and Disclosure).

15.3.6. **Regulatory Transfer Support**. In furtherance of the assignment of Regulatory Submissions and Regulatory Approvals and other data pursuant to Section 15.3.4

(Regulatory Submissions and Regulatory Approvals) and Section 15.3.5 (Assignment and Disclosure), Partner will appoint Kiniksa as Partner's or its Affiliate's agent for all Licensed Product-related matters involving Regulatory Authorities until all Regulatory Approvals, Regulatory Submissions, and other governmental or regulatory filings that are not then in Kiniksa's or its Affiliate's name have been assigned to Kiniksa or its designee. In the event of failure to obtain such assignment, Partner hereby consents and grants to Kiniksa the right to access and reference (without any further action required on the part of Partner, whose authorization to file this consent with any Regulatory Authority is hereby granted) any such item with respect to the Licensed Product.

15.3.7. **Transfer of Prosecution and Maintenance Responsibilities**. Partner will transfer to Kiniksa any and all responsibility for Patent Prosecution for the Kiniksa Patent Rights, including transferring all files related to the Patent Prosecution of such Kiniksa Patent Rights, and at the request of Kiniksa, Partner will make appropriate personnel available to Partner to answer such reasonable questions as Kiniksa may have in connection with such transfer of Patent Prosecution of such Patent Rights.

15.3.8. **Know-How Transfer Support**. In furtherance of the assignment of Know-How pursuant to Section 15.3.5 (Assignment and Disclosure), Partner will, for a period of [***] months from the effective date of termination of this Agreement, provide such reasonable consultation or other reasonable assistance as Kiniksa may reasonably request to assist Kiniksa in becoming familiar with such Know-How in order for Kiniksa to undertake further Exploitation of the Licensed Product at Kiniksa's cost and expense at Partner's FTE Rate.

15.3.9. **Inventory**. At Kiniksa's election and request, unless Kiniksa elects to grant to Partner the continued right to sell the Licensed Product in such country or region from its inventory pursuant to clause (b) of Section 15.3.3 (Appointment as Exclusive Distributor), Partner will either (a) transfer to Kiniksa or its designee some or all inventory of, or (b) destroy, in each case ((a) and (b)), the Licensed Product (including all final product, bulk drug substance, intermediates, works-in-process, formulation materials, reference standards, drug product clinical reserve samples, packaged retention samples, and the like) then in the possession or Control of Partner, its Affiliates or Sublicensees. In the event that Kiniksa elects to proceed under clause (a), then Kiniksa will pay Partner a price equal to the price paid by Partner to Kiniksa for such transferred Licensed Product (if Manufactured by Kiniksa) or at Partner's Fully Burdened Manufacturing Cost (if Manufactured by Partner).

15.3.10. **Wind Down and Transition**. Except as provided under Section 15.3.14 (Termination by Partner for Kiniksa's Breach), Partner will be responsible, at its own cost and expense, for the wind-down of Partner's and its Affiliates' and its Sublicensees' Exploitation of the Licensed Product. Partner will, and will cause its Affiliates and Sublicensees to, reasonably cooperate with Kiniksa to facilitate orderly transition of the Exploitation of the Licensed Product to Kiniksa or its designee, including (a) assigning or amending as appropriate, upon request of Kiniksa, any agreements or arrangements with Third Party vendors (including distributors) to Exploit the Licensed Product or, to the extent any such Third Party agreement or arrangement is not assignable to Kiniksa, reasonably cooperating with Kiniksa to arrange to continue to provide such services for a reasonable time after termination of this Agreement with respect to the Licensed Product; and (b) to the extent that Partner or its Affiliate is performing any activities described in the foregoing clause (a), reasonably cooperating with Kiniksa to transfer such activities to Kiniksa or its designee and continuing to perform such activities on Kiniksa's behalf for a reasonable

time after termination of this Agreement with respect to the Licensed Product until such transfer is completed.

15.3.11. **Ongoing Clinical Trials**.

(a) **Transfer to Kiniksa**. If, as of the effective date of termination of this Agreement with respect to the Licensed Product, Partner or its Affiliates are conducting any Clinical Trials for the Licensed Product, then, at Kiniksa's election on a Clinical Trial-by-Clinical Trial basis, Partner will fully cooperate, and will ensure that its Affiliates fully cooperate, with Kiniksa to transfer the conduct of such Clinical Trial to Kiniksa or its designees. If Kiniksa so elects, then Partner will continue to conduct such Clinical Trial, at Kiniksa's cost, to enable such transfer to be completed without interruption of any such Clinical Trial (including the assignment of all related Regulatory Submissions and investigator and other agreements related to such Clinical Trials). Partner will provide such knowledge transfer and other training to Kiniksa or its designated Affiliate or Third Party as reasonably necessary for Kiniksa or such designated Affiliate or Third Party to continue such Clinical Trial for the Licensed Product.

(b) **Wind-Down**. If Kiniksa does not elect to assume control of any such Clinical Trials for the Licensed Product, then Partner will, in accordance with accepted pharmaceutical industry norms and ethical practices, wind-down the conduct of any such Clinical Trial in an orderly manner. Except for Partner's termination of this Agreement under Section 15.2.2 (Termination for Material Breach) or Section 15.2.6 (Termination for Insolvency), Partner will be responsible for any costs and expenses associated with such wind-down.

