REFINITIV

DELTA REPORT

10-Q

KNSA - KINIKSA PHARMACEUTICALS,

10-Q - JUNE 30, 2024 COMPARED TO 10-Q - MARCH 31, 2024

The following comparison report has been automatically generated

TOTAL DELTAS	4816
CHANGES	239
DELETIONS	1528
ADDITIONS	3049

REFINITIV

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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, June 30, 2024

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. International, plc

(Exact Name of Registrant as Specified in Its Charter)

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

Kiniksa Pharmaceuticals, Ltd. 23 Old Bond Street, Floor 3
Clarendon House London, WIS 4PZ
2 Church Street England, United Kingdom
Hamilton HM11, Bermuda
(808) 451-3453 (781) 431-9100

(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)

Kiniksa Pharmaceuticals, Ltd.
Clarendon House
2 Church Street
Hamilton HM11, Bermuda

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 Ordinary 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 19, 2024 July 19, 2024, there were 70,940,145 common 71,243,712 ordinary shares outstanding in aggregate, comprised of:

40,305,405 40,608,972 Class A common ordinary shares, par nominal value $0.000273235 per share

1,795,158 Class B common ordinary shares, par nominal value $0.000273235 per share

12,781,964 Class A1 common ordinary shares, par nominal value $0.000273235 per share

16,057,618 Class B1 common ordinary shares, par nominal value $0.000273235 per share

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Kiniksa Pharmaceuticals Ltd. International, plc

FORM 10-Q

FOR THE THREE MONTHS ENDED MARCH 31, JUNE 30, 2024

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this "Quarterly Report"), contains forward-looking statements. All statements other than statements of historical facts contained in this Quarterly Report including statements regarding our commercial strategy; potential value drivers; potential indications; potential market opportunities and competitive position; ongoing, planned and potential clinical trials and other studies; timing and potential impact of clinical data; future results of operations and financial position; expected timeline for our cash, cash equivalents and short-term investments; product development; prospective products and product candidates; supply of drug products at acceptable cost and quality; collaborators, license and other strategic arrangements; the expected timeline for achievement of our clinical milestones; potential marketing authorization from the U.S. Food and Drug Administration (the "FDA") or regulatory authorities in other jurisdictions; potential and ongoing coverage and reimbursement for our products and product candidates, if approved; clinical and 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 “Summary Risk Factors,” “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:

- our ability to complete the change of domicile of our principal holding company from Bermuda to the United Kingdom (the “Redomiciliation”);
- our continued ability to commercialize ARCALYST® (rilonacept) and to develop and commercialize our current and future product candidates, if approved;
- incurring losses in the future, potentially requiring us to raise additional funds;
- our ability to source sufficient quantities of our products and product candidates to meet patient and partner demand at acceptable cost and quality specifications;
- our ability to successfully complete the technology transfer of the manufacturing process for ARCALYST drug substance;
- 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;

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- the decision of third party payors not to cover or maintain coverage of or to establish burdensome requirements prior to covering or maintaining coverage of ARCALYST or any of our current or future product candidates, if approved;

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- the lengthy and expensive clinical development process with its uncertain outcomes and potential for clinical failure or delay;
- the decision by any applicable regulatory authority to permit clinical development of, to grant regulatory exclusivity for and to approve marketing and sale of our current and future product candidates;

- our ability to anticipate and prevent adverse events caused by our products and product candidates;
- our ability to identify, in-license, acquire, discover or develop additional product candidates;
- our ability to undertake and execute on business combinations, out-licensing activities, collaborations or other strategic transactions and our ability to realize value therefrom;
- potential product liability claims;
- 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; 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 place undue reliance on our forward-looking statements. Except as required by applicable law, we do not assume and specifically disclaim any obligation to update any forward-looking statements, whether as a result of any new information, future events, changed circumstances or otherwise.

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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 ordinary shares. The principal risks and uncertainties affecting our business include the following:

- we are currently conducting the Redomiciliation, which will require significant time and resource expenditure and be subject to significant risk and uncertainty;
- we have a history of losses and to further our operational plans, we may require substantial additional financing, which we may not be able to obtain when needed or on acceptable terms;
- we may not be able to continue to commercialize ARCALYST or be successful in commercializing any future products, which may materially impact our ability to generate revenue;
- successful commercialization of our products and product candidates, if approved, will depend in part on the extent to which third party payors, including governmental authorities and private health insurers, provide funding, establish and maintain favorable coverage and pricing policies and set adequate reimbursement levels;
- if we are unable to advance our product candidates in clinical development, obtain regulatory approval and pursue commercialization, or experience significant delays in doing so, our business may be materially harmed;
- the incidence and prevalence for target patient populations of our products and product candidates have not been established with precision; if the market opportunities for our products and product candidates are smaller than we estimate, or any approval that we obtain is based on a narrower definition of our targeted 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 preclinical studies and/or clinical trials, including as a result of delays in obtaining regulatory approvals to conduct clinical trials, activating sites, enrolling participants, and conducting trials, which could delay or prevent our product development activities;

- we rely on third parties, including independent contract development and manufacturing organizations (“CDMOs”) to manufacture our commercial supply of ARCALYST and our product candidates for preclinical and clinical development; and if these third parties do not have sufficient manufacturing capacity at our desired times or otherwise fail to perform satisfactorily, including by producing insufficient supply of commercial and clinical stock to meet patient demand or clinical trial requirements, or are impacted by delays or supply shortages, our product development activities, regulatory approval, and commercialization efforts may be delayed, prevented or impaired;
- we are conducting a technology transfer of the manufacturing process for ARCALYST drug substance from Regeneron Pharmaceuticals, Inc. (“Regeneron”) to a new CDMO, Samsung Biologics Co., Ltd. (“Samsung”), and the analytical testing methods of ARCALYST drug substance and drug product to new contract testing labs (“CTLs”) and the process to complete the technology transfer and qualify a new CDMO Samsung and the CTLs may be subject to significant risks and uncertainties;
- we rely, and expect to continue to rely, on third parties, including independent investigators and contract research organizations (“CROs”) to activate sites, conduct or otherwise support our research activities, preclinical studies, clinical trials and other trials for our product candidates; if these third parties do not perform satisfactorily or comply with regulatory requirements, our product development activities may be delayed, prevented or impaired and our business could be substantially harmed;

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- for our products and product candidates that 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

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candidates, or to secure and maintain freedom to operate, others could preclude us from commercializing such products and product candidates, if approved, or compete against us more directly;

- if the scope of our patent protection is not sufficiently broad or the terms of our patents are insufficient to protect our products and 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;
- 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, 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;
- 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 products and product candidates; such arrangements or transactions may not be successful or on favorable terms, which could adversely affect our ability to develop, commercialize or attempt to realize value from our products and product candidates;and
- concentration of ownership of the voting power of our common ordinary shares, including our Class B common ordinary shares, and conversion rights of the holders of our Class A1 and Class B1 common ordinary shares, which are held primarily by entities affiliated with certain of our directors, may prevent new investors from influencing significant corporate decisions and may have an adverse effect on the price of our Class A common shares. ordinary shares; and

- we have recently completed the Redomiciliation (as defined below), and are now subject to a different risk profile as a result of the laws and regulations of the new country of incorporation of our principal holding company.

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. Solely for convenience, trademarks, service marks, and trade names referred to in this Quarterly Report may be listed without identifying symbols.

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Part I — Financial Information

Item 1. Financial Statements (unaudited)

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

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 141,078	$ 107,954
Short-term investments	72,474	98,417
Accounts receivable, net	15,995	21,266
Inventory	27,278	31,122
Prepaid expenses and other current assets	13,766	17,538
Total current assets	270,591	276,297
Property and equipment, net	712	734
Operating lease right-of-use assets	12,324	11,931
Other long-term assets	4,128	827
Intangible asset, net	17,000	17,250
Deferred tax assets	214,918	219,283
Total assets	$ 519,673	$ 526,322
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 5,632	$ 8,246
Accrued expenses	44,718	44,667
Deferred revenue	156	307
Operating lease liabilities	2,279	2,253

Other current liabilities	11,427	8,193
Total current liabilities	64,212	63,666
Non-current liabilities:		
Non-current deferred revenue	11,811	11,954
Non-current operating lease liabilities	9,864	10,005
Other long-term liabilities	1,891	1,858
Total liabilities	87,778	87,483
Commitments and contingencies (Note 13)		
Shareholders' equity:		
Class A common shares, par value of $0.000273235 per share; 40,184,356 shares and 35,781,373 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	11	10
Class B common shares, par value of $0.000273235 per share; 1,795,158 shares issued and outstanding as of March 31, 2024 and December 31, 2023	1	1
Class A1 common shares, $0.000273235 par value; 12,781,964 and 16,826,468 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	4	5
Class B1 common shares, $0.000273235 par value; 16,057,618 shares issued and outstanding as of March 31, 2024 and December 31, 2023	4	4
Additional paid-in capital	927,582	916,763
Accumulated other comprehensive income (loss)	(53)	6
Accumulated deficit	(495,654)	(477,950)
Total shareholders' equity	431,895	438,839
Total liabilities and shareholders' equity	$ 519,673	$ 526,322

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 99,271	$ 107,954
Short-term investments	119,487	98,417
Accounts receivable, net	20,451	21,266
Inventory	34,858	31,122
Prepaid expenses and other current assets	26,954	17,538
Total current assets	301,021	276,297
Property and equipment, net	625	734
Operating lease right-of-use assets	11,779	11,931
Other long-term assets	7,904	827
Intangible asset, net	16,750	17,250
Deferred tax assets	204,349	219,283
Total assets	$ 542,428	$ 526,322
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 7,393	$ 8,246
Accrued collaboration expenses	29,943	16,939
Accrued expenses	33,374	27,728
Deferred revenue	12	307
Operating lease liabilities	2,085	2,253
Other current liabilities	11,484	8,193
Total current liabilities	84,291	63,666
Non-current liabilities:		
Non-current deferred revenue	11,799	11,954
Non-current operating lease liabilities	9,317	10,005
Other long-term liabilities	1,926	1,858
Total liabilities	107,333	87,483

Commitments and contingencies (Note 13)		
Shareholders' equity:		
Class A ordinary shares, nominal value of $0.000273235 per share; 40,447,538 shares and 35,781,373 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	11	10
Class B ordinary shares, nominal value of $0.000273235 per share; 1,795,158 shares issued and outstanding as of June 30, 2024 and December 31, 2023	1	1
Class A1 ordinary shares, $0.000273235 nominal value; 12,781,964 and 16,826,468 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	4	5
Class B1 ordinary shares, $0.000273235 nominal value; 16,057,618 shares issued and outstanding as of June 30, 2024 and December 31, 2023	4	4
Additional paid-in capital	934,767	916,763
Accumulated other comprehensive income (loss)	(130)	6
Accumulated deficit	(499,562)	(477,950)
Total shareholders' equity	435,095	438,839
Total liabilities and shareholders' equity	$ 542,428	$ 526,322

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

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

	Three Months Ended March 31,	
	2024	2023
Revenue:		
Product revenue, net	$ 78,885	$ 42,659
License and collaboration revenue	973	5,686
Total revenue	79,858	48,345
Costs and operating expenses:		
Cost of goods sold	10,583	7,036
Collaboration expenses	20,801	8,288
Research and development	26,334	15,172
Selling, general and administrative	38,682	29,045
Total operating expenses	96,400	59,541
Loss from operations	(16,542)	(11,196)
Other income	2,266	1,832
Loss before income taxes	(14,276)	(9,364)
Provision for income taxes	(3,428)	(2,906)
Net loss	$ (17,704)	$ (12,270)
Net loss per share attributable to common shareholders—basic and diluted	$ (0.25)	$ (0.18)
Weighted average common shares outstanding—basic and diluted	70,633,023	69,751,697
Comprehensive loss:		

Net loss	$ (17,704)	$ (12,270)
Other comprehensive income (loss):		
Unrealized gain (loss) on short-term investments and currency translation adjustments, net of tax	(59)	11
Total other comprehensive income (loss)	(59)	11
Total comprehensive loss	$ (17,763)	$ (12,259)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue:				
Product revenue, net	$ 103,394	$ 54,495	$ 182,279	$ 97,154
License and collaboration revenue	5,237	16,978	6,210	22,664
Total revenue	108,631	71,473	188,489	119,818
Costs and operating expenses:				
Cost of goods sold	12,322	7,699	22,905	14,735
Collaboration expenses	30,014	13,986	50,815	22,274
Research and development	24,017	23,767	50,351	38,939
Selling, general and administrative	42,395	29,175	81,077	58,220
Total operating expenses	108,748	74,627	205,148	134,168
Loss from operations	(117)	(3,154)	(16,659)	(14,350)
Other income	2,421	1,915	4,687	3,747
Income (loss) before income taxes	2,304	(1,239)	(11,972)	(10,603)
Benefit (provision) for income taxes	(6,212)	16,211	(9,640)	13,305
Net income (loss)	$ (3,908)	$ 14,972	$ (21,612)	$ 2,702
Net income (loss) per share attributable to ordinary shareholders—basic	$ (0.06)	$ 0.21	$ (0.31)	$ 0.04
Net income (loss) per share attributable to ordinary shareholders—diluted	$ (0.06)	$ 0.21	$ (0.31)	$ 0.04
Weighted average ordinary shares outstanding—basic	71,004,640	69,918,287	70,818,831	69,835,452
Weighted average ordinary shares outstanding—diluted	71,004,640	71,634,729	70,818,831	71,420,026
Comprehensive income (loss):				
Net income (loss)	$ (3,908)	$ 14,972	$ (21,612)	$ 2,702
Other comprehensive income (loss):				
Unrealized gain (loss) on short-term investments and currency translation adjustments, net of tax	(77)	(42)	(136)	(31)
Total other comprehensive income (loss)	(77)	(42)	(136)	(31)
Total comprehensive income (loss)	$ (3,985)	$ 14,930	$ (21,748)	$ 2,671

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

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KINIKSA PHARMACEUTICALS LTD.INTERNATIONAL, PLC
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, 2023	70,460,617	$ 20	$ 916,763	$ 6	$ (477,950)	$ 438,839
Issuance of Class A common shares under incentive award plans	358,479	—	3,613	—	—	3,613
Share-based compensation expense	—	—	7,206	—	—	7,206
Unrealized loss on short-term investments and currency translation adjustments	—	—	—	(59)	—	(59)
Net loss	—	—	—	—	(17,704)	(17,704)
Balances at March 31, 2024	70,819,096	$ 20	$ 927,582	$ (53)	$ (495,654)	$ 431,895

	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, 2022	69,697,503	$ 19	$ 888,120	$ 44	$ (492,034)	$ 396,149
Issuance of Class A common shares under incentive award plans	135,576	—	90	—	—	90
Share-based compensation expense	—	—	6,115	—	—	6,115
Unrealized gain on short-term investments and currency translation adjustments	—	—	—	11	—	11
Net loss	—	—	—	—	(12,270)	(12,270)
Balances at March 31, 2023	69,833,079	$ 19	$ 894,325	$ 55	$ (504,304)	$ 390,095

	Ordinary Shares (Class A, B, A1 and B1)		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Shareholders'
	Shares	Amount	Capital	Income (loss)	Deficit	Equity
Balances at December 31, 2023	70,460,617	$ 20	$ 916,763	$ 6	$ (477,950)	$ 438,839
Issuance of Class A ordinary shares under incentive award plans	358,479	—	3,613	—	—	3,613
Share-based compensation expense	—	—	7,206	—	—	7,206
Unrealized loss on short-term investments and currency translation adjustments	—	—	—	(59)	—	(59)
Net loss	—	—	—	—	(17,704)	(17,704)
Balances at March 31, 2024	70,819,096	$ 20	$ 927,582	$ (53)	$ (495,654)	$ 431,895
Issuance of Class A ordinary shares under incentive award plans	263,182	—	(178)	—	—	(178)
Share-based compensation expense	—	—	7,363	—	—	7,363
Unrealized loss on short-term investments and currency translation adjustments	—	—	—	(77)	—	(77)
Net loss	—	—	—	—	(3,908)	(3,908)
Balances at June 30, 2024	71,082,278	$ 20	$ 934,767	$ (130)	$ (499,562)	$ 435,095

	Ordinary 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, 2022	69,697,503	$ 19	$ 888,120	$ 44	$ (492,034)	$ 396,149
Issuance of Class A ordinary shares under incentive award plans	135,576	—	90	—	—	90
Share-based compensation expense	—	—	6,115	—	—	6,115
Unrealized gain on short-term investments and currency translation adjustments	—	—	—	11	—	11
Net loss	—	—	—	—	(12,270)	(12,270)
Balances at March 31, 2023	69,833,079	$ 19	$ 894,325	$ 55	$ (504,304)	$ 390,095
Issuance of Class A ordinary shares under incentive award plans	169,584	—	158	—	—	158
Share-based compensation expense	—	—	6,473	—	—	6,473
Unrealized gain on short-term investments and currency translation adjustments	—	—	—	(42)	—	(42)
Net income	—	—	—	—	14,972	14,972
Balances at June 30, 2023	70,002,663	$ 19	$ 900,956	$ 13	$ (489,332)	$ 411,656

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

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

	Three Months Ended March 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (17,704)	$ (12,270)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization expense	466	596
Share-based compensation expense	7,206	6,115
Non-cash lease expense	779	841
Amortization of premiums and accretion of discounts on short-term investments	297	(1,061)
Loss on disposal of property and equipment	—	175
Deferred income taxes	4,365	1,077
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	3,750	(2,634)
Accounts receivable, net	5,271	5,236
Inventory	3,844	(1,826)
Contract asset	—	7,656
Other long-term assets	(3,362)	3,268
Accounts payable	(2,662)	(6,508)
Accrued expenses and other current liabilities	3,285	(10,647)
Operating lease liabilities	(1,287)	(988)
Deferred revenue	(294)	6,658
Other long-term liabilities	33	45
Net cash provided by (used in) operating activities	3,987	(4,267)
Cash flows from investing activities:		
Purchases of property and equipment	(84)	(24)
Purchases of short-term investments	(36,276)	(52,896)
Proceeds from the maturities of short-term investments	61,884	15,000
Net cash provided by (used in) investing activities	25,524	(37,920)
Cash flows from financing activities:		
Proceeds from issuance of Class A common shares under incentive award plans and employee share purchase plan	3,994	510
Payments in connection with Common Stock tendered for employee tax obligations	(381)	(420)
Net cash provided by financing activities	3,613	90
Net increase (decrease) in cash and cash equivalents	33,124	(42,097)
Cash and cash equivalents at beginning of period	107,954	122,715
Cash and cash equivalents at end of period	$ 141,078	$ 80,618
Supplemental information:		

Cash paid for income taxes	$ —	$ 3,196
Supplemental disclosure of non-cash investing and financing activities:		
Change in right-of-use asset as a result of new, modified, and terminated leases	$ 1,172	$ 684
Additions to property and equipment included in accounts payable and accrued expenses and other liabilities	102	—

	Six Months Ended June 30,	
	2024	**2023**
Cash flows from operating activities:		
Net income (loss)	$ (21,612)	$ 2,702
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization expense	896	1,198
Share-based compensation expense	14,569	12,588
Non-cash lease expense	1,615	1,610
Amortization of premiums and accretion of discounts on short-term investments	109	(2,213)
Gain on disposal of property and equipment	(25)	—
Loss on disposal of property and equipment	1	175
Deferred income taxes	14,934	(18,367)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(9,517)	(1,925)
Accounts receivable, net	815	(11,990)
Inventory	(3,736)	(2,359)
Contract asset	—	7,656
Other long-term assets	(7,201)	3,178
Accounts payable	(933)	(7,251)
Accrued expenses, accrued collaboration expenses and other current liabilities	21,940	4,046
Operating lease liabilities	(2,319)	(1,814)
Deferred revenue	(449)	4,680
Other long-term liabilities	68	76
Net cash provided by (used in) operating activities	9,155	(8,010)
Cash flows from investing activities:		
Proceeds from sale of property and equipment	25	—
Purchases of property and equipment	(84)	(58)
Purchases of short-term investments	(125,539)	(91,028)
Proceeds from the maturities of short-term investments	104,325	88,700
Net cash used in investing activities	(21,273)	(2,386)
Cash flows from financing activities:		
Proceeds from issuance of Class A ordinary shares under incentive award plans and employee share purchase plan	5,129	1,087
Payments in connection with Ordinary Stock tendered for employee tax obligations	(1,694)	(839)
Net cash provided by financing activities	3,435	248
Net decrease in cash and cash equivalents	(8,683)	(10,148)
Cash and cash equivalents at beginning of period	107,954	122,715
Cash and cash equivalents at end of period	$ 99,271	$ 112,567
Supplemental information:		
Cash paid for income taxes	$ 1,510	$ 6,716
Supplemental disclosure of non-cash investing and financing activities:		
Change in right-of-use asset as a result of new, modified, and terminated leases	$ 1,463	$ 9,416
Additions to property and equipment included in accounts payable and accrued expenses and other liabilities	178	—

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

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1. Nature of the Business and Basis of Presentation

Kiniksa Pharmaceuticals Ltd. International, plc (the "Company" or "Kiniksa International") is a commercial-stage 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 immune-modulating assets is based on strong biologic rationale or validated mechanisms, targets a spectrum of underserved cardiovascular and autoimmune conditions and offers the potential for differentiation.

The Company is the successor issuer to Kiniksa Pharmaceuticals, Ltd. ("Kiniksa Bermuda"). On June 27, 2024, the Company and Kiniksa Bermuda completed a transaction pursuant to a Bermuda court-approved scheme of arrangement (the "Scheme"), which had been previously approved by Kiniksa Bermuda's shareholders. Pursuant to the Scheme, the shareholders of Kiniksa Bermuda became the shareholders of the Company and the Company became the ultimate parent and holding company of the Kiniksa organization, thereby effecting a change of incorporation from Bermuda to the United Kingdom (the "Redomiciliation"). As used herein, and unless the context otherwise requires, references to the "Company" prior to the Redomiciliation shall refer to Kiniksa Pharmaceuticals, Ltd. and from and after the Redomiciliation, to Kiniksa Pharmaceuticals International, plc.

The Company is subject to risks and uncertainties common to commercial-stage companies in the biopharmaceutical industry and global health, societal, economic and market conditions, including the Company's dependence on third parties, including contract research organizations and contract manufacturing organizations, 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, the uncertainty that any current or future product candidates will obtain necessary government regulatory approval, that ARCALYST will continue to be commercially viable and whether any of the Company's current or future product candidates, if approved, will be commercially viable. Such risks and uncertainties may be subject to substantial and uncertain changes, which may cause significant disruption to the Company's business and operations, preclinical studies and clinical trials, the business and operations of the third parties with whom the Company conducts business and the national and global economies, all of which may have material impacts on the Company's business, financial condition and results of operations.

Principles of Consolidation

The Redomiciliation was accounted for as a change in the reporting entity between entities under common control and the historical basis of accounting was retained as if the entities had always been combined for financial reporting process. The consolidated financial statements for periods prior to the Redomiciliation are the consolidated statements of Kiniksa Bermuda as the predecessor to the Company for accounting and reporting purposes and, upon completion of the Redomiciliation, such historical consolidated financial statements became Kiniksa International's historical consolidated financial statements.

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"), Kiniksa Bermuda 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. Where the Kiniksa Pharmaceuticals Ltd. International, plc entity is referred to in its single, unconsolidated form, it is referred to as "Kiniksa Bermuda" International".

Reclassifications

Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the reported results of operations and comprehensive income (loss) or cash flows. A

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reclassification has been made to the Consolidated Balance Sheet for fiscal year ended December 31, 2023, to reclassify the collaboration accrued expenses to be a separate line item.

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 accrual for research and development expenses, and the valuation of our deferred tax assets. 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, 2023 (the "2023 Form 10-K"). The Company's accounting policies are described in the Notes to Consolidated Financial Statements included in the Company's 2023 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

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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, 2024 June 30, 2024 and the results of its operations for the three and six months ended March 31, 2024 June 30, 2024 and 2023, the changes in its shareholders' equity for the three and six months ended March 31, 2024 June 30, 2024 and 2023 and its cash flows for the three six months ended March 31, 2024 June 30, 2024 and 2023. The results for the three and six months ended March 31, 2024 June 30, 2024 are not necessarily indicative of results to be expected for the year ending December 31, 2024, 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, 2024 June 30, 2024, the Company had an accumulated deficit of $495,654. $499,562. During the three six months ended March

31, 2024 June 30, 2024, the Company reported a net loss of $17,704 $21,612 and had provided $3,987 $9,155 cash from operating activities. As of March 31, 2024 June 30, 2024, the Company had cash, cash equivalents and short-term investments of $213,552. $218,758. 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.

Summary of Significant Accounting Policies

Inventory

Inventories are stated at the lower of cost or estimated net realizable value with cost based on the first-in first-out method. The Company classifies inventory as long-term when the inventory is expected to be utilized beyond the Company's normal operating cycle and includes such amounts in other long-term assets in our consolidated balance sheets. Prior to the regulatory approval of its drug candidates, the Company incurs expenses for the manufacture of product candidate supplies to support clinical development that could potentially be available to support the commercial launch of those therapeutics. Until the date at which regulatory approval has been received or is otherwise considered

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probable, the Company records all such costs as research and development expenses. The Company performs an assessment of the recoverability of capitalized inventories during each reporting period and writes down any excess and obsolete inventory to its net realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded as a component of cost of sales in the Company's consolidated statements of operations and comprehensive income (loss). The determination of whether inventory costs will be realizable requires the use of estimates by management. If actual market conditions are less favorable than projected by management, additional writedown of inventory may be required.

Finished goods that can be used in either the production of clinical or commercial products is expensed as research and development costs when identified and labeled for use in clinical trials as the products are required to be re-labeled for alternative uses. The finished goods inventory that will ultimately be distributed free of charge under our patient assistance program are recognized as selling expense when they are labeled as free goods.

The Company is conducting a technology transfer of ARCALYST drug substance manufacturing from Regeneron Pharmaceuticals, Inc. ("Regeneron") to a new contract development and manufacturing organization Samsung Biologics Co., Ltd. ("CDMO" Samsung"). Costs associated with the establishment of ARCALYST production at a new manufacturing site that do not meet the criteria for research and development or capitalization into inventory, including raw materials consumed, are included in cost of goods sold in the period incurred. During the three and six months ended March 31, 2024 June 30, 2024 the Company incurred $2,126 $2,814 and $4,940 of expense related to the technology transfer of ARCALYST drug substance manufacturing in cost of goods sold. No During the three and six months ended June 30, 2023 the Company incurred $491 of expenses were incurred related to the technology transfer of ARCALYST drug substance manufacturing in cost of goods sold.

Share-Based Compensation

The Company measures all share-based awards granted to employees and directors based on their fair value on the date of grant. The Company issues share-based awards with both service-based, performance-based and market-based vesting conditions. The Company recognizes compensation expense for awards with service and market conditions on a straight-line basis over the requisite service period. For awards that contain performance conditions, we determine the appropriate amount to expense based on the anticipated achievement of performance targets, which requires judgment, including forecasting the achievement of future specified targets. At the date performance conditions are determined to be probable of achievement, we record a cumulative expense catch-up, with remaining expense amortized over the remaining service period. Throughout the performance period, we re-assess the estimated performance and update the number of performance-based awards that we believe will ultimately vest.

For share-based awards granted to consultants and non-employees, compensation expense is recognized over the vesting period of the awards, which is generally the period during which services are rendered by such consultants and non-employees until completed.

The Company classifies share-based compensation expense in its consolidated statements of operations and comprehensive income (loss) in the three months ended March 31, 2023. same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the expected share price volatility, the expected term of the award, the risk-free interest rate and expected dividends. Prior to May 2018, the Company was a private company and, accordingly, lacks company-specific historical and implied volatility information for its shares. Therefore, it estimates its expected share price volatility based on the historical volatility of the Company and historical volatility of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded share price. The expected term of the Company's options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The expected dividend yield is zero based on the fact that the Company has never paid cash dividends on its shares and does not expect to pay any cash dividends in the foreseeable future.

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The fair value of each restricted share unit award is based on the closing price of the Company's Class A ordinary shares on the date of grant, with the exception of PSUs with market conditions, which are measured using the Monte Carlo simulation method. The Monte-Carlo valuation model requires the use of assumptions, including but not limited to the expected volatility, correlation coefficients, risk free rate, expected dividend yield and expected term.