15.3.12. **Return of Confidential Information**. At the Disclosing Party's election, the Receiving Party will return (at Disclosing Party's expense) or destroy all tangible materials comprising, bearing, or containing any Confidential Information of the Disclosing Party relating to the Licensed Product that are in the Receiving Party's or its Affiliates' or Sublicensees' possession or control and provide written certification of such destruction (except to the extent any information is the Confidential Information of both Parties or to the extent that the Receiving Party has the continuing right to use the Confidential Information under this Agreement); *provided* that the Receiving Party may retain one copy of such Confidential Information for its legal archives. Notwithstanding any provision to the contrary set forth in this Agreement, the Receiving Party will not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information.

15.3.13. **Further Assistance**. Except as provided under Section 15.3.14 (Termination by Partner for Kiniksa's Breach), Partner will provide any other assistance or take any other actions, in each case, reasonably requested by Kiniksa as necessary to transfer to Kiniksa the Exploitation of the Licensed Product or as otherwise required to comply with the terms of any Third Party IP Agreement, and will execute all documents as may be reasonably requested by Kiniksa in order to give effect to this Section 15.3 (Effects of Termination).

15.3.14. **Termination by Partner for Kiniksa's Breach or Insolvency**. Notwithstanding any provision to the contrary in this Article 15 (Term and Termination), if Partner terminates

this Agreement pursuant to Section 15.2.2 (Termination for Material Breach) or Section 15.2.6 (Termination for Insolvency), then Kiniksa will be responsible for the reasonable out-of-pocket costs incurred by Partner directly in connection with the performance of the activities set forth in this Section 15.3 (Effects of Termination). Partner will invoice Kiniksa [***] for the foregoing costs incurred by or on behalf of Partner in such Calendar Quarter, and Kiniksa will pay the undisputed invoiced amounts within [***] days after the date of any such invoice.

15.4. **Survival**. Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, the following provisions of this Agreement will survive the expiration or termination of this Agreement: Article 1 (Definitions), Section 2.3 (License Grant to Kiniksa), Section 10.3.4 (Royalty Reports and Payments) (solely with respect to Net Sales during the Term), Section 10.6 (No Refunds) (with respect to amounts that come due during the Term), Section 10.7 (Accounting Standards) (solely with respect to amounts that come due during the Term), Section 10.8 (Currency; Exchange Rate) (solely with respect to amounts that come due during the Term), Section 10.9 (Blocked Payments) (solely with respect to amounts that become due during the Term), Section 10.10 (Late Payments) (solely with respect to amounts that become due during the Term), Section 10.11 (Financial Records and Audits) (only for so long as payments may be due under this Agreement), Section 10.12 (Taxes), Section 10.13 (VAT Credits), Section 11.1 (Duty of Confidence), Section 11.2 (Confidential Information), Section 11.3 (Exemptions), Section 11.4 (Authorized Disclosures), Section 12.7 (Time for Claims), Section 13.1 (Indemnification; By Partner), Section 13.2 (Indemnification; By Kiniksa), Section 13.3 (Indemnification Procedure), Section 13.4 (Insurance), Section 14.1.1 (Ownership), Section 14.1.3 (Assignment by Partner), Section 14.1.4 (Practice Under and other Use of Joint Collaboration Technology), Section 14.3.3 (Joint Collaboration Patent Rights), Section 14.4.2(a)(iv) (Joint Collaboration Patent Rights), Section 14.4.4 (Recoveries) (as to recoveries resulting from an enforcement action of a Joint Collaboration Patent Right), Section 15.1 (Term), Section 15.3 (Effects of Termination), Section 15.4 (Survival), Section 15.5 (Cumulative Remedies; Termination Not Sole Remedy), Article 16 (Dispute Resolution), and Article 17 (Miscellaneous).

15.5. **Cumulative Remedies; Termination Not Sole Remedy**. Except for Kiniksa's exercise of its rights under Section 15.2.3 (Termination for Patent Challenge) to obtain the sole and exclusive remedy of increasing the Milestone Payments and Royalty Payments as liquidated damages if Kiniksa determines that termination is not an available remedy in the event of Partner's Patent Challenge, no other remedies referred to in this Agreement are intended to be exclusive, but each will be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Applicable Law. Without limiting the generality of the foregoing, termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding any provision to the contrary set forth in this Agreement, all other remedies will remain available except as expressly set forth herein.

ARTICLE 16
DISPUTE RESOLUTION

16.1. **General**. The Parties recognize that a dispute may arise relating to this Agreement (a "**Dispute**"). Except as otherwise expressly set forth in this Agreement, any Dispute, including Disputes that may involve the Affiliates of any Party, will be resolved in accordance with this Article 16 (Dispute Resolution).

16.2. **Continuance of Rights and Obligations During Pendency of Dispute Resolution**. If the alleged breaching Party disputes in good faith the existence of a breach specified in a notice provided by the other Party in accordance with Section 15.2.2 (Termination for Material Breach) and such alleged breaching Party provides the other Party notice of such Dispute within the applicable cure period with respect to such breach, then the cure period set forth in Section 15.2.2 (Termination for Material Breach) will be tolled during the pendency of the dispute resolution process as set forth in Article 16 (Dispute Resolution) and the non-breaching Party will not have the right to terminate this Agreement under Section 15.2.2 (Termination for Material Breach) unless and until such dispute resolution process has been completed and such process results in a determination that the alleged breaching Party has materially breached this Agreement and failed to cure such breach within the applicable cure period. During the pendency of such dispute, all of the terms and conditions of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder.

16.3. **Negotiation; Escalation**. The Parties will negotiate and use reasonable efforts to settle any Dispute under this Agreement, other than matters subject to resolution under Article 3 (Governance). Any Dispute as to the breach, enforcement, interpretation, or validity of this Agreement will be referred to the Executive Officers for attempted resolution. If the Executive Officers are unable to resolve such Dispute within [***] Business Days after such Dispute is referred to them, then, upon the written request of either Party to the other Party, other than a Dispute relating to the scope, validity, enforceability, or infringement of any Patent Rights or trademark rights (which will be submitted for resolution to a court of competent jurisdiction in the country or region in which such Patent Rights or trademark rights were granted or arose), the Dispute will be subject to arbitration in accordance with Section 16.5 (Arbitration).

16.4. **Arbitration**. If any Dispute that was subject to Section 16.4 (Negotiation; Escalation) remains [***] Business Days after such Dispute is referred to the Executive Officers, then either Party may at any time after such [***] Business Day period submit such Dispute to be settled by arbitration under the Rules of Arbitration of the International Chamber of Commerce (the "**ICC Rules**"), in accordance with the procedural rules of the ICC Rules in effect at the time of submission. The arbitration will be conducted before an arbitral tribunal composed of three arbitrators, the chairperson of whom will be appointed by the two party arbitrators, and all of whom will have previous judicial experience and experience with the life sciences industry. If, however, the aggregate award sought by the Parties is less than $[***] and equitable relief is not sought, then, unless otherwise agreed by the Parties a single arbitrator will be appointed by agreement of the parties, or, failing such agreement, in accordance ICC Rules. Unless otherwise agreed by the Parties, all such arbitration proceedings will be held in New York, New York, USA, *provided* that proceedings may be conducted by telephone conference call with the consent of the Parties and the arbitrator(s). All arbitration proceedings will be conducted in the English language. The arbitrator(s) will have no authority to award punitive damages. The allocation of expenses of the arbitration, including reasonable attorney's fees, will be determined by the arbitrator(s), or, in the absence of such determination, each party will pay its own expenses. All arbitration proceedings must be completed within [***] days of the notice of commencement of arbitration proceedings. The parties hereby agree that the arbitrator(s) have authority to issue rulings and orders regarding all procedural and evidentiary matters that the arbitrator(s) deem reasonable and necessary with or without petition therefore by the Parties as well as the final ruling and judgment. Rulings will be issued by written order summarizing the arbitration proceedings no more than [***] days after the final submissions of the Parties. All rulings by the arbitrator(s) will be final and binding on the Parties. The provisions of this Section 16.5 (Arbitration) may be enforced and judgment on the award (including without limitation equitable remedies) granted in any arbitration hereunder may

be entered in any court having jurisdiction over the award or any of the parties or any of their respective assets.

16.5. **Injunctive Relief**. Without prejudice to such provisional or interim remedies in aid of arbitration as may be available under the jurisdiction of a competent court, the arbitral tribunal will have authority to grant provisional or interim remedies and to award damages for the failure of any Party to the dispute to respect the arbitral tribunal's order to that effect. Notwithstanding the foregoing, in the event of an actual or threatened breach hereunder, the aggrieved Party may seek equitable relief (including restraining orders, specific performance or other injunctive relief) in any court or other forum, without first submitting to the dispute resolution procedures set forth in Section 16.4 (Negotiation; Escalation) pending a decision by the arbitral tribunal in accordance with Section 16.5 (Arbitration).

16.6. **Waiver of Right to Jury Trial**. IN CONNECTION WITH THE PARTIES' RIGHTS UNDER SECTION 16.5 (ARBITRATION), EACH PARTY, TO THE EXTENT PERMITTED BY APPLICABLE LAWS, KNOWINGLY, VOLUNTARILY, AND INTENTIONALLY WAIVES ITS RIGHT TO A TRIAL BY JURY IN ANY ACTION OR OTHER LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE TRANSACTIONS IT CONTEMPLATES. THIS WAIVER APPLIES TO ANY ACTION OR LEGAL PROCEEDING, WHETHER SOUNDING IN CONTRACT, TORT, OR OTHERWISE.

16.7. **Confidentiality**. Any and all activities conducted under this Article 16 (Dispute Resolution), including any and all non-public proceedings and decisions under Section 16.5 (Arbitration), will be the Confidential Information of each of the Parties, and will be subject to the terms of Article 11 (Confidentiality; Publication).