There have been no other material changes to the significant accounting policies previously disclosed in the Company's 2023 Form 10-K.

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Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued Accounting Standards Update No. 2023-07, Segment Reporting - Improvements to Reportable Segment Disclosures. The amendments require disclosure of incremental segment information on an annual and interim basis. The amendments also require companies with a single reportable segment to provide all disclosures required by this amendment and all existing segment disclosures in Accounting Standards Codification 280, Segment Reporting. The amendments are effective for fiscal years beginning after December 15, 2023, and interim periods beginning after December 15, 2024. The Company does not expect the adoption of the amendments to have a material impact on its financial statements.

In December 2023, the FASB issued Accounting Standards Update No. 2023-09, Income Taxes - Improvements to Income Tax Disclosures. The amendments require (i) enhanced disclosures in connection with an entity's effective tax rate reconciliation and (ii) income

taxes paid disaggregated by jurisdiction. The amendments are effective for annual periods beginning after December 15, 2024. The Company does not expect the adoption of the amendments to have a material impact on its financial statements.

2. 2. 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, 2024 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents — money market funds	$ 114,419	$ —	$ —	$ 114,419
Cash equivalents — U.S. Treasury notes	—	6,358	—	6,358
Short-term investments — U.S. Treasury notes	—	72,474	—	72,474
	$ 114,419	$ 78,832	$ —	$ 193,251

	Fair Value Measurements as of December 31, 2023 Using:				Fair Value Measurements as of June 30, 2024 Using:			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Cash equivalents — money market funds	$ 43,554	$ —	$ —	$ 43,554	$18,122	$ —	$ —	$ 18,122
Cash equivalents — U.S. Treasury notes	—	1,995	—	1,995	—	16,926	—	16,926
Short-term investments — U.S. Treasury notes	—	98,417	—	98,417	—	119,487	—	119,487
	$ 43,554	$ 100,412	$ —	$ 143,966	$18,122	$136,413	$ —	$154,535

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	Fair Value Measurements as of December 31, 2023 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				

Cash equivalents — money market funds	$ 43,554	$ —	$ —	$ 43,554
Cash equivalents — U.S. Treasury notes	—	1,995	—	1,995
Short-term investments — U.S. Treasury notes	—	98,417	—	98,417
	$ 43,554	$ 100,412	$ —	$ 143,966

During the three six months ended March 31, 2024 June 30, 2024 and the year ended December 31, 2023, 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, 2024 June 30, 2024 and December 31, 2023 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.

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Credit Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Credit Losses	Fair Value
March 31, 2024										
June 30, 2024										
Cash equivalents — U.S. Treasury notes	$ 6,358	$ —	$ —	$ —	$ 6,358	$ 16,926	$ —	$ —	$ —	$ 16,926
Short-term investments — U.S. Treasury notes	72,482	1	(9)	—	72,474	119,491	4	(8)	—	119,487
	$ 78,840	$ 1	$ (9)	$ —	$ 78,832	$136,417	$ 4	$ (8)	$ —	$136,413

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Credit Losses	Fair Value
December 31, 2023					
Cash equivalents — U.S. Treasury notes	$ 1,995	$ —	$ —	$ —	$ 1,995
Short-term investments — U.S. Treasury notes	98,387	30	—	—	98,417
	$ 100,382	$ 30	$ —	$ —	$ 100,412

As of March 31, 2024 June 30, 2024, we consider the unrealized losses in our investment portfolio to be temporary in nature and not due to credit losses. We have the ability to hold such investments until recovery of the fair value. We utilize the specific identification method in computing realized gains and losses. We had no realized gains and losses on our available-for-sale securities for the three and three six months ended March 31, 2024 June 30, 2024 or 2023.

3. Product Revenue, Net

Product revenue, net, from sales of ARCALYST was as follows:

	Three Months Ended March 31,		Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023	2024	2023
Product revenue, net	$ 78,885	$ 42,659	$103,394	$54,495	$182,279	$97,154

The following table summarizes balances and activity in each of the product revenue allowance and reserve categories for the three six months ended March 31, 2024 June 30, 2024:

	Contractual Adjustments	Government Rebates	Returns	Total	Contractual Adjustments	Government Rebates	Returns	Total
Balance at December 31, 2023	$ 2,022	$ 3,775	$ 341	$ 6,138	$ 2,022	$ 3,775	$ 341	$ 6,138
Current provisions relating to sales in the current year	7,319	3,916	258	11,493	12,316	8,280	574	21,170
Adjustments relating to prior years	—	(5)	836	831	(31)	(17)	836	788
Payments/returns relating to sales in the current year	(5,034)	(887)	—	(5,921)	(10,655)	(1,727)	—	(12,382)
Payments/returns relating to sales in the prior years	(1,957)	(1,475)	—	(3,432)	(1,957)	(3,620)	(192)	(5,769)
Balance at March 31, 2024	$ 2,350	$ 5,324	$ 1,435	$ 9,109				
Balance at June 30, 2024					$ 1,695	$ 6,691	$ 1,559	$ 9,945

Total revenue-related reserves as of March 31, 2024 June 30, 2024 and December 31, 2023, included in our consolidated balance sheets, are summarized as follows:

	March 31, 2024	December 31, 2023	June 30, 2024	December 31, 2023
Components of accounts receivable	$ (411)	$ (459)	$ (486)	$ (459)
Components of other current liabilities	9,520	6,597	10,431	6,597
Total revenue-related reserves	$ 9,109	$ 6,138	$ 9,945	$ 6,138

Primarily all of the Company's trade accounts receivable arise from product revenue in the United States due from the Company's third party logistics provider.

4. Inventory

Inventory consisted of the following:

	March 31, 2024	December 31, 2023	June 30, 2024	December 31, 2023
Raw materials	$ 2,052	$ —	$10,949	$ —
Semi-finished goods	8,721	18,258	18,092	18,258
Finished goods	17,531	12,864	10,759	12,864
Total inventory	$ 28,304	$ 31,122	$39,800	$ 31,122
Balance Sheet Classification:				
Inventory	$ 27,278	$ 31,122	$34,858	$ 31,122
Other long-term assets	1,026	—	4,942	—
Total inventory	$ 28,304	$ 31,122	$39,800	$ 31,122

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5. Property and Equipment, Net

Property and equipment, net consisted of the following:

	March 31, 2024	December 31, 2023	June 30, 2024	December 31, 2023
Furniture, fixtures and vehicles	$ 224	$ 224	$ 183	$ 224
Computer hardware and software	379	379	379	379
Leasehold improvements	3,931	3,931	3,931	3,931
Lab equipment	4,074	3,972	3,972	3,972
Construction in progress	43	13	178	13
Total property and equipment	8,651	8,519	8,643	8,519
Less: Accumulated depreciation	(7,939)	(7,785)	(8,018)	(7,785)
Total property and equipment, net	$ 712	$ 734	$ 625	$ 734

Depreciation expense was $154 $119 and $289 $292 during the three months ended March 31, 2024 June 30, 2024 and 2023, respectively, and $273 and $581 during the six months ended June 30, 2024 and 2023, respectively.

As of March 31, 2024 June 30, 2024 and December 31, 2023, $116 $110 and $122, respectively, of our property and equipment, net was in the United Kingdom.

6. Intangible Assets

Intangible assets, net of accumulated amortization as of March 31, 2024 June 30, 2024 and December 31, 2023 are summarized in the following table.

	As of March 31, 2024				As of December 31, 2023				As of June 30, 2024				As of December 31, 2		
	Estimated life	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net	Estimated life	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization		
Regulatory milestone	20 years	$20,000	$ 3,000	$17,000	$20,000	$ 2,750	$17,250	20 years	$20,000	$ 3,250	$16,750	$20,000	$ 2,750		

7. Accrued Expenses

Accrued expenses consisted of the following:

	March 31, 2024	December 31, 2023	June 30, 2024	December 31, 2023
Accrued research and development expenses	$ 11,028	$ 7,895	$11,362	$ 7,895
Accrued employee compensation and benefits	7,317	15,954	11,489	15,954
Accrued collaboration expenses	20,123	16,939		
Accrued legal, commercial and professional fees	5,840	3,553	10,412	3,553
Other	410	326	111	326
	$ 44,718	$ 44,667	$33,374	$ 27,728

8. Share-Based Compensation

The Company maintains several As part of the Redomiciliation, Kiniksa International assumed the sponsorship of, and all rights and obligations of Kiniksa Bermuda under Kiniksa Bermuda's equity compensation plans, including which include 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").

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2015 Plan

As of March 31, 2024 June 30, 2024, there were 1,814,958 1,810,614 Class A common ordinary shares subject reserved for issuance pursuant to outstanding awards under the 2015 Plan and reserved for issuance thereunder pursuant that were granted prior to such awards. the effectiveness of the 2018 Plan.

2018 Plan

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. Pursuant to the 2018 Plan's evergreen provision, the number of shares available for future issuance under the 2018 Plan, as of January 1, 2024, increased by 2,818,425 Class A common ordinary shares. As of March 31, 2024 June 30, 2024, 4,207,733 6,030,956 shares remained available for future grant under the 2018 Plan.

2018 ESPP

In December 2023, the Company's board of directors approved an increase, as of January 1, 2024, of 215,000 Class A common ordinary shares under the 2018 ESPP. As of March 31, 2024 June 30, 2024, 702,707 Class A common ordinary shares were available for future issuance under the 2018 ESPP.

Options

Share option activity under the Plans is summarized as follows:

	Number of Shares	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
Outstanding as of December 31, 2023	11,599,089	$ 13.67	11,599,089	$ 13.67
Granted	26,750	$ 18.73	927,563	$ 18.42
Exercised	(282,269)	$ 12.38	(378,975)	$ 12.22
Forfeited	(104,605)	$ 14.21	(367,151)	$ 15.13
Outstanding as of March 31, 2024	11,238,965	$ 13.71		
Share options exercisable as of March 31, 2024	7,489,111	$ 13.67		
Share options unvested as of March 31, 2024	3,749,854	$ 13.71		
Outstanding as of June 30, 2024			11,780,526	$ 14.05
Share options exercisable as of June 30, 2024			7,914,972	$ 13.59
Share options unvested as of June 30, 2024			3,865,554	$ 14.97

As of March 31, 2024 June 30, 2024, total unrecognized compensation expense related to the unvested share option awards was $30,915 $34,951 which is expected to be recognized over a weighted average remaining period of 2.42 2.46 years.

Restricted Share Units

The Company grants 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 ordinary shares issuable under the First RLTIP RSU Awards were determined in accordance with the RLTIP and vested in one installment in March 2022, 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 vested in one installment in March 2023.

During the three months ended March 31, 2024 and 2023, the Company recognized compensation expense of $2,284 and $1,529, respectively, related to RSUs including those granted in connection with the RLTIP.

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The following table summarizes RSU activity, including the RSUs issued under the RLTIP for the three six months ended March 31, 2024 June 30, 2024:

	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Unvested RSUs as of December 31, 2023	2,396,888	$ 14.00	2,396,888	$ 14.00
Granted	41,410	$ 18.59	492,370	$ 18.77
Vested	(55,014)	$ 18.57	(296,202)	$ 12.82
Forfeited	(122,026)	$ 14.12	(264,887)	$ 14.39
Unvested RSUs as of March 31, 2024	2,261,258	$ 13.96		
Unvested RSUs as of June 30, 2024			2,328,169	$ 15.21

As of March 31, 2024 June 30, 2024, total unrecognized compensation cost related to the RSU awards was $25,376 $28,997 which is expected to be recognized over a weighted average remaining period of 2.73 2.75 years.

Market and Performance-Based Shares Units

In the second quarter of 2024, the Company began periodically granting performance-based restricted share units to certain employees under the 2018 Plan. The Company granted awards which are earned based upon the achievement of certain specified ARCALYST revenue targets (“Revenue PSUs”), and awards which are earned based upon the Company’s total shareholder return (“TSR”) relative to the TSR of each member of a specified peer group (“TSR PSUs” and, together with the Revenue PSUs, the “PSUs”). The PSUs are subject to a three year service period.

The following table summarizes PSU activity for the six months ended June 30, 2024:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested PSUs as of December 31, 2023	-	$ -
Granted	62,914	$ 22.06
Forfeited	(3,777)	$ 22.06
Unvested PSUs as of June 30, 2024	59,137	$ 22.06

As of June 30, 2024, total unrecognized compensation cost related to the PSU awards was $1,535 which is expected to be recognized over a weighted average remaining period of 2.50 years.

Share-Based Compensation

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

	Three Months Ended March 31,		Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023	2024	2023
Cost of goods sold	$ 359	$ 286	$ 353	$ 311	$ 712	$ 597
Research and development expenses	1,453	1,444	1,501	1,395	2,954	2,839
Selling, general and administrative expenses	5,394	4,385	5,509	4,767	10,903	9,152
	$ 7,206	$ 6,115	$ 7,363	$ 6,473	$14,569	$12,588

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9. Out-Licensing Agreements

Genentech License Agreement

The Company entered into a license agreement (the "Genentech License Agreement") with Genentech, Inc. and F. Hoffmann-La Roche Ltd (collectively, "Genentech"), effective in September 2022, pursuant to which the Company granted Genentech exclusive worldwide rights to develop, manufacture and commercialize vixarelimab and related antibodies (each, a "Genentech Licensed Product").

Under the Genentech License Agreement, the Company received an upfront payment of $80,000 for the license. During the year ended December 31, 2023, the Company received cash payments of $20,000 following delivery of certain drug supplies to Genentech and $15,000 following Genentech's achievement of a development milestone related to a new indication under the Genentech License Agreement. In the fourth quarter of 2023, following the achievement of a development milestone related to a second indication under the Genentech License Agreement, Genentech became obligated to make an additional cash payment of $10,000 which the Company received in the first quarter of 2024. In the second quarter of 2024, the Company received a cash payment of $5,000 following the achievement of a development milestone related to the third indication under the Genentech License Agreement. Under the terms of the Genentech License Agreement, the Company is eligible to receive a total of approximately $600,000 in contingent payments, including specified development, regulatory and sales-based milestones, before fulfilling the Company's upstream financial obligations, of which approximately $575,000 $570,000 remain as of March 31, 2024 June 30, 2024. The Company will also be eligible to receive tiered percentage royalties on a Genentech Licensed Product-by-Genentech Licensed Product basis ranging from low-double digits to mid-teens on annual net sales of each Genentech Licensed Product, subject to certain customary reductions, with an aggregate minimum floor, before fulfilling the Company's upstream financial obligations. Royalties will be payable on a Genentech Licensed Product-by-Genentech Licensed Product and country-by-country basis until the latest to occur of the expiration of certain patents that cover a Genentech

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Licensed Product, the expiration of regulatory exclusivity for such Genentech Licensed Product, or the tenth anniversary of first commercial sale of such Genentech Licensed Product in such country.

Pursuant and subject to the terms of the Genentech License Agreement, Genentech has the exclusive worldwide right to conduct development and commercialization activities for Genentech Licensed Products at its sole cost. Notwithstanding the foregoing, the Company is responsible, at its sole cost, for finalizing its Phase 2b clinical trial assessing the efficacy, safety and tolerability of vixarelimab in reducing pruritis in prurigo nodularis. Both the Company and Genentech participate in a joint transition committee, which coordinates and oversees the Company's finalization of its Phase 2b clinical trial.

Accounting for the Genentech License Agreement

As of the Genentech Effective Date, the Company identified the following performance obligations in the Genentech License Agreement: (i) the delivery of the exclusive license for vixarelimab; (ii) an initial drug supply delivery; (iii) a drug product resupply delivery; and (iv) completion of the Phase 2b clinical trial for vixarelimab.

The Company determined the transaction price of the Genentech License Agreement consisted of the $80,000 upfront payment and the $20,000 variable consideration related to the delivery of the initial drug supply and drug product resupply which was added to the transaction price in 2022. In 2023 and 2024, the Company added $25,000 and $5,000, respectively, to the transaction price following Genentech's achievement of two development milestones under the Genentech License Agreement.

As noted above, the Company identified four performance obligations in the Genentech License Agreement: (i) the delivery of the exclusive license for vixarelimab; (ii) an initial drug supply delivery; (iii) a drug product resupply delivery; and (iv) completion of the Phase 2b clinical trial for vixarelimab. The selling price of each performance obligation in the Genentech License Agreement was determined based on the Company's standalone selling price 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 transaction price to each of the four performance obligations noted above.

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Performance Obligation	Method of Recognition
Exclusive license for vixarelimab	Point in time; upon transfer of the license to Genentech, as control of the license was transferred on the Genentech Effective Date and Genentech could begin to use and benefit from the license on that date.
Initial drug supply delivery	Point in time upon delivery.
Drug product resupply delivery	Point in time upon delivery.
Completion of the phase 2b clinical trial for vixarelimab	Over time; using the cost-to-cost input method, which is believed to best depict the transfer of control to the customer. Under the cost-to-cost input method, the percent of completion is based on the ratio of actual costs incurred as of the period end to the total estimated costs. Revenue is recorded as a percentage of the allocated transaction price times the percent of completion.

The Company recognized $105 $5,156 and $5,261 of collaboration revenue under the Genentech License Agreement during the three and six months ended March 31, 2024 June 30, 2024, respectively. As a result of the $5,000 development milestone the Company recognized revenue of $4,994 and $4,989 during the three and six months ended June 30, 2024, respectively, related to performance obligations satisfied in prior periods. As of June 30, 2024, the completed portion Company has recognized as revenue all of the Phase 2b clinical trial for vixarelimab. transaction price associated with the Genentech License Agreement. The Company recognized $5,686 $16,978 and $22,664 of collaboration revenue during three and six months ended March 31, 2023 June 30, 2023 under the Genentech License Agreement related to

the license, completed portion of the Phase 2b clinical trial for vixarelimab, and materials delivered. The Company expects to recognize the remaining deferred revenue associated with the Genentech License Agreement over the remaining portion of the Phase 2b clinical trial for vixarelimab.

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Huadong Collaboration Agreements

In February 2022 (the "Effective Date"), the Company entered into two collaboration and license agreements (each, a "Huadong Collaboration Agreement" and together, the "Huadong 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 "Huadong Licensed Product" and together, the "Huadong 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 "Huadong Territory"). The Company otherwise retained its current rights to the Huadong Licensed Products outside the Huadong Territory.

Under the Huadong Collaboration Agreements, the Company received a total upfront cash payment of $22,000, which includes $12,000 for the Huadong Territory license of rilonacept and $10,000 for the Huadong Territory license of mavrilimumab. 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 Huadong Licensed Product-by-Huadong Licensed Product basis ranging from the low-teens to low-twenties on annual net sales of each Huadong Licensed Product in the Huadong 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 Huadong Licensed Product-by-Huadong 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 Huadong Licensed Product in such country or region in the Huadong 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 Huadong Licensed Product in such country or region in the Huadong Territory, and (iii) the expiration of the last regulatory exclusivity for the applicable Huadong Licensed Product in such country or region in the Huadong Territory.

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

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Accounting for the Mavrilimumab Huadong Collaboration Agreement

As of the Effective Date, the Company identified the following performance obligations in the mavrilimumab Huadong Collaboration Agreement: delivery of (i) exclusive license for mavrilimumab in the Huadong Territory and (ii) clinical manufacturing supply of certain materials for mavrilimumab products in the Huadong Territory.

The Company determined the transaction price at the inception of the mavrilimumab Huadong Collaboration Agreement 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.

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 year ended December 31, 2022 under the mavrilimumab Huadong Collaboration Agreement. The Company will recognize

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revenue for the clinical manufacturing supply obligations at a point in time, that is upon each delivery of the supply to Huadong.

Accounting for the Rilonacept Huadong Collaboration Agreement

As of the Effective Date, the Company identified one performance obligation in the rilonacept Huadong Collaboration Agreement: the exclusive license for rilonacept and clinical and commercial manufacturing obligations for rilonacept products in the Huadong Territory. Huadong cannot exploit the value of the exclusive license for rilonacept products in the Huadong Territory without receipt of supply as the exclusive license for rilonacept products in the Huadong Territory does not convey to Huadong the right to manufacture and therefore the Company has combined the exclusive license for rilonacept products in the Huadong Territory and the manufacturing obligations into one performance obligation.

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

The Company recognizes revenue for the single performance obligation in the rilonacept Huadong Collaboration Agreement consisting of the exclusive license for rilonacept and clinical and commercial manufacturing obligations for rilonacept products in the Huadong 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 Huadong Collaboration Agreement and may be reduced or increased based on changes in the various activities.

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The Company recognized $189 of the upfront payment in collaboration revenue during the three six months ended March 31, 2024 June 30, 2024, under the rilonacept Huadong Collaboration Agreement related to materials delivered. The Company did not recognize any revenue from the $12,000 upfront payment under the rilonacept Huadong Collaboration Agreement during the three month months ended March 31, 2023 June 30, 2024. The Company did not recognize any revenue from the $12,000 upfront payment under the rilonacept Huadong Collaboration Agreement during the three and six months ended June 30, 2023. As of March 31, 2024 June 30, 2024, $11,811 $12 of the transaction price is recorded in current deferred revenue and $11,799 of the transaction price is recorded in non-current deferred revenue, based upon timing of anticipated future shipments.

The following table summarizes the Company's contract assets and contract liabilities in connection with license and collaboration agreements for the three six months ended March 31, 2024 June 30, 2024:

	Balance at Beginning of Period	Additions	Revenue Recognized	Reclassification	Balance at End of Period	Balance at Beginning of Period	Additions	Revenue Recognized	Reclassification	Balance at E of Period
Three Months Ended March 31, 2024										
Six Months Ended June 30, 2024										
Contract Liabilities:										
Genentech vixarelimab	$ 261	$ —	$ (105)	$ —	$ 156	$ 261	$ 5,000	$ (5,261)	$ —	$ -
Huadong rilonacept	12,000	—	(189)	—	11,811	12,000	—	(189)	—	11,81
Total Contract Liabilities	$ 12,261	$ —	$ (294)	$ —	$ 11,967	$ 12,261	$ 5,000	$ (5,450)	$ —	$ 11,81

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10. License and Acquisition 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 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 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, 2024 June 30, 2024. Additionally, the Company could be obligated to make up to an aggregate of $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).

In July 2017, the Company and Biogen entered into Amendment No. 1 to the Biogen Agreement, which clarified the scope of the antibodies subject to the Biogen Agreement.

In August 2022, the Company entered into Amendment No. 2 to the Biogen Agreement (the "Second Biogen Amendment"). Pursuant to the terms of the Second Biogen Amendment, commencing on the effective date of the

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Genentech License Agreement, certain defined terms in the Biogen Agreement were amended, including "Net Sales", "Indication", "Product", "Combination Product" and "Valid Claim". In addition, the tiered royalty rates to be paid by the Company to Biogen increased by an amount equal to less than one percent.

Upon the termination or expiration of the Genentech License Agreement, the amendments to the terms of the Biogen Agreement, as set forth in the Second Biogen Amendment, will terminate and all terms of the Biogen Agreement will revert to the version of such terms in effect as of immediately prior to the effective date of the Genentech License Agreement.

During the three and six months ended March 31, 2024 June 30, 2024, the Company recorded research expenses of $11 and development expense of $61 $72, respectively, related to a milestone and the annual maintenance in connection with the Biogen Agreement. During the three and six months ended March 31, 2023 June 30, 2023, the Company did not record any research and development expense recorded expenses of $34, related to the annual maintenance in connection with the Biogen Agreement.

Beth Israel Deaconess Medical Center License Agreement

In 2019, the Company acquired all of the outstanding securities of Primatope Therapeutics, Inc. ("Primatope"), the company that owned or controlled the intellectual property related to abiprubart. In connection with the Company's acquisition of Primatope, 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 abiprubart (the "BIDMC Agreement"). Under the BIDMC Agreement, the Company is solely responsible for all

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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 and six months ended March 31, 2024 June 30, 2024 the Company recorded research expenses of $8 and development expense of $27 $35, respectively, in connection with the BIDMC Agreement. During the three and six months ended March 31, 2023 June 30, 2023, the Company did not record any research and development expense expenses 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 ("BLA") 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 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 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. 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) the technology transfer of the manufacturing process for ARCALYST drug substance will 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

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or other disposition of rights with respect to ARCALYST, including upfront payments, milestone payments and royalties. For the three and six months ended March 31, 2024 and 2023, June 30, 2024, the Company recognized $20,123 $29,943 and $8,288 $50,066 respectively, of expenses related to the profit sharing agreement presented within collaboration expenses. For the three and six months ended June 30, 2023, the Company recognized $13,986 and $22,274 respectively, of expenses related to the profit sharing agreement presented within collaboration expenses.

The Company has a supply agreement with Regeneron pursuant to which the Company may order both clinical and commercial product. The 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 and six months ended March 31, 2024 June 30, 2024 and 2023, the Company did not incur any research and development expense related to the purchase of drug materials under the supply agreement. The $28,851 and $31,122 of the Company's inventory balance as of March 31, 2024 June 30, 2024 and December 31, 2023, of $26,252 and $31,122 respectively, related to the purchase of commercial product under the supply agreement. As of March 31, 2024 June 30, 2024, the Company had non-cancelable purchase commitments under the 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.

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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 the aggregate for the first two indications, of which $57,500 remain as of March 31, 2024 June 30, 2024. 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 milestone payments aggregating up to $1,100,000 upon the achievement of additional specified annual net sales thresholds starting at $1,000,000. 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

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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 and six months ended March 31, 2024 June 30, 2024 and 2023, the Company did not record research and development expense any expenses in connection with milestone payments due under the MedImmune Agreement.

11. Net Loss Income (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 ordinary shares are identical, except with respect to voting, transferability and conversion (see Exhibit 4.2 to the Notes to Consolidated Financial Statements included in our Company's Current Report on Form 10-K 8-K12B, filed on June 28, 2024). As the liquidation and dividend rights are identical, losses are allocated on a proportionate basis and the resulting net income (loss) per share attributed to common ordinary shareholders will, therefore, be the same for both Class A and Class B common ordinary shares on an individual or combined basis.

Basic and diluted net income (loss) attributable to ordinary shareholders was calculated as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Numerator:				
Net income (loss) attributable to ordinary shareholders	$ (3,908)	$ 14,972	$ (21,612)	$ 2,702

Denominator:				
Weighted-average shares outstanding	71,004,640	69,918,287	70,818,831	69,835,452
Effect of dilutive securities				
Options to purchase ordinary shares	—	1,206,683	—	1,165,632
Unvested RSUs	—	509,759	—	418,942
Weighted-average diluted shares	71,004,640	71,634,729	70,818,831	71,420,026
Basic EPS	$ (0.06)	$ 0.21	$ (0.31)	$ 0.04
Diluted EPS	$ (0.06)	$ 0.21	$ (0.31)	$ 0.04

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

Diluted earnings per share includes the assumed exercise of dilutive options and the assumed issuance of unvested RSUs and performance-based awards for which the performance condition has been met as of the date of determination, using the treasury stock method unless the effect is anti-dilutive. The treasury stock method assumes that proceeds, including cash received from the exercise of employee stock options and the average unrecognized compensation expense for unvested share-based compensation awards, would be used to purchase the Company's common stock at the average market price during the period.

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Basic For the three and diluted net loss attributable to common shareholders was calculated as follows:

	Three Months Ended March 31,	
	2024	2023
Numerator:		
Net loss attributable to common shareholders	$ (17,704)	$ (12,270)
Denominator:		
Weighted-average shares outstanding - basic and diluted	70,633,023	69,751,697
Basic and diluted net loss per share	$ (0.25)	$ (0.18)

The Company's unvested RSUs have been excluded from six months ended June 30, 2024, the computation of basic net loss per share attributable to common shareholders.