ARTICLE 17
MISCELLANEOUS

17.1. **Assignment**. This Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the prior written consent of the other Party. Notwithstanding the foregoing, (a) Kiniksa may assign (i) its rights to receive payments under this Agreement to one or more Persons without consent of Partner (including as part of a royalty monetization transaction), (ii) this Agreement in whole or in part to any Affiliate, or (iii) this Agreement in whole to its successor-in-interest in connection with the sale of all or substantially all of its assets to which this Agreement relates, whether in a merger, acquisition, or similar transaction or series of related transactions, and (b) Partner may assign this Agreement in whole or in part to any Subsidiary with Kiniksa's prior written consent, not to be unreasonably withheld, conditioned, or delayed. Any attempted assignment of this Agreement not in accordance with this Section 17.1 (Assignment) will be null, void, and of no legal effect. Any permitted assignee will assume all assigned obligations of its assignor under this Agreement. The terms of this Agreement will be binding upon, and will inure to the benefit of, the Parties and their respected successors and permitted assigns.

17.2. **Limitation of Liability**. NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES, LOSS OF PROFIT (EVEN IF DEEMED DIRECT DAMAGES) ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT IN CONNECTION WITH THIS AGREEMENT, IN EACH CASE, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 17.2 (LIMITATION OF LIABILITY) IS INTENDED TO OR WILL LIMIT OR RESTRICT THE

INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 13.1 (INDEMNIFICATION; BY PARTNER) OR SECTION 13.2 (INDEMNIFICATION; BY KINIKSA), DAMAGES AVAILABLE TO EITHER PARTY FOR THE OTHER PARTY'S BREACH OF Article 11 (CONFIDENTIALITY; PUBLICATION), OR DAMAGES AVAILABLE TO EITHER PARTY FOR THE OTHER PARTY'S FRAUD, GROSS NEGLIGENCE, WILFUL MISCONDUCT, OR BREACH OF ITS OBLIGATIONS HEREUNDER RELATING TO SECTION 2.7 (EXCLUSIVITY COVENANTS) OR AMOUNTS OWED BY EITHER PARTY HEREUNDER (INCLUDING UNDER ARTICLE 10) (PAYMENTS), OR MISAPPROPRIATION OR INFRINGEMENT OF INTELLECTUAL PROPERTY OWNED OR CONTROLLED BY EITHER PARTY.

17.3. **Severability**. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality, and enforceability of the remaining provisions contained herein will not in any way be affected or impaired thereby, then unless the absence of the invalidated provisions adversely affects the substantive rights of the Parties. The Parties will in such an instance use their best efforts to replace the invalid, illegal or unenforceable provisions with valid, legal, and enforceable provisions that, insofar as practical, implement the purposes of this Agreement.

17.4. **Force Majeure**. Both Parties will be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by Force Majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse will continue only so long as the condition constituting Force Majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. When the Force Majeure no longer exists, the affected Party must promptly resume performance. For purposes of this Agreement, "**Force Majeure**" will include conditions beyond the reasonable control of the non-performing Party, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, pandemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, failure of plant or machinery and act (or failure to act) of a government of any country or of any Governmental Authority (other than as a result of the non-performing Party's failure to comply with Applicable Law). The Parties agree the effects of the COVID-19 pandemic that is ongoing as of the Effective Date may be invoked as a Force Majeure for the purposes of this Agreement even though the pandemic is ongoing to the extent those effects are not reasonably foreseeable by the Parties as of the Effective Date. Notwithstanding the foregoing, a Party will not be excused from making payments owed hereunder because of a Force Majeure affecting such Party. The affected Party will notify the other Party in writing of any Force Majeure circumstances that may affect its performance under this Agreement as soon as reasonably practical, will provide a good faith estimate of the period for which its failure or delay in performance under the Agreement is expected to continue based on currently available information, and will undertake reasonable efforts necessary to mitigate and overcome such Force Majeure circumstances and resume normal performance of its obligations hereunder as soon as reasonably practicable under the circumstances. Throughout the duration of the Force Majeure event, the affected Party will update such notice to the other Party on a bi-weekly basis, or more frequently if requested by the other Party, to provide updated summaries of its mitigation efforts and its estimates of when normal performance under the Agreement will be able to resume. In any event, if a Party's failure to perform its obligations under this Agreement as a result of a Force Majeure event continues for longer than [***] days, then the other Party may terminate this Agreement by providing written notice to the Party affected by the Force Majeure event.

17.5. **Notices**. All notices that are required or permitted hereunder will be in writing and sufficient if delivered by internationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, and in each case, addressed as follows (with a courtesy copy sent by email, which will not constitute notice):

If to Kiniksa:
Kiniksa Pharmaceuticals (UK), Ltd.
Third Floor
23 Old Bond Street
London, UK, W1S 4PZ
Attention: Chief Commercial Officer

with a copy to:
Kiniksa Pharmaceuticals Corp.
100 Hayden Ave.
Lexington, MA 02421
United States
Attention: General Counsel

with a copy to (which will not constitute notice):
Ropes & Gray LLP
800 Boylston Street; Prudential Tower
Boston, MA 02199
Attention: Hannah H. England
Email: Hannah.England@ropesgray.com

If to Partner:
Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd.
No.866, Moganshan Road
Hangzhou, People's Republic of China
Attention: [**]
Email: [**]

with a copy to (which copy will not constitute notice):

Greenberg Traurig LLP
3333 Piedmont Road
Suite 2500
Atlanta, Georgia 30305
Attention: [**]
Email: [**]

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given: (a) on the Business Day after dispatch if sent by internationally-recognized overnight courier; or (b) on the [***] Business Day after dispatch if sent by registered or certified mail, postage prepaid, return receipt requested.