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

	Three Months Ended March 31,		Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023	2024	2023
Share options to purchase common shares	11,238,965	10,084,986				
Share options to purchase ordinary shares			11,780,526	8,204,258	11,780,526	8,219,041
Unvested RSUs	2,261,258	1,656,077	2,328,169	255,769	2,328,169	690,695
Unvested PSUs			28,824	—	28,824	—
Total anti-dilutive shares	13,500,223	11,741,063	14,137,519	8,460,027	14,137,519	8,909,736

12. Income Taxes

As a company incorporated in Bermuda, Prior to the Redomiciliation, the Company is was incorporated and principally subject to taxation in Bermuda. Following the Redomiciliation, the Company is incorporated and principally subject to taxation in the United Kingdom. Under the current laws of Bermuda, tax on a company's income is assessed at a zero percent tax rate. As a result, the Company has not recorded any income tax benefits from its losses incurred in Bermuda during each the reporting period, periods in which it was incorporated there, and no net operating loss carryforwards will be available to the Company for those losses. Following the Redomiciliation, the Company's income is subject to the enacted United Kingdom statutory corporate tax rate and net operating losses incurred have an indefinite carryforward. 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 Bermuda remains subject to taxation, if any, in Bermuda, though it is treated as a pass-through entity for income tax purposes. The Company's wholly owned subsidiary Kiniksa UK, and its Kiniksa UK's 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.

Although Bermuda has no corporate income tax, the Company's income tax rate for the three and six months ended March 31, 2024 June 30, 2024 was due to Kiniksa UK's, Kiniksa UK's Swiss branch office's and Kiniksa US's income subject to taxation in each of their respective countries. Income tax provision for the three and six months ended March 31, 2024 June 30, 2024 was $3,428. $6,212 and $9,640, respectively. The provision for income taxes is primarily driven by income earned in the UK, United Kingdom, Switzerland and U.S. offset in part by tax benefits from Foreign Derived Intangible Income ("FDII") deduction and U.S. federal and state research and development credits.

Income tax benefit for the three and six months ended June 30, 2023 was $16,211 and $13,305, respectively. The benefit for income taxes is primarily driven by the release of the valuation allowance on the Company's U.S. deferred tax assets. This is partially offset by provision for income taxes driven by income earned in the UK and U.S. reduced by tax benefits from FDII deduction and U.S. federal and state research and development credits.

Management regularly assesses the need for a valuation allowance on the Company's deferred income tax assets. Valuation allowances require an assessment of both positive and negative evidence when determining whether it is more likely than not that the Company will be able to recover its deferred tax assets. Such assessment is required on a

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jurisdiction-by-jurisdiction basis. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible.

Since 2021, the Company has engaged in a series of intra-entity asset transfers and allocations to contribute assets to its wholly owned Switzerland subsidiary, UK subsidiary and its UK Swiss branch office.

In January 2021, in connection with its launch readiness activities, Kiniksa Bermuda contributed all of its rights, title and interest in, among other things, certain contracts (including the Regeneron Agreement), intellectual property rights, product filings and approvals and other information, plans and materials owned or controlled by Kiniksa Bermuda insofar as they related exclusively or primarily to ARCALYST to Kiniksa UK.

In February 2022, Kiniksa Bermuda contributed its exclusive rights to develop and commercialize mavrilimumab in the Huadong Territory to Kiniksa UK.

In July 2022, Kiniksa Bermuda contributed all of its rights, title and interest in, among other things, certain contracts (including the Biogen Agreement), intellectual property rights, product filings and approvals and other information, plans and materials owned or controlled by Kiniksa Bermuda insofar as they related exclusively or primarily to vixarelimab to Kiniksa UK.

The consolidated Company did not incur tax liabilities on any of these intra-entity transfers since the transferor, Kiniksa Bermuda, is exempt from income tax in Bermuda, its jurisdiction of incorporation. Kiniksa UK accounted for the 2021 and 2022 intra-entity transfers as transfers of assets between related parties and received stepped up tax bases in the contributed intellectual property assets, equal to the fair value of the assets at the time of transfer. The Company recorded UK deferred tax assets as a result of these contributions, which represent the difference between the stepped-up tax bases and the book bases for financial statement purposes. At the time of the 2021 and 2022 transfers of the relevant assets, the Company recorded a valuation allowance on the full amount of the recognized deferred tax assets.

The fair value of the January 2021 transfer of ARCALYST intellectual property assets was determined utilizing forecasted cash flows attributable to commercial operations and estimated probabilities of success of such cash flows, discounted to present value utilizing the discounted cash flow method. The fair values of the transferred mavrilimumab and vixarelimab intellectual property assets were determined utilizing future cash flows related to agreements with third parties for the use of the applicable intellectual property and estimated probabilities of success of such cash flows, discounted to present value utilizing the discounted cash flow method.

In December 2023, Kiniksa UK allocated all of its rights, title and interest in, among other things, certain contracts (including the Regeneron Agreement), intellectual property rights, product filings and approvals and other information, plans and inventory owned or controlled by the Company insofar as they related exclusively or primarily to ARCALYST to Kiniksa UK's Swiss branch office.

The December 2023 allocation of the assets to the Swiss branch did not result in a taxable disposal for Kiniksa UK as the allocation was to a branch within the entity. The future results of Kiniksa UK's Swiss branch office are subject to income taxes in Switzerland and the Company expects it will not be subject to tax in the UK. United Kingdom. Kiniksa UK's Swiss branch office received a step up in basis resulting in a Swiss deferred tax asset. The fair value of the allocated ARCALYST intellectual property assets was determined utilizing forecasted cash flows attributable to commercial operations and estimated probabilities of success of such cash flows, discounted to present value utilizing the discounted cash flow method. The fair value of the ARCALYST inventory was determined utilizing the average net selling price less estimated costs to sell.

In January 2024, Kiniksa Bermuda transferred to Kiniksa Switzerland all rights, title and interest in, among other things, certain contracts, intellectual property rights, product filings and approvals and other information, plans and materials owned insofar as they related exclusively or primarily to abiprubart, mavrilimumab and other preclinical assets, excluding certain rights necessary for the completion of Cohort 4 of the Company's ongoing Phase 2 clinical trial of abiprubart in rheumatoid arthritis. In June 2024, Kiniksa UK terminated its exclusive rights to develop and commercialize mavrilimumab in the Huadong Territory, with such rights reverting to Kiniksa Switzerland. Thereafter Kiniksa Switzerland held worldwide rights to develop and commercialize mavrilimumab.

The consolidated Company did not incur tax liabilities on any of the January 2024 intra-entity transfers since the transferor, Kiniksa Bermuda, is exempt from income tax in Bermuda, its jurisdiction of incorporation. Kiniksa

Switzerland accounted for the intra-entity transfers as transfers of assets between related parties and received stepped up tax bases in the contributed intellectual property assets, equal to the fair value of the assets at the time of transfer. The fair values of the transferred assets were determined utilizing future cash flows of projected operations and estimated

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probabilities of success of such cash flows, discounted to present value utilizing the discounted cash flow method. The Company recorded deferred tax assets as a result of these contributions, which represent the difference between the stepped-up tax bases and the book bases for financial statement purposes. At the time of the transfers of the relevant assets, the Company recorded a valuation allowance on the full amount of the Switzerland deferred tax assets. There are no material deferred tax assets in the jurisdictions outside the United States, UK and Switzerland.

13. 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 10).

Manufacturing Commitments

The Company has a supply agreement with Regeneron pursuant to which the Company may order both clinical and commercial product (see Note 10). In May 2023, June 2024, the Company signed entered into a letter Master Services Agreement and a Product Specific Agreement with Samsung as part of intent with a contract development and manufacturing organization (a "CDMO") related to its technology transfer of the manufacturing process for ARCALYST drug substance. The Company has additionally entered into agreements with several CDMOs contract development and manufacturing organizations to provide the Company with preclinical and clinical trial materials for its non-ARCALYST assets. As of March 31, 2024 June 30, 2024, the Company had committed to minimum payments under all of these agreements totaling $148,039, $180,741, of which $56,140 $43,322 is due within one year.

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, 2024 June 30, 2024 or December 31, 2023.

Legal Proceedings

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

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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, and our audited consolidated financial statements and related notes for the year ended December 31, 2023 included in our Annual Report on Form 10-K (our "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. 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 (the "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 commercial-stage 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 immune-modulating assets, ARCALYST, abiprubart and mavrilimumab, is based on strong biologic rationale or validated mechanisms, targets a spectrum of underserved cardiovascular and autoimmune conditions, and offers the potential for differentiation.

ARCALYST is an interleukin-1α and interleukin-1β cytokine trap. In 2017, we licensed ARCALYST from Regeneron, which 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 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 United States prevalent population of approximately 40,000 patients seeking and receiving medical treatment. ARCALYST is commercially available across the United States through a select network of distributors. specialty pharmacies. ARCALYST is also approved in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes ("CAPS"), including Familial Cold Autoinflammatory Syndrome ("FCAS") and Muckle-Wells Syndrome in adults and children 12 years and older, and the maintenance of remission in Deficiency of Interleukin-1 Receptor Antagonist ("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, as well as third party proceeds, with Regeneron.

Abiprubart is an investigational monoclonal antibody inhibitor of CD40-CD154 costimulatory interaction. In 2019, we acquired all of the outstanding securities of Primatope Therapeutics, Inc. ("Primatope"), the company that owned or controlled the intellectual property related to abiprubart. In connection with our acquisition of Primatope, we acquired an exclusive world-wide license to abiprubart from Beth Israel Deaconess Medical Center, Inc. ("BIDMC"). 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 costimulatory interaction is an attractive approach to address multiple autoimmune disease pathologies. In December 2021, we initiated a Phase 2 clinical trial of abiprubart in rheumatoid arthritis ("RA"), which is designed to evaluate pharmacokinetics, safety and efficacy with subcutaneous administration. In January 2024, we announced topline clinical data from Cohorts 1, 2 and 3 of the trial and that the trial met its primary efficacy endpoint in Cohort 3 at the weekly dose level. In April 2024, we announced (a) topline clinical data from Cohort 4 of the RA trial and (b) our plan to initiate a Phase 2b clinical trial of abiprubart in Sjögren's Disease in the second half of 2024. In July 2024, we announced that we had commenced enrollment in such trial.

Mavrilimumab is an investigational monoclonal antibody inhibitor targeting granulocyte-macrophage colony stimulating factor receptor alpha ("GM-CSFRα"). In 2017, we licensed exclusive worldwide rights in all indications to mavrilimumab from MedImmune, Limited ("MedImmune"). We are currently evaluating potential partnership opportunities to advance mavrilimumab's development. We previously evaluated mavrilimumab in giant cell arteritis ("GCA"), a chronic inflammatory disease of the medium-to-large arteries, and COVID-19-related acute respiratory distress syndrome ("ARDS").

In March 2024, 30

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On June 27, 2024, we announced our plans for the Redomiciliation, which, if carried out, would result in completion of the change of place of incorporation of our principal holding company from Bermuda to the UK. The Redomiciliation

Table United Kingdom (the “Redomiciliation”), pursuant to a scheme of Contents

remains subject to approval arrangement approved by our shareholders and both the Bermuda Supreme Court of Bermuda. If carried out, and our shareholders. As used herein, and unless the issued context otherwise requires, references to “we”, “us”, “our” and outstanding shares of our current principal holding company, similar words or phrases prior to the Redomiciliation shall refer to Kiniksa Pharmaceuticals, Ltd. (“Kiniksa Bermuda”) will be canceled, and our shareholders will receive new shares of from and after the Redomiciliation, to Kiniksa Pharmaceuticals International, plc, a UK-domiciled company (“New Kiniksa”) on a one-for-one basis. See *“Risk Factors –Risks Related to Our Redomiciliation from Bermuda to the United Kingdom*” for more information. plc.

Our ability to generate product revenue sufficient to sustain our organization will depend heavily on a number of factors, including the continued commercialization of ARCALYST, the development and eventual commercialization of one or more of our current or future product candidates, if approved, and the management of our costs consistent with our current operating plan. For the three and six months ended March 31, 2024 June 30, 2024, our net loss was $17.7 million. $3.9 million and $21.6 million, respectively. As of March 31, 2024 June 30, 2024, we had an accumulated deficit of $495.7 $499.6 million.

As of March 31, 2024 June 30, 2024, we had cash, cash equivalents and short-term investments of $213.6 million $218.8 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

We have been generating product revenue from sales of ARCALYST since April 2021. ARCALYST is sold through a third party logistics provider that distributes primarily through a select network of specialty pharmacies (collectively, “customers”), which deliver the medication to patients by mail.

Net revenue from product sales is recognized at the transaction price when the customer obtains 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.

License and collaboration revenue

License and collaboration revenue includes amounts recognized related to upfront payments, royalty revenue, milestone payments and products sold under collaboration agreements.

In February 2022, we entered into two collaboration and license agreements (the “Huadong Collaboration Agreements”), with Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. (“Huadong”), pursuant to which we granted Huadong exclusive rights to develop and commercialize rilonacept and mavrilimumab (the “Huadong Licensed Products”), in the Asia Pacific region excluding Japan (the “Huadong Territory”). We otherwise retained our current rights to the Licensed Products outside the Territory.

Under the Huadong Collaboration Agreements, we received a total upfront cash payment of $22.0 million, which included $12.0 million for the Huadong Territory license of rilonacept and $10.0 million for the Huadong 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

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on a Huadong Licensed Product-by-Huadong Licensed Product basis ranging from the low-teens to low-twenties on annual net sales of each Huadong Licensed Product in the Huadong 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 Huadong Licensed Product-by-Huadong 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 Huadong Licensed Product in such country or region in the Huadong 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 Huadong Licensed Product in such country or region in the Huadong Territory, and (iii) the expiration of the last regulatory exclusivity for the applicable Huadong Licensed Product in such country or region in the Huadong Territory. We recognized the $10.0 million related to the mavrilimumab license during the year ended December 31, 2022. We have recognized $0.2 million of revenue of the $12.0 million transaction price under the rilonacept license agreement as of March 31, 2024 June 30, 2024, and will recognize the remaining revenue as materials are shipped.

We are party to a license agreement (the “Genentech License Agreement”) with Genentech, effective September 2022, pursuant to which we granted Genentech exclusive worldwide rights to develop and commercialize vixarelimab and related antibodies (each, a “Genentech Licensed Product”).

Under the Genentech License Agreement, we received an upfront payment of $80.0 million for the license. Additionally, in 2023, we received a total of $35.0 million in additional payments from Genentech related to delivery of certain drug material to Genentech and Genentech’s achievement of a development milestone. In the fourth quarter of 2023, following the achievement of a development milestone related to a second indication under the Genentech License Agreement, Genentech became obligated to make an additional cash payment of $10.0 million, which was received in the first quarter of 2024. In the second quarter of 2024, we received $5.0 million following the achievement of a development milestone related to a third indication under the Genentech License Agreement. We will be eligible to receive up to a total of approximately $600.0 million in contingent payments, including specified development, regulatory and sales-based milestones, of which approximately $575.0 million $570.0 million remains as of March 31, 2024 June 30, 2024. We will also be eligible to receive tiered percentage royalties on a Genentech Licensed Product-by-Genentech Licensed Product basis ranging from low-double digits to mid-teens on annual net sales of each Genentech Licensed Product, subject to certain customary reductions, with an aggregate minimum floor, before fulfilling our upstream financial obligations. Royalties will be payable on a Genentech Licensed Product-by-Genentech Licensed Product and country-by-country basis until the latest to occur of the expiration of certain patents that cover a Genentech Licensed Product, the expiration of regulatory exclusivity for such Genentech Licensed Product, or the tenth anniversary of first commercial sale of such Genentech Licensed Product in such country. We As of June 30, 2024, we have recognized $124.8 million of revenue of the $125.0 million transaction price $130.0 million received from Genentech under the Genentech License Agreement and will recognize the remaining revenue over the remaining duration of the in-progress Phase 2b clinical trial of vixarelimab in prurigo nodularis. as revenue.

Operating Expenses

Cost of Goods Sold

Cost of goods sold includes production and distribution costs of ARCALYST, 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 labor and overhead costs associated with the production of ARCALYST associated with supply chain, quality and regulatory activities, and the technology transfer of the manufacturing process for the ARCALYST drug substance.

Collaboration expenses

Collaboration expenses consist of Regeneron's share of the profit related to ARCALYST sales under the Regeneron Agreement and the cost of products sold under collaboration agreements. 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. With respect to the technology

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transfer of ARCALYST drug substance manufacturing initiated by from Regeneron in March 2023, to Samsung, to the extent permitted by the Regeneron Agreement, the fully-burdened costs of each of us and Regeneron incurred in performing 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 CROs that are primarily engaged in the oversight and conduct of our clinical trials and CDMOs 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, CDMOs 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.

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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.

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 revenue from the sale of our current or future product candidates. 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, including 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 external commercialization, marketing, and professional fees for legal, patent, and accounting services.

We have been commercializing ARCALYST since April 2021 and expect that our selling, general and administrative expenses will continue to increase in the future.

Other Income

Other income consists of interest income recognized from investments in money market funds, United States Treasury notes and other miscellaneous income offset by expenses related to investments.

Income Taxes

Kiniksa Bermuda is an exempted Prior to the Redomiciliation, our principal holding company was incorporated under the laws of Bermuda, we are and principally subject to taxation in Bermuda. Following the Redomiciliation, our principal holding company is incorporated and principally subject to taxation in the United Kingdom. Under the current laws of Bermuda, there is no corporate income tax levied on an exempted company’s income, resulting in an effective 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. In December 2023, Bermuda passed legislation enacting a corporate income tax effective in 2025 on companies that meet certain requirements. If we meet those requirements, we could become subject to taxation in Bermuda in the future. Our wholly owned United States subsidiaries, Kiniksa US, and Primatope are subject to federal and state income taxes in the United States. Our wholly owned subsidiary Kiniksa UK, its Swiss branch office, and Kiniksa UK’s wholly owned subsidiaries, Kiniksa Pharmaceuticals (Germany) GmbH, Kiniksa Pharmaceuticals (France) SARL, and Kiniksa Pharmaceuticals, GmbH (“Kiniksa Switzerland”) are subject to taxation in their respective countries.

In the first quarter of 2024, Kiniksa Bermuda transferred to Kiniksa Switzerland all rights, title and interest in, among other things, certain contracts, intellectual property rights, product filings and approvals and other information, plans and materials owned insofar as they related exclusively or primarily to abiprubart, mavrilimumab and other preclinical assets, with such exceptions as necessary to allow the completion of Cohort 4 of the Company’s ongoing Phase 2 clinical trial of abiprubart in rheumatoid arthritis. In connection with the foregoing transfer, we recognized a step-up in basis and did not incur any material tax liabilities.

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Results of Operations

Comparison of the Three Months Ended March 31, 2024 June 30, 2024 and 2023

The following table summarizes our results of operations for the three months ended March 31, 2024 June 30, 2024 and 2023:

	Three Months Ended March 31,			Three Months Ended June 30,		
	2024	2023	Change	2024	2023	Change
	(in thousands)			(in thousands)		
Revenue:						
Product revenue, net	$ 78,885	$ 42,659	$ 36,226	$103,394	$54,495	$ 48,899
License and collaboration revenue	973	5,686	(4,713)	5,237	16,978	(11,741)
Total revenue	79,858	48,345	31,513	108,631	71,473	37,158
Costs and Operating expenses:						
Cost of goods sold	10,583	7,036	3,547	12,322	7,699	4,623
Collaboration expenses	20,801	8,288	12,513	30,014	13,986	16,028
Research and development	26,334	15,172	11,162	24,017	23,767	250
Selling, general and administrative	38,682	29,045	9,637	42,395	29,175	13,220
Total operating expenses	96,400	59,541	36,859	108,748	74,627	34,121
Loss from operations	(16,542)	(11,196)	(5,346)	(117)	(3,154)	3,037
Other income	2,266	1,832	434	2,421	1,915	506
Loss before provision for income taxes	(14,276)	(9,364)	(4,912)			
Provision for income taxes	(3,428)	(2,906)	(522)			
Net loss	$ (17,704)	$ (12,270)	$ (5,434)			
Income (loss) before benefit (provision) for income taxes				2,304	(1,239)	3,543
Benefit (provision) for income taxes				(6,212)	16,211	(22,423)
Net Income (loss)				$ (3,908)	$14,972	$(18,880)

Product Revenue, Net

We recognized net revenue from the sale of ARCALYST of $78.9 million $103.4 million for the three months ended March 31, 2024 June 30, 2024, compared to $42.7 million $54.5 million for the three months ended March 31, 2023 June 30, 2023, an increase of $36.2 million $48.9 million. The increase in product revenue was primarily driven by an increase in patients.

License and Collaboration Revenue

We reported $1.0 million $5.2 million of license and collaboration revenue for the three months ended March 31, 2024 June 30, 2024, related primarily to $0.7 million driven by the achievement of products sold under the Rilonacept Huadong Collaboration Agreements, $0.2 million of deferred revenue recognized a $5.0 million development milestone related to the delivery of such materials and $0.1 of deferred

revenue a third indication under the Genentech License Agreement. In We reported $17.0 million of license and collaboration revenue for the prior year period, we reported $5.7 million of revenue primarily three months ended June 30, 2023, related to the delivery Genentech License Agreement, primarily driven by the achievement of certain materials a $15.0 million development milestone related to a new indication under the Genentech License Agreement.

Cost of Goods Sold

We recognized cost of goods sold of $10.6 million $12.3 million for the three months ended March 31, 2024 June 30, 2024, compared to $7.0 million $7.7 million for the three months ended March 31, 2023 June 30, 2023, an increase of $3.5 million $4.6 million. The increase in cost of goods sold relates primarily to the increase in sales of ARCALYST and $2.1 million $2.8 million related to the technology transfer of the manufacturing process, offset by a decrease in average cost per unit resulting from favorable production variances.

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Collaboration Expenses

Collaboration expenses were $20.8 million $30.0 million for the three months ended March 31, 2024 June 30, 2024, compared to $8.3 million $14.0 million for the three months ended March 31, 2023 June 30, 2023, an increase of $12.5 million $16.0 million. Collaboration expenses increased due to increased revenue from sales of ARCALYST and improved profitability under the Regeneron Agreement.

Research and Development Expenses

	Three Months Ended March 31,			Three Months Ended June 30,		
	2024	2023	Change	2024	2023	Change
	(in thousands)			(in thousands)		
Rilonacept (ARCALYST)	$ 113	$ 558	$ (445)	$ 597	$ 450	$ 147
Abiprubart	15,089	3,446	11,643	12,368	11,649	719
Mavrilimumab	223	(272)	495	155	308	(153)
Vixarelimab	754	2,047	(1,293)	279	2,278	(1,999)
Unallocated research and development expenses:						
Personnel related (including share-based compensation)	6,138	6,413	(275)	5,853	5,393	460
Other	4,017	2,980	1,037	4,765	3,689	1,076
Total research and development expenses	$ 26,334	$ 15,172	$ 11,162	$24,017	$23,767	$ 250

Research and development expenses were $26.3 million $24.0 million for the three months ended March 31, 2024 June 30, 2024, compared to $15.2 million $23.8 million for the three months ended March 31, 2023 June 30, 2023, an increase of $11.2 million $0.3 million.

The direct costs for our abiprubart program were $15.1 million $12.4 million during the three months ended March 31, 2024 June 30, 2024, compared to $3.4 million $11.6 million during the three months ended March 31, 2023 June 30, 2023, an increase of $11.6 million $0.7 million. The increase in expenses incurred primarily related to the manufacturing of clinical material, continuation of cohort four of our Phase 2 trial in RA and start-up costs of our Phase 2b clinical trial in Sjögren's Disease during the three months ended March 31, 2024 June 30, 2024, as compared to the manufacturing of clinical material, initiation cost of cohort three and continuation of the first two cohorts of our Phase 2 trial in RA incurred during the three months ended March 31, 2023 June 30, 2023.

The direct costs for our vixarelimab program were $0.8 million $0.3 million during the three months ended March 31, 2024 June 30, 2024, compared to $2.0 million $2.3 million during the three months ended March 31, 2023 June 30, 2023, a decrease of $1.3 million $2.0 million. The decrease in expenses was primarily related to the wind-down activities of our Phase 2b clinical trial in prurigo nodularis.

Unallocated research and development expenses were $10.2 million $10.6 million for the three months ended March 31, 2024 June 30, 2024, compared to $9.4 million $9.1 million for the three months ended March 31, 2023 June 30, 2023, an increase of $0.8 million $1.5 million. The increase of $0.8 million $1.5 million in unallocated research and development expenses was primarily due to an increase in preclinical early development activities. Personnel-related costs for the three months ended March 31, 2024 June 30, 2024 and 2023 included share-based compensation of $1.5 million and $1.4 million, respectively.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $38.7 million $42.4 million for the three months ended March 31, 2024 June 30, 2024, compared to $29.0 million $29.2 million for the three months ended March 31, 2023 June 30, 2023. In the second half of 2023, we expanded our ARCALYST salesforce to help drive further prescriber adoption and patient enrollments. The increase of $9.6 million $13.2 million was primarily due to an increase of $6.0 million $5.6 million in personnel-related costs, and an increase in sales and marketing of $1.5 million $4.4 million largely attributable to the expansion of our salesforce. salesforce and an increase in professional fees of $1.5 million largely attributable to the Redomiciliation. Personnel-related costs for the three months ended March 31, 2024 June 30, 2024 and 2023 included share-based compensation of $5.4 million $5.5 million and $4.4 million $4.8 million, respectively.

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Other Income

Other income was $2.3 million $2.4 million for the three months ended March 31, 2024 June 30, 2024 compared to $1.8 million $1.9 million for the three months ended March 31, 2023 June 30, 2023. The increase of $0.4 million $0.5 million was primarily due to higher interest rates on U.S. Treasury notes.

Benefit (provision) for Income Taxes

For the three months ended March 31, 2024 June 30, 2024, we recorded an income tax provision of $3.4 million $6.2 million relating primarily to income earned in the UK, United Kingdom, Switzerland and the U.S., net of the Foreign Derived Intangible Income ("FDII") deduction and U.S. federal and state research and development credits ("R&D Credits") utilized. For the three months ended March 31, 2023 June 30, 2023, we recorded an income tax provision benefit of $2.9 million $16.2 million relating primarily to the release of the valuation allowance on our U.S. deferred tax assets offset by income earned in the UK United Kingdom and the U.S., net of the FDII Foreign Derived Intangible Income ("FDII") deduction and U.S. federal and state research and development credits ("R&D Credits Credits") utilized. We expect that our reported income tax expense for future periods will be higher due to the utilization of our deferred tax assets.

Comparison of the Six Months Ended June 30, 2024 and 2023

The following table summarizes our results of operations for the six months ended June 30, 2024 and 2023:

	Six Months Ended June 30,

	2024	2023	Change
		(in thousands)	
Revenue:			
Product revenue, net	$182,279	$ 97,154	$ 85,125
License and collaboration revenue	6,210	22,664	(16,454)
Total revenue	188,489	119,818	68,671
Operating expenses:			
Cost of goods sold	22,905	14,735	8,170
Collaboration expenses	50,815	22,274	28,541
Research and development	50,351	38,939	11,412
Selling, general and administrative	81,077	58,220	22,857
Total operating expenses	205,148	134,168	70,980
Loss from operations	(16,659)	(14,350)	(2,309)
Other income	4,687	3,747	940
Loss before benefit (provision) for income taxes	(11,972)	(10,603)	(1,369)
Benefit (provision) for income taxes	(9,640)	13,305	(22,945)
Net Income (loss)	$ (21,612)	$ 2,702	$ (24,314)

Product Revenue, Net

We recognized net revenue from the sale of ARCALYST of $182.3 million for the six months ended June 30, 2024, compared to $97.2 million for the six months ended June 30, 2023, an increase of $85.1 million. The increase in product revenue was primarily driven by an increase in patients.

License and Collaboration Revenue

We reported $6.2 million of license and collaboration revenue for the six months ended June 30, 2024, primarily driven by the achievement of a $5.0 million development milestone related to a third indication under the Genentech License Agreement, $0.7 million of products sold under the Rilonacept Huadong Collaboration Agreements, and $0.2 million of deferred revenue recognized related to the delivery of such materials. We reported $22.7 million of

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license and collaboration revenue for the three months ended June 30, 2023, primarily driven by the achievement of a $15.0 million development milestone related to a new indication under the Genentech License Agreement.

Cost of Goods Sold

We recognized cost of goods sold of $22.9 million for the six months ended June 30, 2024, compared to $14.7 million for the six months ended June 30, 2023, an increase of $8.2 million. The increase in cost of goods sold relates primarily to the increase in sales of ARCALYST and $4.9 million related to the technology transfer of the manufacturing process, offset by a decrease in average cost per unit resulting from favorable production variances.