17.6. **Governing Law**. This Agreement, and all claims or causes of action (whether in contract, tort or statute) that may be based upon, arise out of or relate to this Agreement, or the negotiation, execution or performance of this Agreement or the breach thereof (including any claim or cause of

action based upon, arising out of or related to any representation or warranty made in or in connection with this Agreement or as an inducement to enter into this Agreement), will be governed by, and enforced in accordance with, the internal laws of the State of New York, including its statutes of limitations without giving effect to the conflicts of law provisions thereunder.

17.7. Entire Agreement; Amendments. This Agreement, together with the Schedules hereto, contains the entire understanding of the Parties with respect to the collaboration and the licenses granted hereunder. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the collaboration and the licenses granted hereunder are superseded by the terms of this Agreement. The Schedules to this Agreement are incorporated herein by reference and will be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of each Party. The foregoing will not be interpreted as a waiver of any remedies available to either Party or its Affiliates as a result of any breach, prior to the Effective Date, by the other Party or its Affiliates of such Party's or its Affiliate's obligations pursuant to the Confidentiality Disclosure Agreement.

17.8. Headings. The captions to the several Article**s**, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections of this Agreement.

17.9. Independent Contractors. It is expressly agreed that Kiniksa and Partner will be independent contractors and that the relationship between the two Parties will not constitute a partnership, joint venture or agency. Neither Kiniksa nor Partner will have the authority to make any statements, representations, or commitments of any kind, or to take any action that is binding on the other Party without the prior written consent of the other Party.

17.10. Performance by Affiliates or Subsidiaries. Notwithstanding any provision to the contrary set forth in this Agreement, Kiniksa will have the right to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any Affiliate of Kiniksa, and Partner will have the right to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any Subsidiary of Partner. Kiniksa hereby guarantees the performance by its Affiliates of Kiniksa's obligations under this Agreement and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Partner hereby guarantees the performance by its Subsidiaries of Partner's obligations under this Agreement and will cause its Subsidiaries to comply with the provisions of this Agreement in connection with such performance.

17.11. Waiver. Any waiver of any provision of this Agreement will be effective only if in writing and signed by Kiniksa and Partner. No express or implied waiver by a Party of any default under this Agreement will be a waiver of a future or subsequent default. The failure or delay of any Party in exercising any rights under this Agreement will not constitute a waiver of any such right, and any single or partial exercise of any particular right by any Party will not exhaust the same or constitute a waiver of any other right provided in this Agreement.

17.12. Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement will be construed against the drafting Party will not apply.

17.13. Business Day Requirements. If any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business Day, then such notice or other action or omission will be deemed to be required to be taken on the next occurring Business Day.

17.14. Further Actions. Each Party agrees to execute, acknowledge, and deliver such further instruments, and to do all such other acts, as necessary or appropriate in order to carry out the purposes and intent of this Agreement.

17.15. Construction. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words "include," "includes," and "including" will be deemed to be followed by the phrase "without limitation," (c) the word "will" will be construed to have the same meaning and effect as the word "shall," (d) any definition of or reference to any agreement, instrument, or other document herein will be construed as referring to such agreement, instrument, or other document as from time to time amended, supplemented, or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person will be construed to include the person's successors and assigns, (f) the words "herein," "hereof," and "hereunder" and words of similar import, will each be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Articles, Sections, Schedules, or Exhibits will be construed to refer to Articles, Sections, Schedules, or Exhibits of this Agreement, and references to this Agreement include all Schedules hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent," "approve," or the like will require that such agreement, consent, or approval be specific and in writing, whether by written agreement, letter, approved minutes, or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or Section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or."

17.16. Language; Translations. This Agreement is in the English language only, which language will be controlling in all respects, and all versions hereof in any other language will be for accommodation only and will not be binding upon the Parties. All communications and notices to be made or given by one Party to the other pursuant to this Agreement, and any dispute proceeding related to or arising hereunder, will be in the English language. If there is a discrepancy between the English version of this Agreement and any non-English translation of this Agreement, then the English version of this Agreement will prevail. If there is a discrepancy between the non-English original version and the English translation of any agreement with a Sublicensee or Material Subcontractor, audit report, Regulatory Submission, or other communication to or from a Governmental Authority in the Territory regarding the Licensed Product, in each case, that is delivered under this Agreement, then the non-English original version thereof will prevail. Upon Kiniksa's request, Partner will provide to Kiniksa any documentation that is already in English and in Partner's possession to the extent Partner is required to furnish such documentation to Kiniksa in accordance with the terms of this Agreement. Except as expressly set forth in this Agreement, for other data, information, documents, or other materials, Partner will provide to Kiniksa a high-level summary in English upon Kiniksa's reasonable request. In addition, at Kiniksa's request, Partner will provide a full English translation of such data, information, or other materials at Kiniksa's cost and expense. Each Party will invoice the other Party quarterly for the foregoing costs incurred by or on behalf of such Party in such Calendar Quarter, and the other Party will pay

the undisputed amount invoiced within [***] days after the date of any such invoice. Kiniksa acknowledges and agrees that any and all translations provided by Partner under this Agreement will not be certified translations (unless agreed by the Parties).

17.17. Counterparts. This Agreement may be executed in counterparts, all of which taken together will be regarded as one and the same instrument. Counterparts may be delivered via electronic mail, including Adobe™ Portable Document Format (PDF) or any electronic signature complying with the U.S. Federal ESIGN Act of 2000, and any counterpart so delivered will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

[Remainder of the Page Intentionally Left Blank; Signature Page Follows]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this License and Collaboration Agreement to be executed by their respective duly authorized representatives as of the Effective Date.

Kiniksa Pharmaceuticals (UK), Ltd.

By: /s/ Ross Moat

Name: Ross Moat

Title: Director

Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd.

By: /s/ Liang Lu

Name: Liang Lu

Title: Chairman & CEO

Schedule 1.58

Existing In-Licenses

[***]

Schedule 1.106

Kiniksa Patent Rights

[***]

Schedule 2.2.3

Preapproved Subcontractors

Schedule 5.2

Territory Development Plan

[***]

Schedule 5.3

Global Development Plan

[***]

Schedule 11.7.1(a)

Kiniksa Press Release

Kiniksa Pharmaceuticals and Huadong Medicine Announce Strategic Collaboration

– Collaboration includes rights to develop and commercialize ARCALYST® and mavrilimumab in the Asia Pacific Region (excluding Japan) –

– Kiniksa to receive $22 million upfront; eligible to receive development and commercial milestone payments and tiered royalties –

HAMILTON, BERMUDA – February 22, 2022 – Kiniksa Pharmaceuticals, Ltd. (Nasdaq: KNSA) (Kiniksa), a biopharmaceutical company with a portfolio of assets designed to modulate immunological pathways across a spectrum of diseases, and Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd., a wholly-owned subsidiary of Huadong Medicine Co., Ltd. (Huadong Medicine), today announced a strategic collaboration to develop and commercialize Kiniksa's ARCALYST® and mavrilimumab in the Asia Pacific Region.

"This collaboration aims to bring Kiniksa's therapeutics to patients in the Asia Pacific Region suffering from severe autoimmune and inflammatory diseases. With extensive regional experience, proven development and regulatory execution, and deep relationships with a broad network of hospitals and clinics, Huadong Medicine is an ideal partner to help drive value," said Sanj K. Patel, Chairman and Chief Executive Officer of Kiniksa. "The collaboration also provides non-dilutive capital, cost-sharing, and resources for clinical trials to accelerate our drug development and commercialization efforts."

"Kiniksa is an emerging leader in the development of immune-modulating therapies, for which there is significant unmet need across the Asia Pacific Region," said Liang Lv, Chairman and CEO of Huadong Medicine. "In addition to ARCALYST, the first and only FDA-approved treatment for recurrent pericarditis, the compelling clinical data generated to-date for mavrilimumab provide foundational support for development

across a range of underserved diseases. We look forward to working closely with Kiniksa to leverage our clinical, regulatory, and commercial capabilities in the Asia Pacific Region."

Under the terms of the collaboration, Kiniksa will receive $22 million upfront and is eligible to receive up to approximately $640 million in specified development, regulatory and sales-based milestones. Kiniksa is also eligible to receive tiered royalties ranging from the low-teens to the low-twenties on annual net sales. Huadong Medicine will obtain exclusive rights and responsibility for the development and commercialization of ARCALYST and mavrilimumab in the Asia Pacific Region including Greater China, South Korea, Australia, and 18 other countries, but excluding Japan. Kiniksa will otherwise retain all existing development and commercialization rights for both assets.

About Kiniksa
Kiniksa is a biopharmaceutical company focused on discovering, acquiring, developing, and commercializing therapeutic medicines for patients suffering from debilitating diseases with significant unmet medical need. Kiniksa's portfolio assets, ARCALYST, mavrilimumab, vixarelimab and KPL-404, are based on strong biologic rationale or validated mechanisms, target underserved conditions, and offer the potential for differentiation. These assets are designed to modulate immunological pathways across a spectrum of diseases. For more information, please visit www.kiniksa.com.

About ARCALYST
ARCALYST is a weekly, subcutaneously injected recombinant dimeric fusion protein that blocks interleukin-1 alpha (IL-1α) and interleukin-1 beta (IL-1β) signaling. ARCALYST was discovered by Regeneron and is approved by the U.S. Food and Drug Administration (FDA) for recurrent pericarditis, cryopyrin-associated periodic syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome and Muckle-Wells Syndrome, and deficiency of IL-1 receptor antagonist (DIRA). The FDA granted Breakthrough Therapy designation to ARCALYST for the treatment of recurrent pericarditis in 2019 and Orphan Drug designation to ARCALYST for the treatment of pericarditis in 2020. The European Commission granted Orphan Drug Designation to ARCALYST for the treatment of idiopathic pericarditis in 2020.

IMPORTANT SAFETY INFORMATION ABOUT ARCALYST

- ARCALYST may affect your immune system and can lower the ability of your immune system to fight infections. Serious infections, including life-threatening infections and death, have happened in patients taking ARCALYST. If you have any signs of an infection, call your doctor right away. Treatment with

ARCALYST should be stopped if you get a serious infection. You should not begin treatment with ARCALYST if you have an infection or have infections that keep coming back (chronic infection).