Collaboration Expenses

Collaboration expenses were $50.8 million for the six months ended June 30, 2024, compared to $22.3 million for the six months ended June 30, 2023, an increase of $28.5 million. Collaboration expenses increased due to increased revenue from sales of ARCALYST and improved profitability under the Regeneron Agreement.

Research and Development Expenses

	Six Months Ended June 30,		
	2024	2023	Change
	(in thousands)		
Rilonacept (ARCALYST)	$ 710	$ 1,008	$ (298)
Abiprubart	27,457	15,095	12,362
Mavrilimumab	378	36	342
Vixarelimab	1,033	4,325	(3,292)
Unallocated research and development expenses:			
Personnel related (including share-based compensation)	11,991	11,806	185
Other	8,782	6,669	2,113
Total research and development expenses	$50,351	$38,939	$11,412

Research and development expenses were $50.4 million for the six months ended June 30, 2024, compared to $38.9 million for the six months ended June 30, 2023, an increase of $11.4 million.

The direct costs for our abiprubart program were $27.5 million during the six months ended June 30, 2024, compared to $15.1 million during the six months ended June 30, 2023, an increase of $12.4 million. The increase in expenses incurred primarily related to the manufacturing of clinical material, continuation of cohort four of our Phase 2 trial in RA and start-up costs of our Phase 2b clinical trial in Sjögren's Disease during the six months ended June 30, 2024, as compared to the manufacturing of clinical material, initiation cost of cohort three and continuation of the first two cohorts of our Phase 2 trial in RA incurred during the six months ended June 30, 2023.

The direct costs for our vixarelimab program were $1.0 million during the six months ended June 30, 2024, compared to $4.3 million during the six months ended June 30, 2023, a decrease of $3.3 million. The decrease in expenses was primarily related to the wind-down activities of our Phase 2b clinical trial in prurigo nodularis.

Unallocated research and development expenses were $20.8 million for the six months ended June 30, 2024, compared to $18.5 million for the six months ended June 30, 2023, an increase of $2.3 million. The increase of $2.3 million in unallocated research and development expenses was primarily due to an increase in early development activities.Personnel-related costs for the six months ended June 30, 2024 and 2023 included share-based compensation of $3.0 million and $2.8 million, respectively.

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Selling, General and Administrative Expenses

Selling, general and administrative expenses were $81.1 million for the six months ended June 30, 2024, compared to $58.2 million for the six months ended June 30, 2023. In the second half of 2023, we expanded our ARCALYST salesforce to help drive further prescriber adoption and patient enrollments. The increase of $22.9 million was primarily due to an increase of $11.6 million in personnel-related costs, an increase in sales and marketing of $5.9 million largely attributable to the expansion of our salesforce and an increase in professional fees of $2.6 million largely attributable to the Redomiciliation. Personnel-related costs for the three months ended June 30, 2024 and 2023 included share-based compensation of $10.9 million and $9.2 million, respectively.

Other Income

Other income was $4.7 million for the six months ended June 30, 2024,compared to $3.7 million for the six months ended June 30, 2023. The increase of $0.9 million was primarily due to higher interest rates on U.S. Treasury notes.

Benefit (provision) for Income Taxes

For the six months ended June 30, 2024, we recorded an income tax provision of $9.6 million relating primarily to income earned in the United Kingdom, Switzerland and the U.S., net of the Foreign Derived Intangible Income ("FDII") deduction and U.S. federal and state research and development credits ("R&D Credits") utilized. For the six months ended June 30, 2023, we recorded an income tax benefit of $13.3 million relating primarily to the release of the valuation allowance on our U.S. deferred tax assets offset by income earned in the United Kingdom and the U.S., net of the FDII deduction and R&D Credits utilized.

Liquidity and Capital Resources

As of March 31, 2024 June 30, 2024, our principal source of liquidity was cash, cash equivalents and short-term investments, which totaled $213.6 million $218.8 million. Net loss income (loss) was $17.7 million ($3.9) million and $12.3 million $2.7 million for the three six months ended March 31, 2024 June 30, 2024 and 2023, 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, pay annual maintenance fees and to meet due diligence requirements, each based upon specified events. Pursuant to the Regeneron Agreement, we have entered into a supply agreement with Regeneron to purchase both clinical and commercial product. We have committed to minimum payments to Regeneron of $27.1 million $20.3 million, all of which are due within one year. We have entered into lease agreements for office and laboratory space, and vehicles, with total future lease payments of $14.0 million $14.1 million, of which $3.0 million $3.8 million are due within one year. In connection with our ongoing technology transfer of ARCALYST drug substance manufacturing, we have entered into a manufacturing commitment Master Services Agreement and a Product Specific Agreement with a CDMO to establish a new manufacturing site for ARCALYST drug substance. Such commitment, Samsung. Our commitments under such agreements, which includes include the purchase of raw materials and related service fees, will obligate us to minimum payments of $94.2 million $144.7 million, $17.3 million $15.8 million of which are due within one year. We have additionally entered into agreements with several CDMOs to provide the Company with preclinical and clinical trial materials for our non-ARCALYST assets, which obligate us to minimum payments of $26.7 million $15.7 million, $11.7 million $7.2 million of which are due within one year.

Under various agreements with third parties, we are entitled to receive upfront payments, milestone payments, and royalties, each based upon specified milestones. In the first quarter of 2024, following Genentech's achievement of a development milestone in the fourth quarter of 2023 related to a second indication under the Genentech License Agreement, we received $10.0 million. In the second quarter of 2024, following Genentech's achievement of a development milestone related to a third indication under the Genentech License Agreement, we received $5.0 million.

These agreements impact our short-term and long-term liquidity and capital needs.

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Cash Flows

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

	Three Months Ended March 31,		Six Months Ended June 30,	
	2024	2023	2024	2023

	(in thousands)		(in thousands)	
Net cash provided by (used in) operating activities	$ 3,987	$ (4,267)	$ 9,155	$ (8,010)
Net cash provided by (used in) investing activities	25,524	(37,920)		
Net cash used in investing activities			(21,273)	(2,386)
Net cash provided by financing activities	3,613	90	3,435	248
Net increase (decrease) in cash and cash equivalents	$ 33,124	$ (42,097)	$ (8,683)	$(10,148)

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Operating Activities

Net cash provided by operations was $4.0 million $9.2 million for the three six months ended March 31, 2024 June 30, 2024, compared to net cash used in operating activities of $4.3 million $8.0 million for the three six months ended March 31, 2023 June 30, 2023. The increase in cash provided by operating activities is primarily due to an increase in net contribution from higher ARCALYST sales, offset by a decrease in cash received from licensing agreements of $10.0 million $5.0 million.

Investing Activities

Net cash provided by used in investing activities was $25.5 million $21.3 million for the three six months ended March 31, 2024 June 30, 2024, compared to net cash used in investing activities of $37.9 million $2.4 million for the three six months ended March 31, 2023 June 30, 2023. The increase in net cash provided by used in investing activities was driven by managing our cash and short-term investments portfolio mix.

Financing Activities

During the three six months ended March 31, 2024 June 30, 2024 and 2023, net cash provided by financing activities was $3.6 million $3.4 million and $0.1 million $0.2 million, respectively, consisting of proceeds from the exercise of share options offset by payments in connection with Common Stock tendered for employee tax obligations.

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. We may also incur expenses in connection with the in-licensing collaboration, licensing or acquisition of additional product candidates. As a result, other strategic transactions. Further, we expect to may 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 the Redomiciliation;
- support our sales, marketing and distribution capabilities, infrastructure and organization to commercialize ARCALYST and any product candidates for which we may obtain marketing approval;
- conduct new and ongoing research and pre-clinical and clinical development of our product candidates, including our Phase 2 clinical trial of abiprubart in RA and our planned Phase 2b clinical trial of abiprubart in Sjögren's Disease;
- manufacture our products and product candidates for clinical or commercial use, increase our manufacturing capabilities, add additional manufacturers or suppliers and perform activities related to our technology transfer of the process for manufacturing ARCALYST drug substance;

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- seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials, if any;
- make milestone or other payments under any current or future license, acquisition, collaboration or other strategic transaction agreement;

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- seek 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;
- seek to identify, assess, acquire or develop additional product candidates;
- enter into licensing, acquisition, collaboration or other strategic transaction agreements;
- seek to maintain, protect and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our product development and commercialization efforts; and
- experience delays or encounter issues with any of the above, including but not limited to failed trials, complex results, safety issues, regulatory challenges that require longer follow-up of existing trials, additional major trials, additional supportive trials in order to pursue marketing approval, a pandemic or other outbreak of disease or disruptions to the national or global economy.

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 collaboration, licensing or acquisitions of other product candidates and technologies or their related businesses. strategic transactions. We expect to continue to incur significant expenses related to product manufacturing, including technology transfer costs, 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 or additional territories 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 In addition to product revenue, we expect to may also 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 ordinary 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,

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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.

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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.

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, “Financial Statements (Unaudited)” 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;
- revenue recognition; and
- realizability of deferred tax assets.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities related to our short-term investments. There were no material changes to our quantitative and qualitative disclosures about market risk related to our investment activities during the three months ended March 31, 2024 June 30, 2024 as disclosed in “Item 7A. Quantitative and Qualitative Disclosures About Market Risks” of the Annual Report.

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 (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, 2024 June 30, 2024. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2024 June 30, 2024.

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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, 2024 June 30, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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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 ordinary 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 Redomiciliation from Bermuda to the United Kingdom

We may not realize the anticipated benefits of the Redomiciliation.

In March 2024, we announced our intention to change the place of incorporation of our principal holding company from Bermuda to the United Kingdom via the Redomiciliation. The Supreme Court of Bermuda has ordered us to convene the Court-Ordered Special Meeting of Shareholders to approve the Redomiciliation, which is scheduled for June 5, 2024. If approved, the Company expects to complete the Redomiciliation at the end of June 2024.

Subject to the approval of a scheme of arrangement (the "Scheme") by our shareholders and the Supreme Court of Bermuda, the Redomiciliation will result in New Kiniksa becoming our principal holding company. Pursuant to the Scheme, Kiniksa Bermuda's issued and outstanding common shares will be cancelled and our shareholders will receive ordinary shares of New Kiniksa on a one-for-one basis.

We determined that Bermuda was no longer the most desirable jurisdiction for us and believe that redomiciling our principal holding company from Bermuda to a country with a more expansive tax treaty with the United States would be in the best interests of our shareholders, employees and other stakeholders. We believe that the United Kingdom is the best available option for a number of reasons, including:

- Effectively changing the place of incorporation (and tax residence, by extension) of our principal holding company to the UK will improve our position with respect to various Organization for Economic Co-operation and Development ("OECD") withholding and other tax proposals that could adversely affect companies incorporated in jurisdictions like Bermuda;
- The UK possesses robust legal, accounting and financial industries;
- The UK, like Bermuda, is a common law jurisdiction, which we consider to be less prescriptive than many civil law jurisdictions, meaning that we believe the UK's legal system to be more flexible, predictable, familiar and similar to Bermuda than a civil law system; and
- Changing the place of incorporation of our principal holding company to the UK will provide a continuity of legal rights for our shareholders on substantially the same grounds as they enjoy in Bermuda.

These determinations are based on a number of key assumptions and we may not realize the benefits we hope to achieve. For example, while we currently do not expect any adverse material impact on our effective tax rate, we cannot give any assurance as to what our effective tax rate will be after the Redomiciliation because of, among other things, uncertainty regarding the application of the tax laws and policies of the jurisdictions where we operate. Our actual effective tax rate may vary from this expectation, and that variance may be material. Our tax position (including our

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effective tax rate) 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 UK), the United States, and other jurisdictions, as well as being affected by certain changes proposed by the OECD and their action plan on Base Erosion and Profit Shifting (including the Pillar Two global minimum tax). A material increase in our effective tax rate could have an adverse effect on our business, financial condition and results of operations.

The market for the New Kiniksa class A ordinary shares may differ from the market for the Class A common shares.

As part of the Redomiciliation, we plan to list New Kiniksa's newly issued Class A ordinary shares on the Nasdaq Global Select Market ("Nasdaq") under the symbol "KNSA," the same trading symbol under which our Class A common shares currently trade. The market price, trading volume or volatility of the newly issued shares could be different from those of our currently listed shares. See "*Risks Related to Ownership of Our Common Shares – The price of our Class A common shares may be volatile and fluctuate substantially, which could result in substantial losses for holders of our Class A common shares*" for more information on risks related to volatility in the trading price of our listed shares.

The Redomiciliation will result in additional direct and indirect costs, even if the Redomiciliation is not completed.

We have incurred and expect to incur attorneys' fees, accountants' fees, filing fees, mailing expenses and financial printing expenses in connection with the Redomiciliation, even if the Scheme is not approved or completed. We also expect to incur costs and expenses,

including professional fees, to comply with UK corporate and tax laws and financial reporting requirements if the Scheme is completed. The Redomiciliation has also required us to divert the attention of our management and employees from our daily operations.

In addition, the Redomiciliation will require significant additional time, effort and expense to carry out, if approved. We may incur these additional costs for some time, materially impacting our business, operating results and financial condition.

We may choose to abandon or delay the Redomiciliation.

We may abandon or delay the Redomiciliation at any time prior to the Scheme becoming effective, even after receiving approval from our shareholders and the sanction of the Supreme Court of Bermuda. While we currently expect the Redomiciliation to take place as soon as practicable after obtaining shareholder approval of the Scheme, our board of directors may delay the Redomiciliation for a significant time or may abandon the Redomiciliation after its approval because, among other reasons, of an increase in the estimated costs of the Redomiciliation or a determination by our board of directors that the Redomiciliation is no longer in the best interests of our shareholders or may not result in the benefits we expect.

As a result of increased shareholder voting requirements in the UK relative to Bermuda, we will have less flexibility with respect to our ability to issue new shares than we now have.

Under Bermuda law, our directors may issue, without shareholder approval, any authorized but unissued common shares. English law allows our shareholders to authorize the allotment of share capital which can be issued by our board of directors without shareholder approval, but this authorization must be renewed by the shareholders every five years and we cannot guarantee that this authorization will always be approved.

Additionally, subject to specified exceptions, including an opt-out included in the articles of association we plan to approve in connection with the Redomiciliation, English law grants statutory preemptive rights to existing shareholders to subscribe for new issuances of shares for cash. English law requires that this opt-out must be renewed by the shareholders at least every five years, and we cannot guarantee that the opt-out of preemptive rights will always be approved. A waiver of pre-emption rights under English law requires approval of the shareholders holding at least 75% of the voting rights in an English company. In the future, our plans may be impeded due to a lack of the flexibility that we currently enjoy in Bermuda, potentially materially affecting our business, financial condition and results of operations.

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Risks Related to Our Financial Position and Capital Needs

We have a history of operating losses and may incur losses in the future.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. Our ability to generate product revenue sufficient to sustain our organization will depend heavily on a number of factors, including the continued commercialization of ARCALYST, the development and eventual commercialization of one or more of our current or future product candidates, if approved, and the management of our costs consistent with our current operating plan. For the three months ended March 31, 2024 June 30, 2024, our net loss was $17.7 million $3.9 million. As of March 31, 2024 June 30, 2024, we had an accumulated deficit of $495.7 $499.6 million. Our future capital expenditures are expected to be substantial, and we may incur operating losses in the future if we encounter greater than expected expenses as we:

- conduct the Redomiciliation;
- support our sales, marketing and distribution capabilities, infrastructure and organization to commercialize ARCALYST and any product candidates for which we may obtain marketing approval;
- conduct new and ongoing research and pre-clinical and clinical development of our product candidates, including our Phase 2 clinical trial of abiprubart in RA and our planned Phase 2b clinical trial of abiprubart in Sjögren's Disease;
- manufacture our products and product candidates for clinical or commercial use, increase our manufacturing capabilities, add additional manufacturers or suppliers and perform activities related to our technology transfer of the process for manufacturing

ARCALYST drug substance;

- seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials, if any;
- make milestone or other payments under any current or future license, acquisition, collaboration or other strategic transaction agreement;
- seek 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;
- seek to identify, assess, acquire or develop additional product candidates;
- enter into licensing, acquisition, collaboration or other strategic transaction agreements;
- seek to maintain, protect and expand our intellectual property portfolio;

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- seek to attract and retain skilled personnel;
- create additional infrastructure to support our product development and commercialization efforts; and
- experience delays or encounter issues with any of the above, including but not limited to failed trials, complex results, safety issues, regulatory challenges that require longer follow-up of existing trials, additional major trials, additional supportive trials in order to pursue marketing approval, a pandemic or other outbreak of disease or disruptions to the national or global economy.

Further, our financial results 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. Corporate profitability may not be sustained in subsequent periods.

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To further our operational plans, we may require substantial additional financing, which we may not be able to obtain when needed or on acceptable terms.

The development and commercialization of biopharmaceutical products is capital intensive. We are currently commercializing ARCALYST in the United States for the treatment of recurrent pericarditis, CAPS and DIRA. In addition, we are advancing our product candidates through research, preclinical and clinical development, including our Phase 2 clinical trial with abiprubart in RA and our planned Phase 2b clinical trial of abiprubart in Sjögren's Disease.

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, if we are unable to fund our operations through commercial ARCALYST revenue, we may need to obtain substantial additional funding to progress our operating plans via accessing capital markets. If we are unable to raise capital when needed on acceptable terms, if at all, we may 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. Such factors that may significantly impact our funding requirements include such factors listed above, under "*—Risks Related to Our Financial Position and Capital Needs – We have a history of operating losses and may incur losses in the future."* as well as:

- 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 organizational 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;

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- competitive and potentially competitive products and technologies, and patients' and prescribers' receptivity to ARCALYST or any of our product candidates if approved, in light of such competition;
- 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, 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 global political turmoil, including pandemics or other outbreaks of disease and global conflict;

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- the number, size and type of our 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 a Risk Evaluation and Mitigation Strategy (a "REMS") that could be required by regulatory authorities;
- the timing and amount of milestone and other payments we may receive under our agreements with Huadong, Genentech 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 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;
- litigation arising out of, but not limited to, product liability claims, intellectual property disputes, disputes arising from our collaboration and license agreements and employment-related disputes;
- the ongoing costs associated with being a public company; and
- the receptivity of the capital markets to financings by biopharmaceutical companies.

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, if approved.

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.

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

In addition to commercial revenue, we may finance our cash needs through private or public securities offerings, debt financings, 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 ordinary shares to decline.

The sale of additional equity or convertible securities would dilute all of our shareholders. To the extent we raise additional capital by issuing additional equity securities, our shareholders may experience substantial dilution. We may sell such 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 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.

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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 ordinary shares to decline.

Risks Related to Commercialization

We may not be able to continue to commercialize ARCALYST or be successful in commercializing any future products, potentially impairing the commercial potential for our current and future products to generate any revenue.

Since our commercial launch of ARCALYST, we have focused on establishing and expanding 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 realized revenues from such efforts, there is no guarantee that we will be able to maintain the trajectory of growth or 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;
- an absence or reduction in strong scientific-based relationships to drive disease awareness and education;

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- 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 to compete with current or future competitor products and/or biosimilars;
- our inability or delay in gaining or maintaining 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 professionals regarding applicable diseases relevant to ARCALYST or any of our future products;

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- 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 changes in regulatory guidance, or those caused by our reliance on our third party manufacturers;
- any delays in the ongoing technology transfer of the process for manufacturing ARCALYST drug substance;
- 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 or sustain 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;
- our inability to establish and maintain patent and trade secret protection or regulatory exclusivity for our products;
- our inability to enforce and defend our intellectual property rights and claims; and
- unforeseen costs and expenses associated with creating and maintaining a sales, marketing, and access organization.

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.

We rely on a select network of third party specialty pharmacies to market and sell ARCALYST that may not meet our or our patients' needs.

We rely on a select network of third party specialty pharmacies to distribute ARCALYST and expect to use a similar strategy for our current and future product candidates, if approved. We rely on such specialty pharmacies to effectively distribute products in a timely manner, provide certain patient support services, manage prescription intake, collect accurate patient and inventory data and collect payments from payors. While we have entered into agreements with each of these specialty pharmacies, they may not perform as agreed, our strategic priorities may change or they may terminate their agreements with us. Further, an inability of our specialty pharmacies to meet our patients' needs may lead to reputational harm or patient loss. In the event that such network fails to properly meet our or our patients' needs, we

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may need to partner with other specialty pharmacies to replace or supplement our current network and there is no guarantee that we will be able to do so on commercially reasonable terms or at all. In addition, there is a risk that patients may discontinue or suspend their ARCALYST treatment in the process of transitioning between specialty pharmacies, and it may take time to re-integrate such patients into our network, if at all. In such an event our business, results of operations, financial condition and prospects may be materially affected.

Our current or future products may not gain or sustain 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, other healthcare professionals, 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

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ARCALYST has seen near-term success in the United States, 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 its approved indications, or any of our future products, 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 products 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 and our ability to maintain and expand favorable labeling when and if needed;
- limitations or warnings contained in the labeling approved by regulatory authorities, including any additions mandated by authorities after initial approval;
- 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;
- market acceptance of current and future price increases of our products;
- 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;
- publications of scientific literature, consensus papers and treatment guidelines favorable to the administration of our products and product candidates and/or the positioning of the class of drugs to which each of our products and product candidates belongs; and

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- other potential advantages over alternative treatment methods.

If ARCALYST or any of our future approved products, if any, fail to gain or sustain market acceptance, our ability to generate revenue will be adversely affected. Even if ARCALYST or any future products 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 current and future products, if any, will depend in part on the extent to which third party payors, including governmental authorities and private health insurers, provide funding, establish and maintain favorable coverage and pricing policies and set adequate reimbursement levels.

Our ability to continue to commercialize ARCALYST in its approved indications or any of our future products, 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 (including affordability of patient cost-sharing obligations) for ARCALYST or the future product and alternative treatments from third party payors (e.g., governmental authorities, private health insurers and other organizations). We currently enjoy largely favorable coverage and reimbursement from third party payors for ARCALYST in the approved recurrent pericarditis indication and seek to maintain such favorable coverage and reimbursement. We cannot be certain we will continue to effectively execute our coverage and reimbursement strategy in the markets we pursue, which could limit the future commercial potential of ARCALYST in the approved recurrent pericarditis indication or any of our product candidates, if approved.

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, limiting the amount of reimbursement for particular products and 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 including health technology assessment bodies in the European Union (the "EU") and United Kingdom, 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 at which we can sell, 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, our ability to successfully commercialize ARCALYST or any of the product candidates for which we obtain marketing approval may be adversely affected. Moreover, any coverage or reimbursement that may be obtained may be decreased or eliminated in the future. For example, in January 2023, one of the large private health insurers that currently covers ARCALYST placed ARCALYST on its exclusion list for the CAPS indication, which could create hurdles for new patients seeking coverage for their prescriptions in all indications. In addition, obtaining and maintaining favorable coverage and adequate reimbursement may require us to offer pricing concessions to third party payors.

We may also be unable to adequately satisfy a third party payor's value/benefit assessment on an ongoing basis. It is possible that third party payors will select low-cost clinical comparators that serve as benchmarks for determining relative value, including 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 and the potential for a worse relative outcome, including such payors refusing to provide coverage and reimbursement entirely, or finding the evidence not sufficiently compelling to support our desired pricing and reimbursement. Similarly, payors may implement coverage criteria that further restrict 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.

We may be unable to sustain any favorable coverage and reimbursement on an ongoing basis. Third party payors may also revisit their previously established coverage policies from time to time including their assessment of the relative value/benefit provided by a drug product compared to clinical alternatives, such as any competitive products with the same or similar indications and biosimilars. 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. Third party payors often introduce more challenging price negotiation methodologies when competitors exist or enter into the market. 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 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. Third party payors may also employ challenging price negotiation tactics in the event of a proposed price increase of our current and future products. See "*Risks Related to Commercialization – It may be difficult for us to realize the benefit of increasing the price of certain of our commercialized products.*"

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It may be difficult for us to realize the benefit of increasing the price of certain of our commercialized products.

We have and may continue periodically to increase the price of ARCALYST or any of our and may implement similar pricing practices for future products, if approved, and may be unable to realize commercial benefits from such price increases due to unfavorable actions that third party payors (including governmental authorities and private health insurers) may take in response. Even if price increases lie below contractual price protection clauses, payors may request price concessions in exchange for covering our products or may opt to change coverage or reimbursement policies with respect to such products. If we cannot successfully negotiate with such payors, we may be forced to provide significant price concessions or, if we fail to arrive at a satisfactory resolution, lose favorable coverage or reimbursement for patients served by such payor. In such an event, patients may have difficulty obtaining access to, or affording, such products and we may see materially negative impacts on our business operations.

Any price concessions will reduce our overall revenue generation and may impair the benefit of any price increases we may take. Price concessions that reduce our product revenue may require us to rely on potentially dilutive capital-raising efforts to fund our operations, which may impact the price of our common ordinary shares. Even comparatively small discounts, if aggregated across payors, may cause materially lower revenue generation in the long-term, which may offset the increased revenue we hoped to realize through a price increase.

Further, granting price concessions to one or more payors may limit our ability to negotiate prices with other payors or in other territories. Payors, including governmental payors, negotiate drug prices by reference to the prices we have set with other payors. Should payors become aware of price concessions that we have granted, they may request similar concessions. If enough payors request and receive price concessions, our ability to generate revenue may be materially impacted, harming our business, financial condition and results of operations. Further, this may limit our ability to secure acceptable prices in potential new territories, which may materially limit our overall commercial growth. A limitation on our ability to commercialize in new and existing territories may also reduce our access to the patient populations we seek to serve, harming our ability to deliver therapeutics to patients with unmet medical need.

In the event that we cannot successfully negotiate with payors requesting price concessions in connection with a price increase or otherwise, such payors may choose to not cover our current and future products at all or may impose onerous reimbursement policies that limit patient access. We cannot assure you that current payor coverage and reimbursement policies for ARCALYST will continue. The loss of any payor, especially a large payor, or limitations on access to our drugs affecting a sizeable number of patients may materially harm our ability to generate revenue and execute on our commercial strategy. Further, as a company targeting patients with significant unmet medical need, the loss of access to our products may materially harm our targeted patient populations who cannot source adequate alternative therapies.

We are also required to provide discounts or rebates under government healthcare programs or to certain government and private purchases in order to obtain coverage under federal healthcare programs. In addition, price

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increases that outpace inflation may also trigger additional rebate obligations, including under the Medicaid Drug Rebate Program.

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

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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 ARCALYST and any other of our current or future product candidates, if approved, 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 significant and sustained profitability.

Evolving health policy and associated legislative changes related to coverage and reimbursement aimed at lowering healthcare expenditure expenditures 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

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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.

For more information, see "*Risk Factors – General Risk Factors – Enacted and future healthcare legislation may have a material adverse effect on our business and results of operations*."

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

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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 products we commercialize;
- injury to our reputation and significant negative media attention;
- regulatory investigations that could require costly recalls or product modifications;
- difficulty in enrolling participants in clinical trials or withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants;
- 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.

Any future growth outside of the United States would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to commercialize our current and future products in markets outside of the United States either on our own or through 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

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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, 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);

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- 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 certain countries;
- the existence of additional potentially relevant third party intellectual property rights; and
- foreign currency exchange rate fluctuations.

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. For example, the proposed BIOSECURE Act, a draft of which is in the legislative process in the U.S. Congress, would prohibit U.S. federal agencies from contracting with, or extending loans or grants to, any company with current or future commercial arrangements with a "biotechnology company of concern." If enacted, this legislation would restrict the ability of biopharmaceutical companies that receive funding or reimbursement from U.S. federal agencies from purchasing services or products from certain Chinese biotechnology companies.

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 potentially costly clinical trial that compares our product candidate to other available therapies or in population groups not previously observed. Failure to demonstrate sufficiently desirable results to such parties may result in adverse pricing or reimbursement decisions. 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 expenditures could impact the commercialization of our product candidates. Pharmaceutical pricing has been, and likely will continue to be, a central component of these efforts."*

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We are subject to ongoing obligations, regulatory requirements and continued regulatory review, which may result in significant additional expense. Additionally, our current and future products 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 more stringent than 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

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or similar foreign regulations ("cGMP"). As such, we and our CDMOs 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 ("BLAs") or Marketing Authorization Applications ("MAAs"). Accordingly, we and our CDMOs 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 marketing approval is obtained via the accelerated approval pathway, we could be required to conduct a successful confirmatory clinical trial to confirm clinical benefit for our products. An unsuccessful confirmatory 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 ordinary 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 any of our current or future products, such as adverse events of unanticipated severity or frequency, or problems with the facility where a 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; fail to comply with regulatory requirements; or a regulatory agency or enforcement

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authority disagrees with the promotion, marketing or labeling of our products, such 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 CDMOs' facilities;

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- require us to withdraw or correct our marketing materials; 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 or reputational harm. 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, impose restrictions on such product or its manufacture or require us to recall or remove such 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 occur, our ability to sell an affected 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 potentially significant enforcement actions.

Our business operations are subject to extensive healthcare regulation and enforcement by various government entities, and our failure to strictly adhere to these regulatory requirements could have a detrimental impact on our business.

The development and marketing of pharmaceutical products and related arrangements with healthcare professionals, third party payors, patients, and other third parties in the healthcare industry are subject to a wide range of

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healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our current and future products.

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

- the United States 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 United States 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. Pharmaceutical 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, a claim including items and services resulting from a violation of the federal Anti-Kickback Statute is deemed a false or fraudulent claim for purposes of the False Claims Act;

- the United States Foreign Corrupt Practices Act (the "FCPA"), the U.K. Bribery Act 2010 (the "Bribery Act") and similar anti-bribery or anti-corruption laws, regulations or rules in other countries in which prohibits United States we operate, which prohibit 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. The Bribery Act may also create liability where we fail to prevent a person associated with us from committing a bribery offense. In many countries, the healthcare professionals we interact with may meet the FCPA's and Bribery Act'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;

- the United States federal Health Insurance Portability and Accountability Act ("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 services. 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;

- United States federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program;

- the United States 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 medical doctors, dentists, optometrists, podiatrists and chiropractors), certain

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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;

- The United States Federal Food, Drug and Cosmetic Act, which, among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;

- United States federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;

- United States federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- analogous United States state laws and regulations, such as state anti-kickback 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 state laws that require pharmaceutical companies to adopt certain compliance standards; restrict interactions with healthcare professionals; disclose financial interactions with healthcare professionals to the government and public; report pricing information or marketing expenditures; or register sales representatives; and

- similar healthcare laws and regulations in the European Union (the "EU") EU, United Kingdom and other jurisdictions, including including: Directive 2001/83/EC on the Community code relating to medicinal products for human use and its national implementing legislation; the UK Human Medicines Regulations 2012; Directive 2011/83/EU on consumer rights and its national implementing legislation; and reporting requirements detailing interactions with and payments to healthcare professionals, which may be applicable even if we are not commercializing a product in such jurisdictions.

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Given the broad scope and evolving government interpretation and enforcement of these laws, our business activities could be subject to challenge under one or more of such laws. 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.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations may involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. 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

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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

If we are unable to advance our product candidates in clinical development and obtain regulatory approval, or experience significant delays in doing so, our business may be significantly harmed.

Our product candidates are in various stages of clinical development. We base our projections about the future development and potential approval of our product candidates on indirect data from other companies and the results of our preclinical and clinical trials, but ultimate success is uncertain and involves significant risk.

We cannot be certain that any of our product candidates will be successful in their clinical trials. We also cannot be certain that they will receive regulatory approval, even after completing a successful pivotal clinical trial. We may also choose not to commercialize a product candidate that has completed a pivotal trial or received regulatory approval, for a number of reasons, including commercial viability. Such decisions may be for a particular indication or be for the product candidate entirely. In the event that a product candidate is unsuccessful in its

clinical trials, fails to receive regulatory approval or is unviable for another reason, our business may be materially harmed by limiting our ability to recoup our development expenses through a successful commercial launch.

Each of our product candidates requires substantial preclinical or clinical development and manufacturing support as part of our product development strategy. The clinical success of our current and future product candidates depends upon several factors, including, but not limited to, the following:

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

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- successful completion of nonclinical studies, including toxicology studies, pharmacological, and biodistribution studies, as conducted, where applicable, under the FDA's good laboratory practices regulations, or similar foreign standards ("GLP");
- successful site activation for, enrollment in, and completion of clinical trials, including the ability of our CROs to successfully conduct such trials within our planned budget and timing parameters without adversely impacting our trials, and our ability to successfully oversee CRO activities;
- positive data from our clinical programs, including post-marketing trials and those intended to satisfy regulatory commitments or for label expansion, with sufficient quality to 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 approvals from applicable regulatory authorities and maintenance of any such approvals;
- as applicable, acceptance of pediatric study plans by regulatory authorities, and the follow through of any pediatric study commitments, such as development of pediatric formulations, if required;
- 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 CDMO facilities to support our development and commercialization activities in a manner compliant with all regulatory requirements;

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- successful manufacture of sufficient supply of our product candidates within approved specifications for purity, efficacy and cGMP requirements from our facility and from our CDMOs or other sole-source manufacturers in order to meet clinical or commercial demand, as applicable, for ourselves and for our partners;
- continued compliance with any post-marketing requirements imposed by regulatory authorities, including any required post-marketing clinical trial commitments or REMS or similar risk management measures; and
- maintenance of a continued acceptable safety profile of our product candidates before and following approval.

If we do not accomplish one or more of these factors in a timely manner or at all we could experience significant delays in, or an inability to, timely or successfully commercialize our product candidates. 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

may harm our ability to continue our operations by limiting our potential commercial prospects. In such an instance, we may need to seek capital elsewhere. See "*Risk Factors – Risks Related to Our Financial Position and Capital Needs – To further our operational plans, we may require substantial additional financing, which we may not be able to obtain when needed or on acceptable terms"* and "*Risk Factors – Risks Related to Our Financial Position and Capital Needs – Raising additional capital may cause dilution to, or impact the rights of, our shareholders, restrict our operations or require us to relinquish rights to our technologies, or product candidates or products."*

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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 the 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 future clinical trials will be conducted as initially planned or completed on our initial projected schedule, if at all. Further, even if conducted on time, a clinical trial may result in unfavorable or statistically insignificant results, leading us to abandon our pursuit of a particular indication or the development of a product candidate entirely. 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 expenses via successful development could pose material risks to our business. See "*Risk Factors – Risks Related to Product Development – If we are unable to advance our product* candidates *in clinical development and obtain regulatory approval, or experience significant delays in doing so, our business may 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 CTA under the EU Clinical Trials Regulation ("CTR") 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; 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, manufacturing and controls ("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.

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Any of the foregoing 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 an institutional review board (an "IRB"), an ethics committee and/or other applicable committees for each clinical trial site before a trial may be initiated, which approval could be delayed, rejected or suspended. IRBs, regulatory authorities or other applicable safety committees 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 certain supplemental BLAs ("sBLA") to the FDA, an MAA to the European Medicines Agency (the "EMA") or competent authorities of the EU member states, or other applicable regulatory authorities in other countries for each product candidate and, consequently, is a prerequisite to us 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, require redesign, have timely site activation and participant enrollment or be completed on schedule, if at all. Events that

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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, ethics committee approval or positive opinion 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 participants in a particular trial, including due to competition from other companies' clinical trials for a particular indication, 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 manner or in compliance with all applicable laws and regulations, including the FCPA;

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- failure to perform in accordance with the FDA's good clinical practices ("GCPs") or applicable comparable regulatory guidelines in other countries;
- participants not completing a clinical trial or not returning for post-treatment follow-up, including as a result of trial demands on participants;
- clinical trial sites withdrawing from or being unable to conduct activities, or participants withdrawing from clinical trials, including as a result of a pandemic or other outbreak of disease and global conflict;
- participants experiencing serious adverse events or undesirable side effects or being exposed to unacceptable health risks;
- participants 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;

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- 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 sufficient quantities of or phase-appropriate supplies of our product candidates for use in our clinical trials in accordance with applicable 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

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distribution in 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.

Delays in the commencement or completion of our planned and ongoing clinical trials 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. 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, national competent authorities, the EMA, the UK Medicines and Healthcare products Regulatory Agency (the "MHRA") and other applicable regulatory authorities outside of those

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jurisdictions and are subject to oversight by these regulatory authorities and IRBs or ethics committees at the medical institutions where such 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, the EU, the United Kingdom 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, the EU and the EU United Kingdom may subject us to risks associated with the engagement of non-United States, non-EU and non-EU non-United Kingdom CROs who are unknown to the FDA, the EMA or the EU member states' regulatory national component authorities or the MHRA and may have different standards of diagnosis, screening and medical care. Such trial sites may also incur 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, the EU and the EU. United Kingdom.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. Such changes may require us to dedicate time, resources and capital to comply and, if we are unable to do so effectively or on a timely basis, our development plans may be impacted and our business may suffer material harm.

Further, conflicts around the globe may also materially affect our clinical activities and our product candidate development timeline. See "*Risk Factors – General Risk Factors – Conflicts around the globe may have an adverse impact on our operations.*"

We may find it difficult to enroll participants 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.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion, particularly given that many of the conditions for which we are evaluating our current product candidates or may evaluate in the future are in small disease populations. Accordingly, when we encounter difficulties in enrollment, we have experienced and may in the

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future experience delays, or we may be prevented from completing our clinical trials. Participant enrollment depends on many factors, including:

- the size and nature of the patient population;
- the severity of the disease being studied;
- participant referral practices of prescribers;
- participant eligibility criteria for the clinical trial and evolving standards of care;
- the proximity of participants to clinical sites;
- the complexity of the design and nature of the clinical protocol and trial;
- the fact that our product candidates modulate the immune system and carry unique risks associated with immunosuppression, including the risk of serious infections, potential interference with vaccines and other potential serious health risks;
- the availability and nature of competing clinical trials;

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- the availability of standard of care or new drugs approved for the indication the clinical trial is investigating;
- failure to obtain, maintain and/or timely amend participant consents;
- our ability to recruit clinical trial investigators with applicable competencies and experience;
- the risk that participants 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 participants' 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 participants may prove costly, especially since we are looking to identify a subset of the participants eligible for our studies from a relatively small patient population for many of the diseases we are studying. If participants are unable or unwilling to participate in our clinical trials for any reason, or we experience difficulties in participant enrollment for any other reason, our costs may significantly increase and the timeline for recruiting participants, 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,

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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 ("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, including clinical trials evaluating our current products in new indications, or clinical trials conducted by collaboration partners, 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 being developed or commercialized by third parties show the same or similar side effects as those we observed in our trials but to a greater degree or reported report new previously unreported previously-unreported side effects, it could have an impact on the entire class of molecules, in development, as and the applicable regulatory agency may modify, suspend, or terminate our clinical trials, or trials; not authorize us to

Table further clinical trials; require post-marketing clinical trial commitments or safety monitoring (e.g., REMS); or even suspend commercialization of Contents

initiate further trials with our any products or product candidates, as applicable, that contain a molecule in that within such class. Further, third parties may have rights to independently develop and commercialize our current and future products and product candidates, which may increase the likelihood of adverse safety results. For example, Regeneron retains worldwide rights to develop and commercialize ARCALYST for local administration to the eye and ear and oncology, and Huadong holds rights to develop and commercialize ARCALYST and mavrilimumab in the Asia Pacific region, excluding Japan. The development of our product candidates and, if approved, commercialization of our products for new indications or new patient populations by these third parties may increase the possibility of uncovering adverse safety results not previously discovered during our own clinical development process or United States commercialization. Such effects, if uncovered by such third parties, may lead to regulatory authorities ordering us to cease further development of, deny or withdraw any approval of any of our products or product candidates, or require onerous label changes, for any or all targeted indications.

In addition, the compassionate use of our products and product candidates, or evaluation of our products and 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 after use by a significantly larger number of patients, including patients with different demographic characteristics than those that participated in our clinical trials. If we or others later identify undesirable side effects caused by our products or 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;

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- 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 professionals 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.

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Interim, preliminary, and "top-line" data from our clinical trials that we announce or publish from time to time may change as more participant 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 are subject to the risk that one or more of the clinical observations may materially change as participant enrollment continues and more participant 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 candidates 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 ordinary shares.

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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 a 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, who may deny approval based on the results of such submissions and inspections. 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

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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 or such authorities may request additional information that may be difficult to generate or provide. Further, following

approval, the FDA may conduct additional inspections and, based on the results of such inspections, deem the inspected manufacturing facilities to be deficient, suspending our ability to manufacture our product candidates until we can secure satisfactory alternative manufacturing facilities.

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, 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, MAA or equivalent application types, may cause delays in the approval or rejection of an application. For instance, comprehensive proposals have been made for the complete overhaul of the existing 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. The European Commission's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising eligibility for expedited pathways, etc.) was published in April 2023. The proposed revisions remain to be agreed and adopted by received a positive first reading of the European Parliament and European Council (not expected has yet to consider the legislative proposal. It is unlikely that the new law will be adopted through the EU legislative process before early 2025) and 2026. When adopted, the new law 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:

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- 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, which could include a requirement to compare our products or product candidates to other therapies for the treatment of the same indication;
- regulatory authorities, following the discovery of adverse safety signals or side effects from approved therapeutics or therapeutics in development in the same or related class as our products or product candidates, 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, MAA or other submission or to obtain regulatory approval in the United States, Europe or elsewhere;
- the number of participants required for clinical trials 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 participants for 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 believe that we have not sufficiently demonstrated our ability to manufacture our candidates 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 conclude that on-site inspections and data audits have not 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

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- 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 such product candidates for fewer indications or more limited patient populations than we request. Furthermore, regulatory authorities or payers may not approve the price we intend to charge, may grant approval contingent on the performance of costly postmarketing clinical trials, may impose certain postmarketing 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 United States 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 biosimilar 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 exclusivity and designation in the United States for ARCALYST for the treatment of pericarditis and mavrilimumab for the treatment of GCA, respectively. In addition, we have received Orphan Drug designation in the EU for ARCALYST for the treatment of idiopathic pericarditis. In the future, we may seek Orphan Drug designation for certain of our other product candidates in the

United States or 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, which are subject to a number of region-specific (e.g., tax credits, user fee exemptions and potential market exclusivity) rules and regulations.

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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 may seek Breakthrough Therapy or Fast Track designation for one or more of our product candidates, which, if granted, offers the potential for a rolling review of a BLA if a number of conditions are met, which would allow data to be submitted and reviewed as they become available rather than waiting for the full data package to become available to be submitted. Rolling review is often faster than the FDA's standard review process. 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

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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 EMA a PRIME designation from the EMA, a conditional MA or other designations, schemes or tools 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 a PRIME (Priority Medicines) designation from the EMA, a conditional MA or other designations, schemes or tools for one or more of our product candidates, each of which offer incentives similar to a United States Breakthrough Therapy designation. 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.

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

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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 may be unable to successfully obtain marketing approvals for any of our current or future product candidates. Failure to 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.

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, which may impair our ability to generate additional revenue. 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.

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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, which is highly regulated and complex, 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; the commercial manufacture of our current and future products; and labeling and packaging activities for our current and future products. We rely on these third parties to produce our products and product candidates at sufficient quality and quantity to support our and our collaboration partners' commercialization and research and development efforts.

The manufacture of our current and future products and 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. Due to the highly technical requirements of manufacturing our current and future products and 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.

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, or not in a timely manner due to, for example, deviations in operations or manufacturing facility control, or production interruptions caused by equipment failure and an inability to source adequate replacement parts and equipment, which could delay, prevent or impair our commercialization or research and

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development efforts. From time to time, we have identified events in the ARCALYST manufacturing process that prevented distribution of ARCALYST material as planned, though this has yet to materially impact our ability to source sufficient ARCALYST material to cover our needs. Equipment If, in the future, we are unable to source sufficient material, we may stock out or otherwise be unable to meet patient demand for ARCALYST, adversely affecting our business, results of operations and financial condition. In addition, equipment used in the ARCALYST manufacturing process may no longer be supported by vendors in the event of equipment failure. Such equipment may also not be repaired, replaced or qualified in a timely manner. Further, reagents used for the analytical testing of ARCALYST have and may in the future become outdated, requiring qualification before new reagents may be used. These issues may be exacerbated by increased clinical or commercial demand by us or our collaboration partners, or if we decide to develop ARCALYST in one or more additional indications or in additional territories. If we encounter events in

We may be unable to adequately address current and future issues with the future that ARCALYST manufacturing process, which could prevent additional material from being distributed in a timely manner or within specifications, and If we are unable to source additional commercial supply of ARCALYST, if needed, or should future 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.

Regeneron and its CDMOs are is the sole manufacturers manufacturer of ARCALYST drug substance and will remain so until we complete the technology transfer of the manufacturing process for ARCALYST drug substance to a new CDMO. Samsung. 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. ARCALYST (including increased demand arising from our need to replace material lost to manufacturing issues). Regeneron, in turn, relies upon CDMOs

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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 we have with Regeneron. As a result of our reliance on Regeneron and its CDMOs 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. Many of these risks may still be present after successful completion of the technology transfer of ARCALYST drug substance manufacturing and there is no guarantee that such technology transfer will materially diminish our ARCALYST manufacturing risk profile.

We have qualified or engaged, as applicable, CDMOs to produce our clinical product candidates. While we have manufacturing capabilities to support early development for our product candidates, we and our CDMOs may not be able to produce sufficient quantities of our product candidates or produce them at an acceptable quality, including as a result of global supply chain issues, which could delay, prevent or impair our development or commercialization efforts and increase costs.

We have entered into certain collaboration agreements with Huadong for each of ARCALYST and mavrilimumab. Until such time as Huadong is able to manufacture these drugs, either on its own or through a third party CDMO, we are the only source of these drugs for Huadong. If our current suppliers of drug substance and drug product for ARCALYST and mavrilimumab cannot produce sufficient quantities to satisfy our needs and Huadong's needs, then this may have an adverse impact on our and Huadong's business and operations.

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 existing commercial supply or 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 or new manufacturers, which could impact the timing and subsequent success of our planned commercial supply or clinical trials. In addition, as we plan to produce clinical trial and commercial material at a CDMO, the CDMO may be required to adopt different manufacturing protocols or processes. For example, in March 2023, Regeneron formally initiated a technology transfer with respect to the manufacturing process for ARCALYST drug substance. Any Our replacement CDMO, that we select as part of this process may find it necessary to Samsung, will utilize a different modified manufacturing process than from that used by Regeneron, which could require lengthy development, regulatory review and approval. For more information see "*Risk Factors — Risks Related to Manufacturing and Our Reliance on Third Parties — We are conducting a technology transfer with respect to the manufacturing process of ARCALYST drug substance from Regeneron to a new CDMO Samsung and the analytical testing methods of ARCALYST drug substance and drug product to new CTLs. Such technology transfer will be subject to significant risks and uncertainties.*"

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The facilities used by our CDMOs to manufacture ARCALYST and our current and future product candidates may be inspected by regulatory authorities in connection with the submission of our MAs 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 CDMOs for compliance with cGMPs and other regulatory requirements in connection with the manufacture of current and future products and product candidates. If our CDMOs 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 CDMOs and have the ability to audit their compliance and performance, we have no direct control over the ability of our CDMOs to maintain adequate quality control, quality assurance and qualified personnel other than through quality monitoring in accordance with our agreements with the CDMOs. 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

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and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our products or product candidates.

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 and an epidemic, pandemic or other outbreak of disease. 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 select 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.

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 or any replacement CDMO with respect to the commercial supply of ARCALYST, we must place purchase orders based on projected demand. 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. We may also be required to estimate and order safety stock as part of our planned technology transfer of the manufacturing process for ARCALYST drug substance, which will be subject to a number of the same risks and uncertainties. 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 our current and future products. If our current CDMOs 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, establishing a replacement manufacturer for ARCALYST or our product candidates, if required, is unlikely to be accomplished in a timely or cost-effective 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 CDMOs 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.

We are conducting a technology transfer with respect to the manufacturing process of ARCALYST drug substance from Regeneron to a new CDMO Samsung and the analytical testing methods of ARCALYST drug substance and drug product to new CTLs. Such technology transfer will be subject to significant risks and uncertainties.

In March 2023, Regeneron, our sole supplier of ARCALYST drug substance, initiated a technology transfer related to the manufacturing process of ARCALYST drug substance and the analytical testing methods of ARCALYST drug substance and drug product. Since then, we have collaborated with Regeneron to qualify and contract with a new CDMO Samsung who will serve as the new manufacturer of ARCALYST drug substance and new CTLs who will serve as the new testing labs of ARCALYST drug substance and drug product. We have also contracted with Samsung to document the technology transfer and enable the commercial manufacturing of ARCALYST drug substance should the technology transfer succeed.

Pharmaceutical development, manufacture and analytical testing requires significant expertise and capital investment, and the manufacture and testing of biologics, in particular, can be complex and difficult. While we have selected a Samsung as our replacement CDMO and have selected replacement CTLs, we are still in the early stages of the technology transfer process and still must determine whether Samsung and such CDMO and CTLs can meet our requirements regarding production costs and yields, process controls, quality control, quality assurance, data integrity and cGMP compliance, among other factors. We would also need to source sufficient raw materials to facilitate new manufacturing and analytical testing, which may be affected by supply chain disruptions, materials shortages or an inability to negotiate satisfactory terms with suppliers. The technology transfer process is a time-consuming and difficult task that may require significant time and focus from our management and technical teams. Further, because of the complexities of this process, the technology transfer may be subject to substantial delay, which could materially harm our business and operations.

Because such CDMO would Samsung will be manufacturing ARCALYST drug substance at a new manufacturing site and with a potentially different manufacturing process, and such CTLs would will be testing ARCALYST drug substance and drug product at new testing sites and potentially with different testing methods, we expect that the FDA will need to approve such changes before we are able to complete the technology transfer. The FDA generally requires that any new replacement CDMO be able to manufacture drug substance at sufficient levels of comparability with the materials produced by the original manufacturer. We are still in the process of confirming comparability between the drug substance produced by Samsung and the drug substance produced by Regeneron. Failure to provide sufficient evidence of comparability may result in the FDA requesting a bioequivalence or pharmacokinetic study, which would delay our expected technology transfer timeline. Even if such study were to be performed, there is no guarantee that the FDA would accept our findings and approve any new facilities for the manufacture of ARCALYST drug substance.

Table In addition, because the Samsung manufacturing facility is located in South Korea, unlike Regeneron's United States-based manufacturing facility, we may face new risks arising from import/export restrictions, customs proceedings, product being lost or damaged during international shipping, differing regulations, supply chain interruptions and other risks inherent to international operations. These risks, should they occur, could increase our costs and affect our ability to meet clinical and commercial demand for ARCALYST, which could materially impact our business, financial condition and results of Contentsoperations.

Regeneron is contractually obligated to continue manufacturing ARCALYST drug substance for at least a portion of the time that it will take us to qualify Samsung as a replacement CDMO. During such time, Regeneron will remain subject to many of the risks described elsewhere in this "*Risk Factors*" section, including the risk that it is unable to manufacture sufficient quantities of ARCALYST and at sufficient quality to meet ours and our patients' and collaborators' needs. Further, because we expect the timeline for any successful technology transfer to extend beyond Regeneron's contractual obligations, our ability to meet patient demand will depend significantly on whether we can secure sufficient safety stock from Regeneron, negotiate continued ARCALYST drug substance manufacture by

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Regeneron beyond its contractual obligations or some combination thereof. Purchasing significant amounts of safety stock would require substantial upfront capital investment and, if the technology transfer process is delayed beyond our expectation, such safety stock may expire or be depleted before a new CDMO Samsung can begin manufacturing ARCALYST drug substance. Regeneron may also disagree with our forecasted safety stock requirements and manufacture less ARCALYST drug substance than we request, exposing us to risks if the technology transfer process is significantly delayed. Any arrangement that we negotiate with Regeneron to manufacture ARCALYST beyond their contractual obligations may not be on as favorable terms as our current relationship, which could materially increase our costs and as a result negatively impact our financial condition and results of operations. A failure to secure sufficient safety stock or negotiate satisfactory manufacturing terms with Regeneron could result in supply shortages for our patients and collaborators while we work to complete the technology transfer.

A failure to either complete our planned technology transfer on our expected timeline or at an acceptable cost and/or secure sufficient supply of ARCALYST through the technology transfer process would have a material impact on our business, financial condition and results of operations.

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 cleanup 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.

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

The drug substance and drug product used in ARCALYST and mavrilimumab are supplied to us from single-source suppliers and we obtain the drug substance and drug product used in abiprubart from a limited number of sources. Regeneron is currently our sole source manufacturer but with its initiation of and will remain so until we qualify Samsung as a technology transfer of the manufacturing process for ARCALYST drug substance in March 2023, replacement CDMO. We expect that Samsung will cooperate with us to qualify a suitable replacement CDMO. be our sole source manufacturer following such qualification. For more information see "*Risk Factors — Risks Related to Manufacturing and Our Reliance on Third Parties — We are conducting a technology transfer with respect to the manufacturing process of ARCALYST drug substance from Regeneron to a new CDMO Samsung and the analytical testing methods of ARCALYST drug substance and drug product to new*

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CTLs. Such technology transfer will be subject to significant risks and uncertainties." 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. Successful completion of a technology transfer of the manufacturing process for ARCALYST drug substance will be integral to our ability to meet such requirements. With respect to ARCALYST and mavrilimumab, 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 abiprubart, 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 suppliers will be able to meet our demand for our products and product candidates, 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. suppliers given their manufacturing capacity constraints. 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.

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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.

In addition to the above, we have entered into, and may, in the future, enter into collaboration and other agreements requiring us to provide commercial or clinical drug supply to third party partners. A failure by our CDMOs to supply sufficient quantities of drug supply may cause us to breach our contractual obligations, triggering potential penalties under our agreements, including termination of such agreements, if we fail to adequately cure such breach.

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 CDMOs 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 CDMOs 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

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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 such drugs 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.

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 cleanup 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

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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.

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 studies and 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 participants 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

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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 a pandemic or other outbreak of disease or as the result of war, conflict or terrorism;

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- 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 or unsuccessful. In addition, 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, 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 products and 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

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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.*"

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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. ARCALYST currently faces competition in its CAPS and DIRA indications and is facing potential future competition in its recurrent pericarditis indication. In addition, we expect to face competition with respect to our current and future product candidates should we seek to develop or commercialize them in the future. Competition may come from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide, each of whom may market and sell drugs or biologics or pursue 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, Sjögren's Disease, but we are aware of three several programs being developed for this indication. Two indication and which antagonize the CD40/CD154 costimulatory pathway. Novartis A.G. is

developing CFZ-533, or iscalimab (anti-CD40) for subcutaneous administration for the treatment of these Sjögren's Disease and is studying other various indications in clinical development; Amgen Inc. is developing the Tn3 fusion protein, dazodalibep (anti-CD40L) in Sjögren's Disease; and Bristol Myers-Squibb is developing BMS-986325 (anti-CD40) for the treatment of Primary Sjögren's Disease. As far as we are aware, only iscalimab is designed for subcutaneous administration. Dazodalibep is designed for intravenous administration only, and BMS-986325 is not currently being studied in subcutaneous administration, though they do offer the potential for such a design.

Additional programs are in development that antagonize the CD40 / CD154 costimulatory pathway, though they are not currently targeting Sjögren's Disease. Sanofi S.A./ImmuNext Inc. are developing frexilimab (anti-CD40L) for the treatment of Multiple Sclerosis and Systemic Lupus Erythematosus; Biogen, Inc. and UCB S.A. are developing dapirolizumab pegol (anti-CD40L) for the treatment of moderately to severely active clinical development: oneSystemic Lupus Erythematosus and Eledon Pharmaceuticals, Inc. is developing AT-1501 (anti-CD40L) for use by R-Pharm International (RPH-104), which inhibits IL-1α/IL-1β-induced signaling and is in Phase 2 development; the other is an oral cannabidiol patients undergoing kidney transplantation. Both drugs are being developed by Cardiol Therapeutics in a Phase 2 setting. The third program VTX2735, designed to inhibit for intravenous administration only. Other programs present the NLRP3 inflammasome, an intracellular sensor of a broad range of danger signals, that leads to the release of IL-1β potential for subcutaneous administration. Innovent Bio is developing IBI-355 (anti-CD40L, no indication announced) and IL-18, H. Lundbeck A/S is being developed by Ventyx Bioscience. In addition to their development program in CAPS, Ventyx has announced their intention to focus development of VTX2735 in cardiovascular indications including recurrent pericarditis.