- While taking ARCALYST, do not take other medicines that block interleukin-1, such as Kineret® (anakinra), or medicines that block tumor necrosis factor, such as Enbrel® (etanercept), Humira® (adalimumab), or Remicade® (infliximab), as this may increase your risk of getting a serious infection.
- Talk with your doctor about your vaccine history. Ask your doctor whether you should receive any vaccines before you begin treatment with ARCALYST.
- Medicines that affect the immune system may increase the risk of getting cancer.
- Stop taking ARCALYST and call your doctor or get emergency care right away if you have any symptoms of an allergic reaction.
- Your doctor will do blood tests to check for changes in your blood cholesterol and triglycerides.
- Common side effects include injection-site reactions (which may include pain, redness, swelling, itching, bruising, lumps, inflammation, skin rash, blisters, warmth, and bleeding at the injection site), upper respiratory tract infections, joint and muscle aches, rash, ear infection, sore throat, and runny nose.

For more information about ARCALYST, talk to your doctor and see the Product Information.

About Mavrilimumab
Mavrilimumab is an investigational fully human monoclonal antibody that blocks activity of granulocyte macrophage colony stimulating factor (GM-CSF) by specifically binding to the alpha subunit of the GM-CSF receptor (GM-CSFRα). Phase 2 clinical trials of mavrilimumab in rheumatoid arthritis and giant cell arteritis achieved their primary and secondary endpoints with statistical significance.

About Huadong Medicine
Huadong Medicine Co., Ltd. (SZ.000963) is a leading Chinese pharmaceutical company based in Hangzhou, China. Founded in 1993, Huadong Medicine has fully integrated R&D, manufacturing, distribution, sales, and marketing capabilities. Huadong Medicine's product portfolio and pipeline are specialized in oncology, immunology, nephrology, and diabetes. The company has 11,000 employees and one of the most extensive commercial coverage and marketing capabilities in China. 'Patient Centered, Science Driven' is Huadong Medicine's value. For additional information, please visit www.eastchinapharm.com/en.

Kiniksa Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these identifying words. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation, statements regarding the multi-product collaboration between Kiniksa and Huadong Medicine, including anticipated milestone and royalty payments under the collaboration; expectations regarding Kiniksa’s ability to expand its programs for ARCALYST and mavrilimumab globally and in the licensed territory; and statements regarding Kiniksa’s efforts to bring multiple therapeutics to patients suffering from severe autoimmune and inflammatory diseases globally and in the licensed territory.

These forward-looking statements are based on management’s current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including without limitation, the following: delays or difficulty in enrollment of patients in, and activation or continuation of sites for, our clinical trials; delays or difficulty in completing our clinical trials as originally designed; potential for changes between final data and any preliminary, interim, top-line or other data from clinical trials; our inability to replicate results from our earlier clinical trials or studies; impact of additional data from us or other companies, including the potential for our data to produce negative, inconclusive or commercially uncompetitive results; potential undesirable side effects caused by our products and product candidates; our inability to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities; potential for applicable regulatory authorities to not accept our filings, delay or deny approval of any of our product candidates or require additional data or trials to support approval; inability to successfully execute on our commercial strategy for ARCALYST; our reliance on third parties as the sole source of supply of the drug substance and drug product used in our products and product candidates; our reliance on Regeneron as the sole manufacturer of ARCALYST; raw materials, important ancillary products and drug substance and/or drug product shortages; our reliance on third parties to conduct research, clinical trials, and/or certain regulatory activities for our product candidates; complications in coordinating requirements, regulations and guidelines of regulatory authorities across jurisdictions for our clinical trials; the impact of the COVID-19

pandemic and measures taken in response to the pandemic on our business and operations as well as the business and operations of our manufacturers, CROs upon whom we rely to conduct our clinical trials, and other third parties with whom we conduct business or otherwise engage, including the FDA and other regulatory authorities; changes in our operating plan and funding requirements; and existing or new competition.

These and other important factors discussed in our filings with the U.S. Securities and Exchange Commission (the "SEC"), including under the caption "Risk Factors" contained therein, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. Except as required by law, we disclaim any intention or obligation to update or revise any forward-looking statements. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

Every Second Counts!®

Kiniksa Investor and Media Contact

Rachel Frank
(339) 970-9437
rfrank@kiniksa.com

Huadong Medicine Investor and Media Contact

Bo Chen
+86 571 8990 3300
ir@eastchinapharm.com

Schedule 11.7.1(b)

Partner Press Release

华东医药宣布与Kiniksa公司签署战略合作协议

- 华东医药将获得ARCALYST®和Mavrilimumab在亚太区（不包括日本）的独家开发、注册和商业化权益。
- Kiniksa将获得2,200万美元的首付款，并获得开发、注册和销售里程碑付款及分级的销售额提成费。

中国杭州市，2022年2月22日，华东医药股份有限公司（SZ.000963）的全资子公司杭州华东制药有限公司（以下简称“华东医药”）与美国上市公司Kiniksa Pharmaceuticals, Ltd. (Nasdaq: KNSA)的全资子公司Kiniksa Pharmaceuticals (UK), Ltd.（以下简称“Kiniksa”），一家拥有多款调节免疫信号通路治疗自身免疫疾病药物的全球性生物公司，宣布签署战略合作协议。Kiniksa授予华东医药ARCALYST®和Mavrilimumab在亚太区的独家开发、注册和商业化权益。