Other drugs, while not approved for treatment of recurrent pericarditis, compete with ARCALYST in other indications. Anakinra (KINERET), marketed by Swedish Orphan Biovitrum AB, is currently approved for use in RA, CAPS and DIRA 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), Familial Mediterranean Fever (FMF), Still's Disease and Systemic Juvenile Idiopathic Arthritis (SJIA) developing Lu AG22515 (bi-specific, anti-CD40L & Albumin (scFv)2-Fab, no indication announced). We are not aware of any active, industry sponsored development programs using canakinumab seeking a label for recurrent pericarditis.

We are also aware of several other molecules which do not directly compete with our approved indications for ARCALYST but nonetheless target IL-1α and/or IL-1β directly or indirectly. Clinical stage development programs targeting IL-1α and/or IL-1β directly or indirectly via the NLRP3 inflammasome include: Lutikizumab (Abbvie for the treatment of hidradenitis suppurativa); ZYIL-1 (by Zydus Lifesciences in amyotrophic lateral sclerosis); HT-6184 (by Halia in myelodysplastic syndromes); OLT1177 (by Olatec Therapeutics in osteoarthritis of the knee); DFV-890 (by Novartis in FCAS); Selnoflast (by Roche in ulcerative colitis); NT-0167 and NT-0796 (by NodThera, no indication announced); and Somalix and Inzomelid (by Roche, no indications announced). There are 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 product candidates seeking a label for recurrent pericarditis.

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We are not aware of any FDA-approved therapies for Sjögren's Disease, but we are aware of several programs being developed for this indication and which antagonize the CD40/CD154 costimulatory pathway. Novartis A.G. is developing CFZ-533, or iscalimab (anti-CD40) for subcutaneous administration for the treatment of Sjögren's Disease and is studying other various indications in clinical development; Amgen Inc. is developing the Tn3 fusion protein, dazodalibep (anti-CD40L) in Sjögren's Disease; Sanofi S.A./ImmuNext Inc. are developing frexilimab (anti-CD40L) for the treatment of Multiple Sclerosis, Primary Sjögren's Disease and Systemic Lupus Erythematosus; and Bristol Myers-Squibb is developing BMS-986325 (anti-CD40) for the treatment of Primary Sjögren's Disease. As far as we are aware, only iscalimab is designed for subcutaneous administration. Dazodalibep is designed for intravenous administration

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With respect to mavrilimumab, there are programs in clinical development in various indications that modulate GM-CSF signaling from I-MAB Biopharma Co. Ltd. (plonmarlimab in RA), Roivant Sciences Ltd. (gimsilumab and namilumab in sarcoidosis) and Humanigen, Inc. (lenzilumab). All of these competitive programs target the GM-CSF ligand itself versus targeting the GM-CSF receptor like mavrilimumab.

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 and biotechnology 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 participant 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. Further, a competitor conducting a clinical trial in a rare disease indication for which we market a product may reduce the number of patients on our commercial therapy by recruiting such patients to be trial participants. Our competitors also may obtain FDA or other regulatory approval and/or marketing exclusivity for their products more rapidly than we may obtain 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 biosimilar 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 certain of 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 portfolio. 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.

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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:

- we 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, partners or acquisition targets;
- we may incur substantial liabilities as part of an acquisition or merger that may not be offset by the benefits of the acquired assets or the synergies we hope to realize; 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; use of a substantial portion of our available cash for all or a portion of the consideration; or causing 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 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 our products and product candidates, and any such transactions or arrangements that we 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 products and 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 products and product candidates instead of developing or commercializing our products and 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 August 2022, we entered into a license agreement with Genentech where we granted exclusive worldwide rights to develop and commercialize vixarelimab. We are currently seeking collaboration partners for mavrilimumab, and we may seek to jointly develop, commercialize or otherwise

exploit one or more of our other product candidates with a third party in the future. 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 collaborations, 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 not pursue development and commercialization of the applicable licensed drugs or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to their acquisition of competitive products or product candidates or their internal development of competitive products and product candidates, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- raise disputes with respect to the ownership or inventorship of any intellectual property developed pursuant to our collaborations or licenses;
- 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;
- may not achieve applicable development, regulatory, or commercial milestones, which may materially impact the collaboration revenue that we expect to realize from such relationship;

- raise disputes that cause the delay or termination of the research, development or commercialization of our current or future products and product candidates or that results in costly litigation or arbitration that diverts management attention and resources;

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- cause us to be named defendants in lawsuits due to their improper use of the licensed intellectual property and not indemnify us against losses in such lawsuits;

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- enforce licensed intellectual property rights against third parties that lead such third parties to challenge the validity or enforceability of the licensed intellectual property and potentially cause the licensed intellectual property to become invalid or rendered unenforceable;
- fail to maintain issued licensed patents that are under their control, or prosecute licensed patent applications in ways that diminish their value, all of which actions may adversely affect our business if our agreements with them terminate and the rights to the licensed intellectual property return to us or an upstream licensor; may delay, dispute or refuse to pay milestone and royalty payments, which may impact our ability to satisfy upstream payment obligations, if applicable; 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.

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 recruitment and training of qualified personnel. This may result in weaknesses of our systems and infrastructure; 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. Our future financial performance and our ability to commercialize our product candidates, if approved, 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

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ARCALYST, abiprubart and mavrilimumab. 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

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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 rights include 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 BIDMC to patent applications and patents related to abiprubart.

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 we or our licensees may not pursue or maintain in the future, patent protection for our products or product candidates in every country or territory in which our products or product candidates may be sold, 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 (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 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 As with 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 products and 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, abiprubart, mavrilimumab, or any future products and product candidates. A United States patent covering ARCALYST as a composition of matter expired in 2020, and relevant composition of matter patents issued outside of the United States expired in October 2023. A United States patent covering methods of using ARCALYST in the treatment of recurrent pericarditis was 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 abiprubart owned by us have statutory expiration dates in 2036, not including any extensions. The issued composition of matter patents licensed from BIDMC related to abiprubart 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

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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.

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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 (supplementary protection certificate) 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 that the legal requirements are met. We may not receive an extension if we or our licensees 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 or our licensees are unable to obtain patent term extension or the term of any such extension is less than requested, the period during which our patent rights can be enforced for that product will be shortened and 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 and Europe covering ARCALYST as a composition of matter have expired, 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 or patent term extensions, and in 2027 in Europe, not including any patent term extensions. We or our licensees 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 adequate and continuing patent protection sufficient to exclude others from commercializing products similar or identical to our product candidates. In such cases, regulatory exclusivity is expected to be relied upon for our or our licensees' 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

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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

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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 or our licensees 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 even then, 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 or our licensees 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 the date our inventions were invented, or may file patent applications before we or our licensees do. In such case, we or our licensees 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 or our licensees 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, product candidates 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 or our licensees. 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, our licensees or our licensors were the first to file any patent application related to our product and 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.

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In addition, we may in the future be subject to claims by our, our licensees' 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, our licensees' 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 or our licensees' ability to stop others from using or commercializing similar or identical technology and products, without payment to us, could limit the duration of the patent protection covering our technology, product and product candidates, or could reduce the period of time during which our licensees are obligated to make royalty payments to us for the sale of licensed products. Such challenges may also result in our inability to manufacture or commercialize our product and 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 or our licensees 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 our product or 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 or 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 or our licensees' ability to successfully commercialize our product or 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 or product candidates, we could lose the ability to continue the development and commercialization of the related product or product candidate. 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 are party to agreements granting us the rights to develop and commercialize ARCALYST, abiprubart, mavrilimumab and vixarelimab. Each of these agreements requires us to use commercially reasonable efforts to develop and commercialize such drugs, make timely milestone and other payments, provide certain information regarding our activities with respect to such drugs 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. Further, disputes may arise between us and any of these counterparties regarding such obligations under, or the intellectual property subject to, such agreements, including:

- our diligence obligations to develop and commercialize the licensed technology, 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;

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- 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 patents and other rights to third parties;
- the ownership of inventions, know-how and other intellectual property, including intellectual property rights resulting from the joint creation or use of intellectual property by us and our licensors, licensees, partners or collaborators;
- 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 in-licensed, out-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, or our sublicensees cause us to fail, to meet our obligations under our agreements in a material respect, the respective licensor/seller would have the right to terminate the respective agreement. We then not only would have to return the licensed technology, but we may also be required to grant the licensor rights to any intellectual property controlled by us and developed during the period the agreement was in force that relate to the applicable licensed technology. This means that the licensor/seller for each of these agreements could effectively take control of the development and commercialization of our product and 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, or our sublicensees cause us to fail, to meet our obligations under these agreements in any material respect, including seeking to cure any breach by us or our sublicensees, 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 in-licenses could result in our loss of exclusive rights and may lead to a complete termination of our product development and any commercialization efforts for our product and 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 or product candidate could impair our ability to raise additional capital, generate revenue and may significantly harm our business, financial condition and prospects.

Additionally, under the Regeneron Agreement, Regeneron retains worldwide rights to develop and commercialize ARCALYST for local administration to the eye and ear and oncology and 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 identifying adverse safety results that may impact the commercialization of ARCALYST for the treatment of recurrent pericarditis in our territory.

We have also entered into agreements to grant to others licenses under our owned intellectual property and sublicenses under intellectual property that we license from others for those third parties to develop and commercialize ARCALYST, mavrilimumab and vixarelimab, including the Huadong Collaboration Agreements and the Genentech License Agreement. Under each of these agreements, our licensees have certain responsibilities to develop and commercialize the applicable licensed drugs, make timely milestone and royalty payments, provide to us certain information regarding their activities and indemnify us with respect to their development and commercialization activities under the terms of the agreements. Additionally, under the Genentech License Agreement, we granted Genentech the first right to file, prosecute, maintain, defend, enforce and extend the life of the patents that we own and licensed to Genentech. These collaborations may be subject to a number of risks, including those listed under "*—Risks Related to Competition, Executing our Strategy and Managing Growth – 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 products and product candidates, and any such transactions or arrangements that we 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 products and product candidates" above.*

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Finally, 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.

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 sublicensees 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 abiprubart and mavrilimumab. If the claims of any of these patents are asserted against us, we do not believe our proposed activities related to abiprubart and mavrilimumab 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 United States patent in court, we would need to overcome a statutory presumption of validity that attaches to every United States 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

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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 licensees 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 or our licensees 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 or our licensees 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 or our licensees 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 our product or one of our product candidates, we or our licensees 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 or our licensees lose a patent lawsuit outside of the United States, alleging our infringement of a competitor's patents, we or our licensees could be prevented from marketing our current or future products and product candidates in one or more such countries. Any of these outcomes would have a materially adverse effect on our business.

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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 ordinary 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 or our licensees 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 or our licensees 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 or our licensees fail to appropriately file and prosecute patent applications covering the licensed products, product candidate or technologies, and maintain any patent issuing from such patent applications, we or our licensees may not be able to stop a competitor from marketing products that are the same as or similar to the licensed products, product candidates or technologies, 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 and 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

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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 or our licensees may not be able to prevent third parties from practicing inventions covered by our patents, whether owned or in-licensed, in all countries outside the United States. Competitors may use our or their technologies in jurisdictions where we or they have not obtained patent protection, or where we or they 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 or our licensees' ability to enforce our patents to stop infringing activities is

inadequate. These products may compete with our products and product candidates or the products and product candidates that we have out-licensed, and our or our licensees' 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 and product candidates, we cannot ensure that we or our licensees will be able to initiate or maintain similar efforts in all jurisdictions in which we or they may wish to market our or our out-licensed products and product candidates. Accordingly, our or our licensees' 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 the ability to obtain and enforce adequate intellectual property protection for our technology.

In addition, geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product or our current or future 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. Current and proposed patent reform in the United States and other countries may contribute to those uncertainties and costs.

The Supreme Court of the United States 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, future actions by the United States Congress, the United States Courts, the USPTO and relevant law-making bodies in other countries could impact our or our licensees' ability to obtain or maintain patent protection for our or our out-licensed proprietary technology or our or their ability to enforce our or our out-licensed proprietary technology, respectively. For example, with respect to patent term adjustment, the Federal Circuit's recent holding in *In re Cellect, LLC*, 81 F.4th 1216 (Fed. Cir. 2023), that obviousness-type double patent analysis for a patent that has received patent term adjustment must be based on the expiration date of the patent after the patent term adjustment has been added, may negatively impact the term of certain United States patents.

Finally, Europe's new Unitary Patent system and Unified Patent Court (the "UPC") may present uncertainties for our ability to protect and enforce our patent rights against competitors in Europe. In 2012, the European Patent Package (the "EU Patent Package"), regulations were passed with the goal of providing a single pan-European Unitary Patent system and a new UPC, for litigation involving European patents. Implementation of the EU Patent Package occurred in June 2023. Under the UPC, all European patents, including those issued prior to ratification of the European

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Patent Package, will by default automatically fall under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents and allow for the possibility of a competitor to obtain pan-European injunctions. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. Under the EU Patent Package we will have the right to opt our patents out of the UPC over the first seven years of the court's existence, but doing so may preclude us from realizing the benefits of the new unified court.

Depending on future actions by governmental authorities, including legislative bodies, administrative authorities and court systems, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents, or may weaken the patent rights of existing patents in certain situations or to enforce our existing patents and patents that we might obtain in the future. If such an event were to occur, our business, financial condition, results of operations and future prospects may be adversely affected.

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 or 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

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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

Conflicts around the globe may have an adverse impact on our operations.

We operate globally and may be impacted by global and regional conflict. Conflict has adversely affected and may continue to adversely affect our clinical development efforts by, for example, limiting the regions and countries in which we may recruit and conduct clinical trials for our product candidates. In the event that conflict occurs after we have begun trials in a region, we may be unable to secure alternative clinical sites when needed or on acceptable terms, if at all. This in turn may cause significant delays or disruptions to our clinical development efforts, which could have a material impact on our business, operations and financial position.

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Furthermore, it is possible that we or our CROs or other third parties with whom we conduct business or otherwise engage, may be subject to retaliatory cyberattacks perpetrated by hostile state or non-state actors in response to economic sanctions or military action. See "*Risk Factors – General Risk Factors – Our information technology systems, or those of our third party CDMOs, CROs, specialty pharmacies, third party logistics providers and 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, impede our development programs for our product candidates or materially impact our ability to commercialize our products.*"

A global pandemic, such as the COVID-19 pandemic, and measures taken in response to such pandemic, could have an adverse impact that is significant on our business and operations as well as the business or operations of the third parties with whom we conduct business or otherwise engage, which may have a material adverse effect on our business, operations and financial position.

Global pandemics, such as the COVID-19 pandemic, and measures taken in response to such pandemics, 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.

In the past, governmental authorities around the globe implemented 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, where we conduct our clinical trials or where we otherwise conduct business or engage with other third parties. In addition, the COVID-19 had a direct impact on our business and operations by, among other things:

- disrupting global supply chains for our products and product candidates, the raw materials required for manufacturing our products and product candidates and important ancillary products needed to administer our products and product candidates;
- causing disruptions, staffing shortages, production slowdowns, stoppages or reprioritizations at the third party CDMOs that we rely on to produce our products and product candidates;
- impeding clinical trial activities, including activities related to enrolling and monitoring our clinical participants;
- limiting our ability to access third party payors, prescribers and patient advocacy groups to build disease awareness;
- limiting our workforce's ability to collaborate in-person at our facilities; and
- causing disruption and volatility in United States and global capital markets.

Such impacts were also felt by a number of the third parties with whom we interact, which further affected our business and operations. In the event that a new global pandemic emerges, or a new variant of the COVID-19 pandemic emerges, we may be subject to the same or similar restrictions and adverse events. We cannot ultimately predict the scope and severity of any such future event; however, such events may be severe and have a material impact on our business, results of operations and financial condition.

If we fail to comply with reporting and payment obligations under the MDRP 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, including the Medicaid Drug Rebate Program (the "MDRP"), the Federal Supply

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Schedule (the "FSS") "FSS") and the PHS 340B Drug Pricing Program. If we are found to have violated the requirements of such programs, we may become subject to penalties or other enforcement mechanisms, which could have a material adverse effect on our business.

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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. Pursuant to the Inflation Reduction Act of 2022 (the "IRA"), the AMP figures we report will also be used to compute rebates under Medicare Part D triggered by price increases that outpace inflation. 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, the EU, the United Kingdom 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.

In the United States, federal and state governments continue to propose and pass legislation designed to reform delivery of, or payment for, health care, which include initiatives to reduce the cost of healthcare generally and drugs specifically. For example, in March 2010, the U.S. Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (the "ACA"), which expanded health care coverage through Medicaid expansion and the implementation of the individual mandate for health insurance coverage and which included changes to the coverage and reimbursement of drug products under government healthcare programs.

Beyond the ACA, there are ongoing and widespread health care reform efforts, a number of which have focused on regulation of prices or payment for drug products. Drug pricing and payment reform was a focus of the Trump Administration and has been a an ongoing focus of the Biden Administration. For example, federal legislation enacted in 2021 eliminates a statutory cap on Medicaid drug rebate program rebates effective January 1, 2024. As another example, the Inflation Reduction Act ("IRA") of 2022 includes a number of changes intended to address rising prescription drug prices in Medicare Parts B and D, with varying implementation dates. These changes include caps on Medicare Part D out-of-pocket costs, Medicare Part B and Part D drug price inflation rebates, a new Medicare Part D manufacturer discount drug program (replacing the ACA Medicare Part D coverage gap discount program) and a drug price negotiation program for certain high spend Medicare Part B and D drugs (with the first list of drugs announced in 2023). The impact of the IRA on our business and the broader pharmaceutical industry remains uncertain as implementation is ongoing. These changes or other changes could affect the market conditions for our products. We expect continued scrutiny on drug pricing and government price reporting from Congress, agencies, and other bodies.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been 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.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price constraints, restrictions on

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copayment assistance by pharmaceutical manufacturers, value-based pricing, marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing.

Healthcare reform efforts have been and may continue to be subject to scrutiny and legal challenge. For example, with respect to the ACA, tax reform legislation was enacted that eliminated the tax penalty established for

individuals who do not maintain mandated health insurance coverage beginning in 2019 and, in 2021, the U.S. Supreme Court dismissed the latest judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. As another example, revisions to regulations under the federal anti-kickback statute would remove protection for traditional Medicare Part D discounts offered by pharmaceutical manufacturers to pharmacy benefit managers and health plans. Pursuant to court order, the removal was delayed and recent legislation imposed a moratorium on implementation of the rule until January 2032. As another example, the IRA drug price negotiation program has been challenged in litigation filed by various pharmaceutical manufacturers and industry groups.

Health care reform at the federal or state level could affect demand for, or pricing of, our product candidates if approved for sale. We cannot, however, predict the ultimate content, timing, or effect of any federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results.

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, such actions may result in changes to 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 which may have a material impact on our business and operations.

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. In addition, global credit and financial markets have recently experienced volatility and disruptions, including severely diminished liquidity and credit availability, rising interest rates, declines in consumer confidence, declines in economic growth, increase in unemployment rates and uncertainty about economic stability.

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, terrorism, political unrest, outbreak of disease, labor disputes 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 United States 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 CDMOs, CROs, specialty pharmacies, third party logistics providers and 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, impede our development programs for our product candidates or materially impact our ability to commercialize our products.

Despite the implementation of security measures, our information technology systems and those of our third party CDMOs, CROs, specialty pharmacies, third party logistics providers and other contractors, consultants and service providers 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. Technologies such as artificial intelligence and machine learning are additionally being used to create more sophisticated attacks on targets, including targeted social engineering attempts. We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees, such as our commercial field force, 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, because we have outsourced elements of our information technology infrastructure to vendors, such vendors may or could have access to our confidential information. A breach at a CDMO, 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 CDMOs, CROs, specialty pharmacies, third party logistics providers and other contractors, consultants and service providers, the

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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. 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. Further disruptions to our or our third party providers' infrastructure may inhibit our ability to commercialize ARCALYST through, among other things, interruptions in our logistics fulfillment, loss of patient and prescriber information, interruptions in our ability to communicate with the third party providers upon which we rely and impairments in our ability to service our patients and address their concerns. Any of these events could adversely impact our business and ability to generate product revenue. Although we maintain cybersecurity insurance coverage, it may not be adequate to cover all liabilities that we may incur from cyberattacks 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; impede our ability 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 professionals, 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 professional 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, directly from individuals (or their healthcare professionals) who enroll in our patient support program and directly from individuals who consent to be included in our marketing database. 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, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (together, the "CCPA") gives California residents expanded rights to access, correct, and delete their personal information, opt out of certain personal information sharing, receive detailed information about how their personal information is used and also imposes limitation son data uses, new audit requirements for higher risk data and opt outs for certain uses of sensitive data. The CCPA provides for civil penalties for violations, as well as a private right of action

for data breaches that has increased the likelihood of, and the risks associated with data breach litigation. Further, the

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California Privacy Rights Act created a California data protection agency authorized to enforce the CCPA and issue substantive regulations, which could result in increased privacy and information security enforcement. Similar laws have been passed in other states and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States. The Washington My Health My Data Act, which will be applicable to companies doing business in Washington or targeting products or services to consumers in Washington beginning in 2024, imposes disclosure and consent requirements, among other things, with respect to broadly defined consumer health data, and is enforceable through consumer class actions. Additional compliance investment and potential business process changes may also be required.

Furthermore, the Federal Trade Commission ("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 GDPR, and legislation of EU member states and EEA countries implementing it. The GDPR imposes strict requirements for processing the personal data of individuals within the EEA. In addition, some of the personal data we process in respect of clinical trial participants is special category or sensitive personal data under the GDPR, and subject to additional compliance obligations and to local law derogations. 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. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease or change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and/ or civil claims (including class actions).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.

Case law from the Court of Justice of the European Union ("CJEU") states that reliance on the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism) alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. We currently rely on the EU standard contractual clauses and the UK United Kingdom Addendum to the EU standard contractual clauses, as applicable, to transfer personal data outside the EEA and the UK, United Kingdom, including to the United States, with respect to both intragroup and third party transfers. Following a period of legal complexity and uncertainty regarding international personal data transfers, particularly to the United States, we expect the regulatory guidance and enforcement landscape to continue to develop, in relation to transfers to the United States and elsewhere. As a result, we may have to make certain operational changes and we will have to implement revised standard contractual clauses and other relevant documentation for existing data transfers within required time frames.

Further, following the withdrawal of the UK United Kingdom 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 United Kingdom GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK United Kingdom 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. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

The Swiss Federal Act on Data Protection (the "DPA") also applies to the collection and processing of personal data by companies located in Switzerland, or in certain circumstances, by companies located outside of Switzerland. The DPA may lead to an increase in our costs of compliance, risk of noncompliance and penalties for noncompliance as we potentially expand our footprint in Switzerland.

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Failure or perceived failure to comply with the GDPR, the UK United Kingdom GDPR, the DPA and other countries' privacy or data security-related laws, rules or regulations could result in significant regulatory penalties and fines, affect our compliance with contracts entered into with our partners and collaborators, and could have an adverse effect on our reputation, business and financial condition.

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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. In addition, we make public statements about our use, collection, disclosure and other processing of personal data through our privacy policies and information provided on our website. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. If we or our third party CDMOs, CROs or other contractors, consultants or service providers fail to comply, or are perceived to have failed to comply, with applicable regulatory requirements, applicable policies or notices relating to privacy or data protection, contractual or other obligations to third parties, or any other legal obligations, laws, rules, regulations and standards relating to privacy or data protection, 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 investigation or enforcement action, litigation, claims or other proceedings could also generate adverse publicity, harm our reputation, result in significant liability and require that we devote substantial resources that could otherwise be used in other aspects of our business.

Our future success depends on our ability to retain key executives and senior management; attract, retain and motivate qualified personnel; and implement succession planning efforts to ensure our long-term success.

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. An executive terminating their employment or taking an extended leave of absence without sufficient notice may leave a gap in the organization that we may be unable to fill on a timely basis, if at all.

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 corporate, 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

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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

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numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of corporate, scientific, sales, marketing and clinical personnel from other pharmaceutical companies, universities and research institutions, as applicable. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific and clinical personnel. In addition, laws and regulations may restrict our ability to attract, motivate and retain the required level of qualified personnel. For example, our business operations may rely on foreign personnel who require work permits. Any changes in immigration policies, work permit regulations, or visa requirements could adversely affect our ability to retain skilled employees. If work permits are denied, revoked, or not renewed, we may face disruptions in its operations, increased costs for hiring and training replacements, and potential delays in project execution. 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.

Effective succession planning is also important to our long-term success and ability to operate as a generational company. As we encounter employee turnover, including turnover of key personnel, we may be unable to timely train or locate replacement personnel in a way that delays our strategic planning and clinical and commercial execution.

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.

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Conflicts around the globe may have an adverse impact on our operations.

We operate globally and may be impacted by global and regional conflict. Conflict has adversely affected and may continue to adversely affect our clinical development efforts by, for example, limiting the regions and countries in which we may recruit and conduct clinical trials for our product candidates. In the event that conflict occurs after we have begun trials in a region, we may be unable to secure alternative clinical sites when needed or on acceptable terms, if at all. This in turn 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, it is possible that we or our CROs or other third parties with whom we conduct business or otherwise engage, may be subject to retaliatory cyberattacks perpetrated by hostile state or non-state actors in response to economic sanctions or military action. See "*Risk Factors – General Risk Factors – Our information technology systems, or those of our third party CDMOs, CROs, specialty pharmacies, third party logistics providers and 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, impede our development programs for our product candidates or materially impact our ability to commercialize our products.*"

A global pandemic, such as the COVID-19 pandemic, and measures taken in response to such pandemic, could have an adverse impact that is significant on our business and operations as well as the business or operations of the third parties with whom we conduct business or otherwise engage, which may have a material adverse effect on our business, operations and financial position.

Global pandemics, such as the COVID-19 pandemic, and measures taken in response to such pandemics, 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.

In the past, governmental authorities around the globe implemented 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, where we conduct our clinical trials or where we otherwise conduct business or engage with other third parties. In addition, the COVID-19 had a direct impact on our business and operations by, among other things:

- disrupting global supply chains for our products and product candidates, the raw materials required for manufacturing our products and product candidates and important ancillary products needed to administer our products and product candidates;
- causing disruptions, staffing shortages, production slowdowns, stoppages or reprioritizations at the third party CDMOs that we rely on to produce our products and product candidates;
- impeding clinical trial activities, including activities related to enrolling and monitoring our clinical participants;
- limiting our ability to access third party payors, prescribers and patient advocacy groups to build disease awareness;
- limiting our workforce's ability to collaborate in-person at our facilities; and
- causing disruption and volatility in United States and global capital markets.

Such impacts were also felt by a number of the third parties with whom we interact, which further affected our business and operations. In the event that a new global pandemic emerges, or a new variant of the COVID-19 pandemic emerges, we may be subject to the same or similar restrictions and adverse events. We cannot ultimately predict the

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scope and severity of any such future event; however, such events may be severe and have a material impact on our business, results of operations and financial condition.

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. In addition, global credit and financial markets have recently experienced volatility and disruptions, including severely diminished liquidity and credit availability, rising interest rates, declines in consumer confidence, declines in economic growth, increase in unemployment rates and uncertainty about economic stability.

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, terrorism, political unrest, outbreak of disease, labor disputes 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 United States 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.

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Exchange rate fluctuations may materially affect our results of operations and financial condition.

Due to the international scope of our operations, our assets, earnings and cash flows are influenced by movements in exchange rates of several currencies, particularly U.S. dollars, euros, British pounds and Swiss francs. The functional currency of our organization is U.S. dollars, and the majority of our operating expenses and revenue are paid or received, respectively, in U.S. dollars. However, our parent company and many of our subsidiaries are located outside the United States and may pay certain of their expenses in their applicable foreign currency. Further, should we expand our commercial operations outside the United States, we may recognize income in one or more foreign currencies. As a result, our business and operations may be adversely affected by fluctuations in foreign exchange rates between the U.S. dollar, the euro, the British pound, the Swiss franc and other currencies. This may have an adverse impact on our reported results of operations and cash flows from period to period.

The increasing and evolving focus on environmental, social and governance ("ESG") matters could increase our costs, harm our reputation, adversely impact our access to capital and financial results or otherwise adversely impact our business.

There has been increasing and evolving public focus by investors, patients, environmental activists, the media and governmental and nongovernmental organizations on a variety of ESG matters, such as climate change and diversity, equity and inclusion matters. We may experience pressure from stakeholders, including our suppliers, employees, patients and shareholders, to set goals or make commitments relating to ESG matters that affect us, including the design and implementation of specific risk mitigation strategic initiatives relating to ESG topics. If we are not effective in addressing ESG matters affecting our business, or setting and meeting relevant ESG 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 ESG goals that may not be offset by any benefit to our reputation, which could have an adverse impact on our business and financial condition.

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In addition, this emphasis on ESG matters has resulted in the adoption of new laws and regulations, including new reporting requirements, and may result in the adoption of additional laws and regulations in the future. New reporting requirements may be particularly difficult or expensive to comply with and, if we fail to comply, we may be required to issue financial restatements, suffer harm to our reputation or otherwise have our business be adversely impacted. Such ESG matters may also impact our suppliers or patients, which may adversely impact our business, financial condition and results of operations.

In addition, organizations that provide information to investors on corporate governance and related matters have developed ratings processes for evaluating companies on ESG matters. Such ratings are used by some investors to inform their investment or voting decisions.

Unfavorable ESG ratings could lead to negative investor sentiment toward us and/or our industry, which could have a negative impact on our access to and costs of capital. To the extent ESG matters negatively impact our reputation, we may be affected in a number of ways, including an inability to recruit and retain personnel and a decrease in the trading price of our Class A common ordinary shares.

Climate change, and related regulation, may result in increased costs or otherwise negatively impact our operations and harm our business.

The impacts of climate change on the global economy and our industry are rapidly evolving. Physical impacts of climate change (including but not limited to floods, droughts, more frequent and/or intense storms and wildfires), could negatively impact our business and operations, as well as the business and operations of our third party CDMOs and CROs upon whom we rely. Such events may result in damage or loss of our products and product candidates during their manufacture and shipment, cause delays in clinical development due to trial site disasters or result in losses of critical data, any of which may adversely impact our operations. An evolving climate may also result in uncertain and potentially onerous regulatory requirements as agencies and governmental authorities adjust, such as new or changed emissions reporting and auditing requirements. Failure to comply with such requirements in a timely manner may adversely affect our reputation, business, or financial performance.

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Risks Related to Ownership of Our Common Ordinary Shares

The concentration of ownership of our Class B common ordinary 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 ordinary shares, which shares are held primarily by entities affiliated with certain of our directors, and Class B1 common ordinary 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 ordinary shares and may result in our Class A common ordinary shares being undervalued.

Each Class A common ordinary share is entitled to one vote per Class A common ordinary share and each Class B common ordinary share is entitled to ten votes per Class B common ordinary share. Our Class A1 common ordinary shares and Class B1 common ordinary 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 ordinary shares and Class B common ordinary shares. As a result of the multi-class voting structure of our common ordinary shares, our executive officers and certain other members of our senior management collectively control a substantial amount of the voting power of our common ordinary shares and therefore are able to control the outcome of certain matters submitted to our shareholders for approval. As of March 31, 2024 June 30, 2024, the holders of Class A common ordinary shares accounted for approximately 67% 69% of our aggregate voting power and the holders of Class B common ordinary shares accounted for approximately 33% 31% of our aggregate voting power. Our executive officers and certain other members of our senior management hold Class A common ordinary shares and Class B common ordinary shares representing approximately 30% 27% of our aggregate voting power as of March 31, 2024 June 30, 2024 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 ordinary shares, Class A1 common ordinary shares or Class B1 common ordinary shares as set forth in our amended and restated bye-laws. articles of association. For example, as of March 31, 2024 June 30, 2024, entities affiliated with certain members of our directors could convert their Class A1 common ordinary shares and Class B1 common ordinary shares upon 61-days' prior written notice into Class A common ordinary shares and Class B common ordinary shares, respectively, which in the aggregate would result in such entities holding approximately 78% 76% of our aggregate voting

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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 ordinary shares and our Class B1 common ordinary 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 ordinary 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 ordinary shares. Holders of our Class B common ordinary shares, which have ten votes per share on most matters, may have significant control over 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 ordinary 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 ordinary shares may be volatile and fluctuate substantially, which could result in substantial losses for holders of our Class A common ordinary shares.

Our share price may be subject to change as a result of volatility in the stock market driven by events often unrelated to our operating performance. As a result of this volatility, our shareholders may not be able to sell their

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Class A common ordinary shares at or above the price they paid for their shares. The market price for our Class A common ordinary 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;

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- 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 pandemics or other outbreaks of disease and rising inflation rates;
- 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.

Market conditions are often difficult to predict and there can be no assurance as to the performance of our Class A common ordinary shares or that we will not experience any adverse effects that may be material to our consolidated cash flows,

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results of operations, financial position or our ability to access capital. In the past, following periods of volatility in the market, securities class action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management’s attention and resources, which could materially and adversely affect our business and financial condition.

If securities or industry analysts cease publishing about us 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 ordinary 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 ordinary 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 ordinary shares could decrease, which in turn could cause the price of our Class A common ordinary shares or its trading volume to decline.

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

A significant number of our Class A common ordinary shares are issuable upon conversion of our Class B, Class A1, and Class B1 common ordinary shares, subject to certain limitations on conversion. As of March 31, 2024 June 30, 2024, approximately 2.0 million Class A common ordinary shares directly held by our executive officers and directors, inclusive of Class A common ordinary shares issuable upon conversion of our Class B, Class A1, and Class B1 common ordinary 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 (the "Securities Act"), and such rule, Rule 144. In addition, as of March 31, 2024 June 30, 2024, there were approximately 14.0 million 14.2 million Class A common ordinary shares subject to outstanding share options and RSUs under our equity incentive plans that

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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.

A majority of our common ordinary 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, 2024 June 30, 2024, on an as-converted to Class A common ordinary shares basis, these shareholders collectively held approximately 33.8 million of our Class A common ordinary 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 ordinary shares (after certain restrictions on conversion or resale lapse), the market price of our Class A common ordinary shares could decline.

Pursuant to our amended and restated investor rights agreement (our "Investors Rights Agreement"), certain shareholders are entitled to certain registration rights with respect our Class A common ordinary shares, including Class A common ordinary shares issuable upon conversions of our Class B, Class A1, and Class B1 common ordinary shares and upon the exercise of certain rights to acquire Class A common ordinary shares, or collectively registerable securities, under the Securities Act. As of March 31, 2024 June 30, 2024, on an as-converted to Class A common ordinary shares basis, we have registered approximately 31.8 million Class A common ordinary 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 ordinary shares basis, approximately 1.8 million 1.7 million Class A common ordinary shares held by certain of our executive officers as of March 31, 2024 June 30, 2024. If any of these Class A common ordinary 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 ordinary shares could decline.

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

Our amended and restated bye-laws articles of association 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; a limited number of reasons;
- an affirmative vote limitations on the acquisition of 66 2/3% of the voting power more than 30% or more of our voting shares for rights, except through certain "business combination" transactions that have not been approved by our board of directors; defined permitted acquisitions;
- our multiclass common ordinary share structure, which provides our holders of Class B common ordinary 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 ordinary shares; and
- 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. nominated.

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 ordinary 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 ordinary 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.

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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 ordinary 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 Our Jurisdiction of Incorporation and Certain Tax Risks

We are As a result of increased shareholder voting requirements in the United Kingdom relative to Bermuda, company and it we will have less flexibility with respect to our ability to issue new shares.

Under Bermuda law, a company's directors may be difficult for issue, without shareholder approval, any authorized but unissued common shares. English law allows our shareholders to enforce judgments against us or authorize the allotment of share capital which can be issued by our board of directors without shareholder approval, but this authorization must be renewed by the shareholders every five years and executive officers. we cannot guarantee that this authorization will always be approved.

We are a Bermuda exempted company. As a result, the rights of holders of Additionally, subject to specified exceptions, including an opt-out included in our Class A common shares will be governed by Bermuda law and our memorandum articles of association, English law grants statutory preemptive rights to existing shareholders to subscribe for new issuances of shares for cash. English law requires that this opt-out must be renewed by the shareholders at least every five years, and amended and restated bye-laws. The we cannot guarantee that the opt-out of preemptive rights will always be approved. A waiver of pre-emption rights under English law requires approval of the shareholders under Bermuda law may differ from holding at least 75% of the voting rights of shareholders of companies incorporated in other jurisdictions. It an English company. In the future, our plans may be difficult for investors impeded due to enforce in the United States judgments obtained in United States courts against us based on the civil liability provisions a lack of the United States securities laws. It is doubtful whether courts flexibility that we previously enjoyed in Bermuda, will enforce judgments obtained in other jurisdictions, including the United States, against us or potentially materially affecting 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 business, financial condition 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 (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 United States 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 United States corporations. The Bermuda courts, however, would ordinarily be expected to permit a shareholder to commence an

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action***The rights afforded to our shareholders are governed by English law. Not all rights available to shareholders under United States law will be available to holders of our ordinary shares.***

Our parent company is organized under the laws of England and Wales. The rights of holders of our ordinary shares are governed by English law and our articles of association, and these may not provide the same rights as shares offered by American or Bermudan companies.

In addition, English law may be subject change in the name future in ways that are disadvantageous to United States-based shareholders, which could adversely affect the rights of our investors. Rights afforded to shareholders under English law differ in certain respects from the rights of shareholders in companies incorporated in the United States or Bermuda. In particular, English law currently significantly limits the circumstances in which the shareholders of English companies may bring derivative actions (i.e., legal actions brought by a shareholder on behalf of a company to remedy against a wrong to third-party). Under English law, in most cases, only Kiniksa Pharmaceuticals International, plc may be the company where proper plaintiff for the act complained purposes of is alleged to be beyond the corporate power maintaining proceedings in respect of the company or illegal, or would result in the violation wrongful acts committed against it and, generally, neither an individual shareholder, nor any group 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 has 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 in such circumstances. In addition, English law does not afford appraisal rights to dissenting shareholders in the form typically available to shareholders in an American company.

It also may be difficult to enforce foreign civil liabilities against us because of our country of incorporation. See "*—United States investors may find it difficult to enforce their civil liabilities against us.*"

United States investors may find it difficult to enforce their civil liabilities against us.

It may be difficult for U.S. investors to bring and/or effectively enforce suits against us outside of the United States. We are a public limited company incorporated in England and Wales. If a judgment is obtained in the U.S. courts based on civil liability provisions of the U.S. federal securities laws against us or our directors or officers, for any action taken by directors or officers it may, depending on the jurisdiction, be difficult to enforce the judgment in the performance of their duties, except for actions involving fraud non-U.S. courts against us. Accordingly, U.S. shareholders may be forced to bring legal proceedings against us under English law and in the English courts in order to enforce any claims that they may have against us 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 and officers. The enforceability of a U.S. judgment in the United Kingdom will depend on the particular facts of the case as well as the laws and treaties in effect at the time. 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 and the United States.

There are regulatory limitations Kingdom do not currently have a treaty providing for reciprocal recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. Nevertheless, it may be difficult for U.S. shareholders to bring an original action in the English courts to enforce liabilities based 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 U.S. federal 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. laws against us.

We may become subject to unanticipated tax liabilities. liabilities, including liabilities arising from the reallocation of our taxable income among our subsidiaries.

Although we are incorporated under the laws of Bermuda, England and Wales, 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, if greater than our overall effective tax rate, 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 For example, we are currently incorporated under the laws of Bermuda England and currently Wales and have subsidiaries in the United States, the United Kingdom, Bermuda, 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

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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 and uncertainties in laws related to the tax practices and substance requirements system in Bermuda and other jurisdictions the countries in which we have operations, could materially 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 financial condition and Switzerland), the United States, Bermuda, and other jurisdictions, as well as being affected by certain changes currently proposed by the OECD 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 in the future, it could adversely impact our tax position and our effective tax rate. Further, there is no guarantee that we will entirely avoid these risks following the Redomiciliation.

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 reduce net returns to our financial condition. Our actual effective shareholders.

We are unable to predict what tax rate may vary from our expectation and that variance reform 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 proposed 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. 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 carrying on a relevant activity 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”, as defined by the ES Laws, 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 enacted in the future by the Company to comply with United States, United Kingdom, Switzerland or the ES Laws.

In December 2023, the Bermuda Government passed final legislation to introduce a corporate income tax that would be considered when calculating the effective tax rate of Bermuda-incorporated businesses under the OECD's global anti-base erosion ("GloBE") rules. Under this legislation, Bermuda corporate income tax will apply only to multinational enterprises, as defined in the GloBE rules, with EUR 750 million OECD or more in total global revenue in at least two of the previous four accounting periods. The Bermuda corporate income tax legislation will be effective for tax years beginning on or after January 1, 2025. Prior to this legislation, Bermuda did not have corporate income tax. The

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imposition of Bermuda corporate income tax, if applicable to our business, could materially adversely affect the financial condition and results of operations.

Governmental agencies 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 unable to predict whether what effect such changes will occur. If such changes are enacted or implemented, we are unable to predict the ultimate impact would have on our business and therefore there can be no assurance results of operations. Changes in tax rates, laws, practices, treaties, policies or regulations, or the change in interpretation thereof, could increase our business will not be adversely affected. effective tax rate or otherwise affect our financial position, results of operations and financial condition and/or increase the complexity, burden and cost of tax compliance.

We may be treated as a passive foreign investment company ("PFIC") for United States federal income tax purposes. If we were to be classified a PFIC, this could result in adverse United States federal income tax consequences to United States Holders.

We completed an analysis of the Company's and its subsidiaries sources of income and character of their assets for United States federal income tax purposes and determined Although we believe that neither the Company nor any of its subsidiaries would be classified as we were not a PFIC for the taxable year ending December 31, 2022. We plan to perform an analysis to determine whether the Company or its subsidiaries are expected to be treated as PFICs for the taxable year ending December 31, 2023, in 2023 and do not believe that the Company or its subsidiaries will be treated as expect to become a PFIC for the taxable year ending December 31, 2023. However, in 2024, there can be no guarantee that the Company, we, or its our subsidiaries, will not be treated as a PFIC for any taxable period. In this regard, the determination of PFIC classification is not made until after the close of the year and it depends on the amount and character of our annual income and assets, which in turn can depend on the interpretation of regulations and authorities, the application of which can be unclear. A non-United States 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 beneficial owner of our Class A ordinary shares who is (a) an individual who is a citizen of the United States, Holder (as defined below) (b) a corporation organized under the laws of the United States or any state, district or territory thereof, (c) an estate taxable with income subject to United States federal income tax or (d) certain trusts (each, a "United States Holder") owns our Class A common ordinary shares, we will continue to be treated as a PFIC with respect to such United States Holder in all succeeding years during which the United States Holder owns the Class A common ordinary shares, regardless of whether we continue to meet the PFIC test described above, unless we cease to be a PFIC and the United States Holder made a "qualified electing fund" election or "mark-to-market" election for (a) the first taxable year the United States 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 United States Holder made a "deemed sale" election or was qualified to and made a "deemed dividend" election. A "United States Holder" is a beneficial owner of our Class A common shares that, for United States 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 United States federal income tax regardless of its source; or

- a trust that (i) is subject to the supervision of a United States 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 United States 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 United States federal income tax purposes.

If we, or our subsidiaries, are classified as a PFIC for any taxable year during which a United States Holder holds our Class A common ordinary shares, certain adverse United States federal income tax consequences could apply to such United States 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.

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If a United States Holder is treated as owning at least 10% of our shares, by vote or by value, such holder may be subject to adverse United States 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, 2023. Even if we were not classified as a controlled foreign corporation, certain of our non-United States subsidiaries could be treated as controlled foreign corporations because our group includes one or more United States subsidiaries. If a United States Holder is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our shares, such United States 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

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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 United States taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income," and investments in United States 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 United States 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 United States 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-United States 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. United States Holders should consult their tax advisors regarding the potential application of these rules to any investment in our Class A common ordinary shares.

We may encounter unforeseen costs following the Redomiciliation and may not realize meaningful benefits.

On June 27, 2024, we announced the completion of the Redomiciliation pursuant to a scheme of arrangement approved by both the Bermuda Supreme Court and our shareholders. As part of the Redomiciliation, all of the issued and outstanding shares of our former Bermuda parent company were cancelled and our then-shareholders received ordinary shares in our new United Kingdom parent company on a one-for-

one basis. We determined that Bermuda was no longer the most desirable jurisdiction for us and believed that redomiciling our principal holding company to the United Kingdom was in the best interest of our company and shareholders for a number of reasons, including its more expansive tax treaty with the United States. However those determinations were based on a number of key assumptions and we may not realize the benefits we hope to achieve. For example, while we currently do not expect any adverse material impact on our effective tax rate, we cannot give any assurance as to what our effective tax rate will be now that we have completed the Redomiciliation because of, among other things, uncertainty regarding the application of the tax laws and policies of the jurisdictions where we operate. If facts substantially deviate from our assumptions, causing us to not realize the benefits we hope to achieve or to encounter unforeseen costs, our business, financial condition and results of operations could be materially harmed.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

Trading Arrangements

During The following table shows the fiscal quarter ended March 31, 2024, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated a "Rule 10b5-1 trading arrangement" arrangements" or a "non-Rule 10b5-1 trading arrangement" as such terms are arrangements" (as each term is defined under in Item 408 408(a) of Regulation S-K.

S-K) adopted, amended or terminated by our directors and officers during the three months ended June 30, 2024:

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				Trading Arrangement			
Name	Title	Action	Effective Date	Rule 10b5-1	Non Rule 10b5-1	Scheduled Expiration Date of Trading Plan(1)	Maximum Shares Subject to Trading Plan
Sanj K. Patel	Chief Executive Officer and Chairman of the Board	Adoption	April 25, 2024	X		October 17, 2024	325,271
Eben Tessari	SVP, Chief Operating Officer	Adoption	April 29, 2024	X		December 18, 2025	715,680

Ross Moat	SVP, Chief Commercial Officer	Adoption	May 3, 2024	X	April 17, 2025	109,506
John Paolini	SVP, Chief Medical Officer	Adoption	May 16, 2024	X	October 17, 2024	112,217

(1) A trading arrangement may expire on an earlier date if all contemplated transactions are completed before such trading arrangement's expiration date, upon termination by broker or the holder of the trading arrangement or as otherwise provided in the trading arrangement.

Item 6. Exhibits

		Incorporated by Reference				
Exhibit Number	Exhibit Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
3.1	Articles of Association of Kiniksa Pharmaceuticals International, plc	8-K12B	001-38492	3.1	6/28/24	
4.1	Specimen Share Certificate evidencing Class A Ordinary Shares	8-K12B	001-38492	4.1	6/28/24	
4.2	Description of Kiniksa Pharmaceuticals International, plc Securities	8-K12B	001-38492	4.2	6/28/24	
10.1#	Form of Indemnification Agreement for Directors	8-K12B	001-38492	10.1	6/28/24	
10.2#	Form of Indemnification Agreement for Officers	8-K12B	001-38492	10.2	6/28/24	
10.3#	2015 Equity Incentive Plan.	8-K12B	001-38492	10.3	6/28/24	

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		Incorporated by Reference				
Exhibit Number	Exhibit Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
10.4#	2018 Incentive Award Plan and forms of award agreement thereunder	8-K12B	001-38492	10.4	6/28/24	
10.1#+ 10.5#	Consulting 2018 Incentive Award Plan; Subplan for UK Employees and forms of award agreement thereunder	8-K12B	001-38492	10.5	6/28/24	

10.6#	2018 Incentive Award Plan forms of option grant notice and option agreement for German participants, restricted share grant notice and restricted share agreement for German participants, and restricted share unit grant notice and restricted share unit agreement for German participants	8-K12B	001-38492	10.6	6/28/24	
10.7#	2018 Incentive Award Plan forms of option grant notice and option agreement for Swiss participants, restricted share grant notice and restricted share agreement for Swiss participants, and restricted share unit grant notice and restricted share unit agreement for Swiss participants	8-K12B	001-38492	10.7	6/28/24	
10.8#	2018 Employee Share Purchase Plan	8-K12B	001-38492	10.8	6/28/24	
10.9#	Offering document under the 2018 Employee Share Purchase Plan	8-K12B	001-38492	10.9	6/28/24	
10.10#	Agreement for the Provision of Depositary Services and Custody Services, dated as of June 28, 2024, in respect of Kiniksa Pharmaceuticals International, plc A Depositary Receipts and A1 Depositary Receipts among Computershare Trust Company, N.A., Kiniksa Pharmaceuticals International, plc and Holders of A Depositary Receipts and A1 Depositary Receipts	8-K12B	001-38492	10.10	6/28/24	
10.11#	Agreement for the Provision of Depositary Services and Custody Services, dated as of June 28, 2024, in respect of Kiniksa Pharmaceuticals International, plc B Depositary Receipts and B1 Depositary Receipts among Computershare Trust Company, N.A., Kiniksa Pharmaceuticals International, plc and Holders of B Depositary Receipts and B1 Depositary Receipts	8-K12B	001-38492	10.12	6/28/24	
10.12†	Master Services Agreement, dated June 25, 2024, by and between Kiniksa Pharmaceuticals (UK), Ltd. and Dr. Richard Levy Samsung Biologics Co., Ltd.					*
10.2#† 10.13†	Form of 2024 Performance Share Unit Grant Notice Product Specific Agreement, dated June 25, 2024, by and 2024 Performance Share Unit Award Agreement between Kiniksa Pharmaceuticals (UK), Ltd. and Samsung Biologics Co., Ltd.					*
31.1	Rule 13a-14(a) / 15d-14(a) Certification of Chief Executive Officer					*

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		Incorporated by Reference				
Exhibit Number	Exhibit Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith

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	***
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	***

# Indicates management contract or compensatory plan

† Portions of the exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv)

+ Portions of the exhibit have been redacted in compliance with Regulation S-K Item 601(a)(6)

* Filed herewith

** Furnished herewith

*** Submitted electronically herewith

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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. INTERNATIONAL, PLC

Date: April 25, 2024 July 25, 2024

By: /s/ Mark Ragosa

Mark Ragosa

Senior Vice President and Chief Financial Officer

(Principal Financial Officer)

Exhibit 10.1 10.12

MASTER SERVICES AGREEMENT

between

SAMSUNG BIOLOGICS CO., LTD.

and

KINIKSA PHARMACEUTICALS (UK), LTD.

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

This Consulting Master Services Agreement (the (this "**Agreement MSA**") is made and entered into as of November 3, 2023 June 21, 2024 (the "**Effective Date**") by and between Kiniksa Pharmaceuticals (UK), Ltd., a Bermuda exempted private company organized under the laws of England and Wales with a business address Swiss branch office located at Clarendon House, 2 Church Street, Hamilton HM 11, Bermuda ("Grafenaustrasse 5, 6300 Zug, Switzerland (**Kiniksa "Client"**"), and Dr. Richard S. Levy with an address Samsung BioLogics Co., Ltd., a Korean corporation having its principal place of business at [***] ("300, Songdo bio-daero, Yeonsu-gu, Incheon, 21987, Republic of Korea (**Consultant "SBL"**"). Client and SBL are sometimes referred to herein individually as a

WHEREAS, Kiniksa wants the benefit of Consultant's knowledge Client and expertise; and

WHEREAS, Consultant wants SBL wish to enter into a business relationship whereby SBL will provide Services (as defined below) Client with certain services related to Kiniksa, its designees and affiliates, in connection with its global programs and operations, as provided in and subject to this Agreement; biologics development and/or manufacturing;

NOW, THEREFORE,, in consideration of the premises and of the following mutual promises, covenants and conditions herein contained, hereinafter set forth and intending to be legally bound, Kiniksa and Consultant for other valuable consideration, the Parties agree as follows:

1. SECTION 1 Services DEFINITIONS. Kiniksa retains Consultant and Consultant agrees to provide consulting services (the "**Services**") to Kiniksa, its designees and affiliates as Kiniksa may from time to time reasonably request and as specified in Exhibit A attached hereto. Any changes to the Services (and any related compensation adjustments) must be agreed upon in writing between Consultant and Kiniksa prior to commencement
Each of the changes. following capitalized terms as used in this MSA, whether in the singular or plural, shall have the respective meanings set forth below.

1.1 "**Acceptance Procedure**" means the review of the Batch Related Documents and the performance of any test of a Batch of Product that is necessary to verify that the Product delivered meets the Specifications and complies with Regulatory Authority requirements, which activities are conducted by Client before or after SBL's release of a Batch of Product in accordance with the terms and conditions of the applicable PSA and the Quality Agreement.

1.2 "**Affected Party**" means the Party affected by a Force Majeure Event.

1.3 "**Affiliate**" means, with respect to a Party, any corporation, company, partnership or other entity which directly or indirectly, controls, is controlled by or is under common control with such Party. A corporation or other entity shall be regarded as controlling another corporation or other entity if it owns or directly or indirectly controls more than fifty percent (50%) of the voting stock or other ownership interest of the corporation or other entity, or if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or other entity or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other entity.

1.4 "**Annual Service Fees**" means the total Service Fees paid or payable by Client to SBL in a given calendar year (excluding costs of Raw Materials, SBL handling fees, and other expense or cost reimbursements) pursuant to a particular Product Specific Agreement.

1.1 Performance. Consultant agrees to render the Services to Kiniksa or to its designees and affiliates (a) under the general supervision of Kiniksa or its designees and affiliates, and (b) in accordance with prevailing industry standards and practices for the performance of similar services. Consultant will comply with all rules, procedures and standards

promulgated from time to time by Kiniksa with regard to Consultant's access to and use of Kiniksa's property, information, equipment and facilities.

1.2 Third Party Confidential Information. Consultant agrees not to use any trade secrets or other confidential information of any other person, firm, corporation, institution or other entity in connection with any of the Services.

1.3 No Conflicts. Consultant is under no contractual or other obligation or restriction which is inconsistent with Consultant's execution of this Agreement or the performance of the Services. During the Term (as defined below), Consultant will not enter into any agreement, either written or oral, in conflict with Consultant's obligations under this Agreement. Consultant will arrange to provide the Services in such manner and at such times that the Services will not conflict with Consultant's responsibilities under any other agreement, arrangement or understanding or pursuant to any employment relationship Consultant has at any time with any third party.

1.4 Compliance with Applicable Laws. Consultant shall comply with all federal, state, and local applicable laws and regulations in Consultant's performance of the Services.

1.5 Absence of Debarment. Consultant represents that Consultant has not been (a) debarred, convicted, or is not subject to a pending debarment or conviction, pursuant to section 306 of the United States Food Drug and Cosmetic Act, 21 U.S.C. § 335a, (b) listed by any government or regulatory agencies as ineligible to participate in any government healthcare programs or government procurement or non-procurement programs (as that term is defined in 42 U.S.C. 1320a-7b(f)), or excluded, debarred, suspended or otherwise made ineligible to participate in any such program, or (c) convicted of a criminal offense related to the provision of healthcare items or services, or is not subject to any such pending action. Consultant agrees to inform Kiniksa in writing promptly if Consultant is subject to the foregoing, or if any action, suit, claim, investigation, or proceeding relating to the foregoing is pending, or to the best of Consultant's knowledge, is threatened.

1.5 "**Anti-Corruption Laws**" means all Applicable Laws regarding 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 U.S. Foreign Corrupt Practices Act of 1977 (15 U.S.C.§§78dd-1, *et seq*.) as amended, the U.S. Travel Act, the UK Bribery Act 2010, and other anti-corruption laws, in each case, as amended.

1.6 "**Applicable Laws**" means any and all laws, rules, or regulations of any jurisdiction which are applicable to the Parties in carrying out activities described in this MSA or any PSAs that may be in effect from time to time.

1.7 "**Assignment**", "**Assigning**", or to "**Assign**" means a merger, change of control, sale of stock, inheritance of stock, transfer of all or substantially all of the assets, or transfer of all or substantially all rights to any Product.

1.8 "**Background IP**" means any Intellectual Property related to a Product, its use, and/or the Manufacture of such Product, in each case, that is owned and/or controlled by a Party prior to the Effective Date or during the Term other than in the performance of activities under this MSA or any PSAs.

1.9 "**Batch**" means the quantity of Product Manufactured by SBL that results from a single run of the applicable Manufacturing Process.