华东医药董事长兼首席执行官吕梁表示：“Kiniksa是免疫调节疗法开发领域的新兴领导者，该治疗领域在亚太地区存在巨大未被满足的临床需求。ARCALYST®是目前第一款也是唯一一款FDA批准的用于治疗复发性心包炎的药物。此外，Mavrilimumab迄今为止产生的临床数据也为一系列难治疾病的治疗提供了基础支持。我们期待与Kiniksa密切合作，充分发挥华东医药在亚太地区的临床，注册和商业化能力。”

Kiniksa的董事长兼首席执行官Sanj K. Patel表示：“本次合作旨在将Kiniksa的治疗方法惠及整个亚太地区患有严重自身免疫和炎症疾病的患者。华东医药在亚太地区拥有丰富的区域经验，成熟的开发、注册能力，以及广泛的营销网络。华东医药是帮助ARCALYST®和Mavrilimumab在亚太区的实现最大价值的理想合作伙伴。本次合作提供的资金，成本分摊及其他资源，将有助于加快产品的临床开发和商业化。”

根据协议条款，Kiniksa 将获得2,200万美元的首付款，并有权在实现开发、注册及销售里程碑后，获得最高不超过6.4亿美元的里程碑付款，Kiniksa还将获得分级的两位数的净销售额提成费。华东医药将获得ARCALYST®和Mavrilimumab在亚太区（包括中国、韩国、澳大利亚和其他18个国家和地区，但不包括日本）的独家开发、注册和商业化权益。Kiniksa将保留许可产品在许可区域以外的开发和商业化权益。

关于华东医药

华东医药股份有限公司（SZ.000963）总部位于中国杭州，公司成立于1993年，具有完整的产品研发，生产，经销能力。产品管线主要专注于肿瘤，免疫，肾科以及糖尿病领域，覆盖中药、化学药、生物药、医疗器械等多个品类。2020年公司年收入超过 50 亿美元，拥有员工11,000余人，“以科研为基础,以患者为中心”是华东医药秉承的企业理念。更多信息请登录更多信息请浏览www.eastchinapharm.com

关于Kiniksa

Kiniksa是一家以满足患者临床需求为企业愿景，致力于发现、获取、开发和商业化调节免疫信号通路治疗药物的全球性生物制药公司。Kiniksa的4款产品ARCALYST®，

Mavrilimumab，Vixarelimab，KPL-404都基于坚实的生物学原理或经过验证的机制，用于调节一系列免疫疾病的免疫信号通路，具有实现差异化的巨大潜力。
更多信息请浏览www.kiniksa.com

关于ARCALYST®

ARCALYST®是一种每周进行皮下注射给药的重组二聚体融合蛋白，可阻断白细胞介素-1α（IL-1α）和白细胞介素-1β（IL-1β）的信号传导。ARCALYST®最早由Regeneron研发，获得FDA批准用于治疗冷吡啉相关的周期性综合征（CAPS），包括家族性寒冷型自身炎症综合征和穆-韦二氏综合征，以及IL-1受体拮抗剂缺乏症（DIRA）。2019年，ARCALYST®获得FDA突破性疗法认定，用于治疗复发性心包炎。2020年，FDA授予ARCALYST®用于治疗心包炎的孤儿药认定。2020年，欧盟委员会授予ARCALYST®孤儿药认定，用于治疗特发性心包炎。

关于Mavrilimumab

Mavrilimumab是一种全人源单克隆抗体，可特异性结合粒细胞-巨噬细胞集落刺激因子受体α（GM-CSFRα），并抑制粒细胞-巨噬细胞集落刺激因子（GM-CSF）的信号传导。Mavrilimumab针对类风湿性关节炎和巨细胞动脉炎（GCA）的2期临床研究都达到了主要和次要终点，并具有统计学意义。

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Schedule 12.3

Partner Disclosures

[***]

Exhibit 31.1

CERTIFICATIONS

I, Sanj K. Patel, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Kiniksa Pharmaceuticals, Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 5, 2022

/s/ Sanj K. Patel

Sanj K. Patel
Chief Executive Officer and Chairman of the Board of Directors
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Mark Ragosa, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Kiniksa Pharmaceuticals, Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 5, 2022

/s/ Mark Ragosa
Mark Ragosa
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Sanj K. Patel, Chief Executive Officer and Chairman of the Board of Directors of Kiniksa Pharmaceuticals, Ltd. (the "Company"), hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Quarterly Report on Form 10-Q of the Company for the period ended March 31, 2022 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 5, 2022

/s/ Sanj K. Patel
Sanj K. Patel
Chief Executive Officer and Chairman of the Board of Directors
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark Ragosa, Chief Financial Officer of Kiniksa Pharmaceuticals, Ltd. (the "Company"), hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Quarterly Report on Form 10-Q of the Company for the period ended March 31, 2022 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 5, 2022

/s/ Mark Ragosa
Mark Ragosa
Chief Financial Officer
(Principal Financial Officer)