1.10 "**Batch Failure**" means that a Batch is Non-Conforming Product as reasonably determined by the Core Team during Manufacture of a Batch and prior to SBL's Batch release.

1.11 "**Batch Record**", if not defined in the Quality Agreement, means the document, proposed by SBL and approved by Client, that defines the manufacturing methods, test methods, and other procedures, direction, and controls associated with the Manufacturing and testing of Product.

1.12 "**Batch Related Documents**" means Manufacturing Documentation in support of SBL's release of a Product.

1.13 "**Cell Line**" means, with respect to a Product, the cell bank vials supplied or otherwise made available to SBL by Client to perform the Services.

1.14 "**Certificate of Analysis**", if not defined in the Quality Agreement, means a document prepared by SBL listing tests performed by SBL or a Permitted Subcontractor and the results of such tests.

1.15 "**Certificate of Compliance**" means a document prepared by SBL with respect to a particular Batch that verifies completion of all operations in accordance with the Batch Record and cGMP, if applicable.

1.16 "**Change**" means any modification, alteration, adjustment, or correction to the Manufacturing Process (including equipment used in the Manufacturing Process), Services, or Specifications.

1.17 "**Client**" is defined in the preamble.

1.18 "**Client Invention**" means any Invention, whether solely made by one or more employees or officers of SBL (or its third party consultant or subcontractor), or jointly made by the Parties, that in each case is derived from, arises out of, or specifically relates to, Client's Background IP, Client Technology, Client's Confidential Information, or any other proprietary right of Client or its third party licensors, vendors, contractors, or other partners or clients. For the avoidance of doubt, notwithstanding any provision to the contrary in this MSA, Inventions that are specific to (a) [***], or (b) [***], are, in each of (a) and (b), Client Inventions provided that Client Inventions do not include [***].

1.19 "**Client Materials**" means reagents and other materials supplied by Client or its third party supplier to be used in the Services hereunder. In the case of a Drug Product PSA, Client Materials may also include Formulated Drug Substance and/or other active pharmaceutical ingredients, which may or may not have been Manufactured by SBL.

1.20 "**Client Technology**" means Know-How, technology, research and other information of Client provided by Client to SBL in connection with this MSA and any applicable PSA, including any such information relating to the Services, Manufacturing Process, analytical methods, quality control analysis, specifications, transportation and storage requirements.

1.21 "**Clinical Product**" means a Formulated Drug Substance or Drug Product that is Manufactured by SBL pursuant to a PSA and that is to be used by Client in a clinical trial in humans.

1.22 "**Commercial Product**" means a Formulated Drug Substance or Drug Product that is Manufactured by SBL pursuant to a PSA and that is intended for commercial sale for use in humans and for importation or exportation into countries or regions designated in such PSA and, with respect to Formulated Drug Substance, is manufactured after SBL obtains any necessary Regulatory Approvals certifying that the Manufacturing Process and the Facility meet the appropriate requirements and comply with cGMP. By way of example and not by way of limitation, any Batches manufactured prior to PAI (defined below) and including the PAI Batches shall not be considered Commercial Product, even if such Batches are intended for commercial sale and use in humans.

1.23 "**Commercially Reasonable Efforts**" means, with respect to an activity to be carried out by a Party pursuant to this MSA or any particular PSA, the carrying out of such activity in a diligent manner, and using efforts and resources comparable to the efforts and resources commonly used in the contract manufacturing of biologics (in the case of SBL) or in the biopharmaceutical industry (in the case of Client) by companies with resources and expertise similar to those of such Party. "Commercially Reasonable Efforts" requires prompt assignment of responsibility for such task or activity to specific qualified employee(s) and allocation of resources designed to advance progress

1.6Non-Referral. The parties agree with respect to such task or activity but does not require the taking of actions that Consultant is under no obligation to solicit, refer, or solicit referrals of patients for any Kiniksa business. Consultant will not receive any benefit of any kind for making any referrals nor suffer any detriment for not making such referrals. The parties further agree that no amount paid hereunder is intended to be, nor shall be construed as, an inducement or payment for referral of or recommending referral of patients for any Kiniksa business by Consultant to Kiniksa or by Kiniksa to Consultant. In addition, the fees charged hereunder do not include any discount, rebate, kickback, or other reduction in charge, and the fees charged hereunder are not intended to be, nor shall they be construed as, an inducement or payment for referral, or recommendation of referral, of business by Consultant to Kiniksa or by Kiniksa to Consultant. The sole purpose of the fee paid to Consultant hereunder is to pay fair market value for the Services provided by Consultant to Kiniksa hereunder.

1.7 Disclosure Requirements. The parties to this Agreement acknowledge that certain states, the United States government, and/or governments and industry groups outside of the United States and/or the federal government require pharmaceutical companies to disclose information on compensation, gifts or other remuneration provided to physicians and other health care professionals and health care organizations. Kiniksa may report information about remuneration provided under this Agreement, as required by law or industry group code. Once reported, such information may be publicly accessible.

2. Compensation.

In consideration for the Services rendered by Consultant to Kiniksa, Kiniksa agrees to pay Consultant the fees set forth in Exhibit A attached hereto. The parties represent and warrant that the fees were determined by the parties through good faith and arms' length bargaining, constitute fair market value for the Services, and have not been determined in a manner that takes into account the volume or value of any business between the parties. Consultant is not required to use or recommend Kiniksa products, and the parties represent and warrant that the fees are not intended to reward Consultant for the use or recommendation of Kiniksa products or to induce Consultant to use or recommend Kiniksa products.

3. Materials; Deliverables.

3.1 Materials. All documentation, information, and biological, chemical and other materials controlled by Kiniksa and furnished to Consultant by or on behalf of Kiniksa ("**Materials**") and all associated intellectual property rights will remain the exclusive property of Kiniksa. Consultant will use Materials provided by Kiniksa only as necessary to perform the Services and will treat them in accordance with the requirements of this Section 3.1. Consultant agrees that it will not use or evaluate those Materials or any portions thereof for any other purpose except as directed or permitted in writing by Kiniksa. Without Kiniksa's prior express written consent, Consultant agrees that it will not analyze the Materials, or transfer or make the Materials available to third parties.

3.2 Deliverables. Consultant shall assign, and hereby assigns, to Kiniksa all rights in and to inventions, discoveries, improvements, ideas, designs, processes, formulations, products, computer programs, works of authorship, databases, mask works, trade secrets, know-how, information, data, documentation, reports, research, creations and other products arising from or made in the performance of the Services (whether or not patentable or subject to copyright or trade secret protection) (collectively, "**Deliverables**"). For purposes of the copyright laws of the United States, Deliverables will constitute "works made for hire," except to the extent such Deliverables cannot by law be "works made for hire." Kiniksa will have the right to use Deliverables for any and all purposes. During and after the term of this Agreement, Consultant will cooperate fully in obtaining patent and other proprietary protection for any patentable Deliverables, all in the name of Kiniksa and at Kiniksa's cost and expense. Such cooperation will include, without limitation, executing and delivering all requested applications, assignments and other documents, and taking such other measures as Kiniksa may reasonably request in order to perfect and enforce Kiniksa's rights in the Deliverables. Consultant appoints Kiniksa its attorney-in-fact to execute and deliver any such documents on behalf of Consultant if Consultant fails to do so. Consultant will, however, retain full ownership rights in and to all templates, programs and other materials developed or obtained or licensed from third parties by Consultant ("**Consultant Property**") prior to or independent of the Services, regardless of whether such Consultant Property is used in the performance of the Services.

Consultant hereby grants to Kiniksa a perpetual, non-exclusive, fully paid-up worldwide license to use Consultant Property solely to the extent required for Kiniksa's use of the Deliverables.

3.3 Third Party Intellectual Property. Consultant will not use any third party intellectual property in performing the Services without Kiniksa's prior written consent.

3.4 Records; Records Storage. Consultant will maintain all materials and all other data and documentation obtained or generated by Consultant in the course of preparing for and providing the Services, including all computerized records and files (the "**Records**") in a secure area reasonably protected from fire, theft and destruction. These Records will be "works made for hire" and will remain the exclusive property of Kiniksa. Upon written instruction of Kiniksa, all Records will, at Kiniksa's option either be (a) delivered to Kiniksa or to its designee, [***], or (b) disposed of, unless such Records are otherwise required to be stored or maintained by Consultant as a matter of law or regulation. In no event will Consultant dispose of any such Records without first giving Kiniksa sixty (60) days' prior written notice of Consultant's intent to do so. Consultant may, however, retain copies of any Records as are reasonably necessary for regulatory or insurance purposes, subject to Consultant's obligation of confidentiality**[***].**

1.24 4.Confidential Information and Publicity.

4.1 Definition."**Common Raw Material**" means a Raw Material that is able to be used across multiple products and/or SBL clients.

1.25 "**Confidential Information**" means any and all scientific, business, financial, contractual, marketing and technical financial information of or business about a Party or a Product that has been or may be disclosed, or to which access is provided, by such Party ("**Disclosing Party**") or any of its representatives to the other Party ("**Receiving Party**") or any of its representatives, that (a) if in writing, is marked "confidential", "proprietary" or with other similar marking at the time of disclosure, or (b) if provided orally or visually, is identified as confidential at the time of disclosure and confirmed in writing to Receiving Party within [***] of such disclosure, or (c) Receiving Party knows or has reason to know is confidential, trade secret or proprietary information owned, possessed of the Disclosing Party at the time of disclosure, or used (d) by Kiniksa its nature is confidential and would be judged so under a reasonable person standard, or its affiliates, learned is disclosed, or provided, under circumstances reasonably indicating it is confidential or proprietary. For clarity, the terms of by Consultant this MSA shall be deemed to be the Confidential Information of both Parties.

1.26 "**Core Team**" means a committee composed of representatives from each of SBL and Client to oversee, review, and coordinate the day-to-day performance of the Services and/or developed by Consultant in connection Manufacture with the goal of ensuring effective communication between the Parties.

1.27 "**Current Good Manufacturing Practices**" or "**cGMP**" means current good manufacturing practices and regulations applicable to the Manufacture of Product that are promulgated by any Regulatory Authority, including as promulgated under and in accordance with (i) the U.S. Federal Food, Drug and Cosmetic Act, Title 21 of the U.S. Code of Federal Regulations, Parts 210, 211, 600, 601 and 610, (ii) relevant EU legislation, including European Directive 2003/94/EC or national implementations of that Directive, (iii) relevant guidelines, including the EU Guidelines for Good Manufacturing Practices for Medicinal Products (Eudralex Vol. 4 and Annexes thereto), (iv) International Conference on Harmonisation Good Manufacturing Practice Guide for Active Pharmaceuticals Ingredients and (v) and any analogous set of regulations, guidelines or standards as defined, from time to time, by any relevant Regulatory Authority having jurisdiction over the development, manufacture or commercialization of the Product, as applicable, in each case as in effect as of the date such manufacturing for the Product are or were conducted.

1.28 "**Damages**" means any direct damages, costs, expenses, fines, penalties (including reasonable attorneys' fees and costs), losses and liabilities.

1.29 "**Decision Memo**" or "**Decision Report**" means a binding memorandum summarizing and memorializing the Parties' discussion, understanding, and agreement as to any aspect of the Manufacture that is not directly and/or specifically elaborated in the MSA, PSA, or any previous Decision Memo.

1.30 "**Development**" means development services that SBL agrees to provide to Client pursuant a separate PSA and/or Scope of Work, which may include but are not limited to, cell line development, analytical and process development conducted to create, transfer, characterize, or test the manufacturing process, optimization studies, laboratory process scale-up, and generation of materials for toxicology studies. These activities are typically not cGMP in nature and conducted in laboratory facilities.

1.31 "**Drug Product**" means a finished or intermediate dosage form that contains a Formulated Drug Substance, generally, but not necessarily, in association with one or more other ingredients.

1.32 "**Drug Substance**" or "**Formulated Drug Substance**" means an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates used in the synthesis of such ingredient.

1.33 "**Effective Date**" is defined in the preamble.

1.34 "**EMA**" means the European Medicines Agency, or any successor agency.

1.35 "**Engineering Batch**" or **"Engineering Run"** or **"ER"** means a Batch manufactured with the purpose of confirming successful transfer and/or implementation of the Manufacturing Process to the Facility.

1.36 "**Facility**" means one or more of the facilities of SBL where the Services shall be performed, as further specified in each PSA.

1.37 "**FDA**" means the United States Food and Drug Administration, or any successor agency.

1.38 "**Firm Period**" has the meaning set forth in the Product Specific Agreement.

1.39 "**Forecast**" means a projection of Client's requirements for delivery of Product.

1.40 "**Force Majeure Event**" means any event or occurrence that is beyond the non-performing Party's control, without such Party's fault or negligence and that by its nature could not have been foreseen by such Party or, if it could have been foreseen, was unavoidable, which events may include fire, explosion, flood, landslide, epidemics, or other acts of God; acts, regulations, export and/or import restrictions, embargos (including but not limited to those promulgated by any U.S. Regulatory Authority), or laws of any government; terrorism, war; failure of public utilities; or acts of decisions of duly constituted municipal, state, national or supra-national governmental authorities or of courts of law. For clarity, changes in cost or availability of materials, components or services, or market conditions will not be deemed Force Majeure Events, provided that it is understood that a Force Majeure Event may make certain materials, components, equipment, fuel, or services unavailable or difficult to procure.

1.41 "**Implementation Plan and Budget**" means an estimated plan and budget of the reasonable and necessary costs that would be incurred by SBL as a result of the implementation of any Change(s), including, without limitation, costs related to (i) process and analytical development and validation; (ii) equipment and/or Facility modifications, qualification, validation, maintenance, and decommissioning/disposal; (iii) document revisions or changes; (iv) additional stability testing; and (v) preparing submissions to Regulatory Authorities.

1.42 "**Indemnified Party**" has the meaning set forth in Section 12.3.

1.43 "**Indemnifying Party**" has the meaning set forth in Section 12.3.

1.44 "**Intellectual Property**" means: (i) patents, trade secrets, copyrights, trademarks, trade names and domain names, rights in designs, rights in computer software, database rights, Know-How, and any other intellectual property rights, in each case whether registered or unregistered; (ii) all applications (or rights to apply) for, and renewals or extensions of, any of the rights described in the foregoing sub-clause (i); and (iii) all rights and applications that are similar or equivalent to the rights and applications described in the foregoing sub-clauses (i) and (ii), that exist now, or that come to exist in the future, in any part of the world.

1.45 "**Invention**" means any Intellectual Property that arises out of or results from the Services under this MSA or any applicable PSA.

1.46 "**Joint Steering Committee**" or "**JSC**" means a committee composed of representatives from each of SBL and Client to provide guidance to the Core Team and resolve any issues or disputes which are not able to be resolved by the Core Team.

1.47 **"Know-How"** means 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, processes, practices, discoveries, inventions, specifications, dosage regimens, analytical and control assays, product specifications, analytical and quality control data, marketing, pricing, distribution cost and sales data or descriptions, designs, trade secrets, regulatory documentation, and other technology, whether or not labeled "Confidential", 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.

1.48 "**Manufacturing**" or to "**Manufacture**" means the cGMP manufacturing of the Product, and any services relating to such manufacturing, including, but not limited to, (a) Deliverables, Materials, scientific data process development, Engineering Batch services, processing, testing, filling, finishing, quality assurance, quality control, documentations, archiving, and sequence information, (b) marketing plans, business strategies, financial information, forecasts, personnel information packaging, and customer lists of Kiniksa and its affiliates, and (c) all information of third parties that Kiniksa has an obligation up to keep confidential.

4.2 **Obligations of Confidentiality**. During the Term and for a period of five (5) years thereafter, Consultant will not directly or indirectly publish, disseminate or otherwise disclose, use for Consultant's own benefit or for the benefit of a third party, deliver or make available to any third party, any Confidential Information, other than in furtherance release of the purposes of Product, to be performed by SBL under this Agreement, MSA and only then with the prior written consent of Kiniksa. Consultant will exercise all reasonable precautions to physically protect the integrity and confidentiality of the Confidential Information. any applicable PSA.

1.49 **4.3**"**Exceptions. Manufacturing Documentation**Consultant will have no obligations of confidentiality and non-use" means, with respect to any portion a given Product, the data acquired and generated, documents and records describing or otherwise related to the Manufacturing Process including, without limitation: documents and records consisting of or containing process descriptions, requirements and specifications; Client Materials and Specifications; analytical methods, process trend and variability data; validations protocols and reports; Batch Records; Batch Related Documents, and SOPs.

1.50 "**Manufacturing Process**" means, with respect to a given Product, the mutually agreed production process for the Manufacturing of such Product, which shall be deemed to commence at the OOF date for Formulated Drug Substance and the thawing date for Drug Product, as applicable, and end with SBL's release of the Confidential Information which: Product.

(a) **1.51** "**Non-Affected Party**is " means the Party other than the Affected Party.

1.52 "**Non-Conforming Product**" means a Batch of Product that fails to conform to (a) the Specifications, or later becomes generally available to (b) other mutually agreed upon written express requirements, which [***].

1.53 "**OOF**" or "**Out-of-Freeze**" means the public by use, publication thawing of the cell bank vials.

1.54 "**Party**" and "**Parties**" has the meaning set forth in the preamble.

1.55 "**Permitted Subcontractor**" has the meaning set forth in Section 3.4.

1.56 "**Pilot Batch**" means a Batch of Product (not in compliance with cGMP or the like, through no fault Specifications) used in the process development or optimization stage and may be used to support formal stability studies and also to support pre-clinical and clinical evaluations.

1.57 "**Pre-Approval Inspection**" or "**PAI**" means an on-site inspection of Consultant; the Facility by a Regulatory Authority prior to granting Regulatory Approval for Commercial Product as required by such Regulatory Authority to ensure that the Manufacturing Process and the Facility meet the appropriate requirements and comply with cGMP.

(b) **1.58** "**Pre-Approval Inspection Batch**is obtained " or "**PAI Batch**" means a Batch of Product produced during or in support of a Regulatory Authority granting Regulatory Approval for SBL to produce Commercial Product.

1.59 "**Process Validation Batch**" or "**Process Performance Qualification Batch**" or "**PPQ Batch**" means a Batch of Product produced from a third process validation run conducted by SBL to (i) demonstrate and document the consistency and reproducibility of the Manufacturing Process at the Facility, and (ii) support the Regulatory Approval of both the Product Manufactured and the Manufacturing Process at the Facility.

1.60 "**Product**" means Clinical Product or Commercial Product Manufactured by SBL pursuant to this MSA and any applicable PSA and any Formulated Drug Substance manufactured by SBL pursuant to this MSA and any applicable PSA, including PPQ Batches and PAI Batches.

1.61 "**Product-in-process**" means any unfinished Product under the Manufacturing Process.

1.62 "**Product Purchase Commitment**" has the meaning set forth in Section 4.10.

1.63 "**Product Specific Agreement**" or "**PSA**" means a separate written agreement specific to each Product and/or Service (Formulated Drug Substance, Drug Product, Cell Line development, etc.), entered into and mutually agreed to from time to time by duly authorized representatives of the Parties. Each PSA shall refer to and be integrated in this MSA and may include, without limitation, details such as (i) a clearly defined scope of work of the Services to be performed under such PSA which describes key activities and assumptions, (ii) the Product for which SBL will perform such Services for Client, (iii) the fees to be paid to SBL by Client for the Services, and (iv) any other deliverables.

1.64 "**PSA Effective Date**" means the effective date of any PSA.

1.65 "**Public Official or Entity**" means any officer, employee, agent, representative, department, agency, de facto official, corporate entity, or instrumentality or subdivision of any government, military, or international organization, including any state-owned or affiliated company or hospital, or any candidate for political office, any political party, who had or any official of a political party.

1.66 "**Purchase Order**" is a commercial document issued by Client to SBL indicating, among other things, the legal right quantity of Product to disclose it be manufactured, the Services to Consultant; be performed, the applicable prices for Product and/or Services, and the estimated delivery or deliverable date, as applicable.

(c) 1.67 "**Quality Agreement**Consultant already possesses, " means the written quality agreement entered into by the Parties that governs the responsibilities related to quality systems and quality requirements for the Product(s) Manufactured hereunder, including quality control, testing and release of such Product(s) at the Facility.

1.68 "**Quarter**" means each period of three (3) consecutive calendar months beginning on January 1, April 1, July 1, or October 1 of each calendar year.

1.69 "**Raw Materials**" means those materials procured by SBL that are used in performing Services, including, but not limited to, chemicals, reagents, filters, excipients, disposable consumables, and secondary packaging materials. Raw Materials exclude the Client Materials.

1.70 "**Regulatory Approval**" means, with respect to a Product, all approvals, licenses, registrations or authorizations from any Regulatory Authority that are necessary for the Manufacture and sale of such Product in a country or other regulatory jurisdiction anywhere in the world.

1.71 "**Regulatory Authority**" or "**Regulatory Authorities**" means any national (e.g., the FDA), supra-national (e.g., the EMA), regional, provincial, state or local regulatory agency, department, bureau, commission, council or other governmental entity anywhere in the world with authority with respect to development, manufacturing, marketing, commercialization, reimbursement or pricing of a pharmaceutical product.

1.72 "**Reserved Capacity**" means the capacity for Manufacturing the Product within SBL's Facility reserved and dedicated to Client, as evidenced further defined in the PSA.

1.73 "**SBL Assignable Error**" means [***].

1.74 "**SBL Invention**" means any Invention, other than a Client Invention.

1.75 "**Scope of Work**" means the document generally forming part of a PSA, specifying in detail the scope and schedule of the Services and the Service Fees as mutually agreed upon by Consultant's the Parties.

1.76 "**Service**" or "**Services**" means any service performed by SBL and related to development and/or manufacturing for Client as specified in a PSA.

1.77 "**Service Fee**" means the fee due and payable to SBL as consideration for SBL's performance of Services and other obligations, but excluding the costs of Raw Materials, SBL handling fees, and other expense or cost reimbursements, as specified in a PSA.

1.78 "**Specialized Raw Material**" means a Raw Material that is intended to be used for a specific Product only.

1.79 "**Specification(s)**" means the mutually agreed tests, references to analytical procedures and acceptance criteria or other criteria for the Products, Client Materials, or Raw Materials, as the case may be, that are provided in documentation as reviewed and approved in writing by the Parties.

1.80 "**Standard Operating Procedure(s)**" or "**SOP(s)**" means the written records that predate standard operating procedures established by and mutually agreed upon by both Parties regarding the receipt thereof. Manufacturing Process.

1.81 In the event that Consultant is required"**Tax**" means all taxes, charges, customs duties, fees, levies, imposts, or withholding of whatever nature imposed by any law or court order regulations in any country in respect of the Services, importation or exportation of Raw Materials, Client Materials, Batches, and Product.

1.82 "**Technology Transfer**" means the activities by the Parties necessary for SBL to disclose any Confidential Information, Consultant will give Kiniksa prompt notice thereof so that Kiniksa perform the Services as further described in the applicable PSA, which may seek an appropriate protective order. Consultant will reasonably cooperate with Kiniksa include, among other things: (i) transfer of the Background IP and Client Material from Client to SBL; (ii) implementation of the Manufacturing Process at the Facility; (iii) Manufacturing Process fit activities; and (iv) tests and studies.

1.83 "**Term**" means the duration for which this MSA stays in its efforts to seek such a protective order.

5. Term and Termination.

5.1 Term. This Agreement will commence on effect, which shall begin as of the Effective Date and remain will be in effect for six (6) months (the as long as any PSA is in effect.

1.84 "**Term U.S. Export Control Laws**") means all applicable U.S. laws and regulations relating to the export or re-export of commodities, technologies, or services, including the Export Administration Act of 1979, 24 U.S.C.§§ 2401-2420, the International Emergency Economic Powers Act, 50 U.S.C.§§ 1701-1706, the Trading with the Enemy Act, 50 U.S.C.§§ 1 et. seq., the Arms Export Control Act, 22 U.S.C.§§ 2778 and 2779, and the International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986.

1.85 "**Warehouse**" means SBL's warehouse for storage of the Product located at [***]. This

SECTION 2 RELATED AGREEMENTS AND EXHIBITS

2.1 Product Specific Agreements. SBL will perform Services for Client as specified in PSAs and in accordance with the terms and conditions of this MSA. In the event of a conflict between any provision of this MSA and the PSA, this MSA shall control, except where the PSA specifically states otherwise.

2.2 **Quality Agreement.** As required, the Parties shall negotiate and enter into a reasonable and customary Quality Agreement(s) applying to the Services performed by and/or Product Manufactured by SBL. If there is any inconsistency between this MSA and the Quality Agreement, the terms and conditions of this MSA shall control, except with respect to matters regarding cGMP and/or Product quality or regulatory requirements, in which case, the Quality Agreement shall control.

SECTION 3 MANAGEMENT OF SERVICE

3.1 **General.** SBL shall adequately staff the Facility with personnel with necessary expertise to perform its obligations under this MSA and any applicable PSA. Each Party will be responsible for its internal decision-making process and for reasonably informing the other Party of decisions and the status of activities affecting the Services in a regular and timely manner. SBL and Client shall at all times make Commercially Reasonable Efforts to complete the Services, as applicable, in accordance with the estimated timelines set forth in the applicable PSA. Client shall use Commercially Reasonable Efforts to supply to SBL all information or materials that may be extended only reasonably required by written agreement between SBL to perform the parties. Services, and SBL shall not [***]. Client shall be responsible for [***].

3.2 **Core Team and Joint Steering Committee.**

3.2.1 **Core Team and Joint Steering Committee**.

(a) Promptly after the Effective Date, the Parties shall establish the Core Team, which shall promptly resolve any issues arising from the Services, including but not limited to those relating to changes to the project assumptions and timelines, development activities, Specifications, or Manufacturing Process. Each Party may temporarily or

permanently replace its Core Team members upon written notice to the other Party (which notice may be provided by email).

(b) **5.2**Promptly after the Effective Date, the Parties shall also establish a Joint Steering Committee, which shall consist of at least **Termination.** Either party [***] senior representatives (at least [***] level or equivalent) appointed by each Party with experience appropriate for service on the JSC given the Services being requested by Client and performed by SBL. Each Party may terminate this Agreement immediately at any time temporarily or permanently replace its JSC members upon written notice to the other party. Party (which notice may be provided by email), *provided that* such replacement meets the requirements outlined above.

3.2.2 **Meetings and Decision Making.** The Core Team and JSC shall meet on schedules and in manners that are acceptable to their respective members. Each Party may, in its reasonable discretion, invite non-member representatives of such Party to attend Core Team or JSC meetings, *provided* that such additional non-member representatives are under enforceable obligations of confidentiality and non-use applicable to the Confidential Information of the other Party at least as stringent as those set forth in this MSA. Each Party shall be responsible for its own expenses of traveling to and participating in any Core Team or JSC meeting. All decisions of the Core Team and JSC shall be made by the unanimous agreement of all of their members or their designated representatives, and shall be reflected in written meeting reports. Written reports of the Core Team and JSC shall be subject to approval by the authorized representatives of the Parties. For clarity, the Core Team and JSC do not have any authority or power to amend or waive any provision of this MSA or any PSA.

3.2.3 **Disputes.** In the event that the Core Team is unable, despite the good faith efforts of the members, to resolve a disputed issue that is within the purview of the Core Team for a period of [***] business days, one Party shall formally request referral of the issue to the JSC. If the dispute still cannot be resolved within an additional [***] days after referral to the JSC, the matter may be handled in accordance with Section 15 (Dispute Resolution).

3.3 **5.3 Effect of Expiration/Termination. Person in Plant.** Upon expiration or termination Client may request up to [***] of this Agreement, neither Consultant nor Kiniksa will have any further obligations its personnel to be on-site at the Facility to observe and consult with SBL during the performance of Services under this Agreement, except that (a) Consultant will terminate MSA and any PSA and such additional personnel in such numbers as deemed necessary shall be accommodated upon mutual agreement. Reasonable expenses associated with such on-site Client personnel shall be passed through to Client by SBL. While at the Facility, all

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Services in progress in an orderly and non-disruptive manner as soon as practical and in accordance with a schedule agreed to by Kiniksa, unless Kiniksa specifies in the notice of termination that Services in progress should be completed, (b) Consultant will deliver to Kiniksa any Materials in Consultant's possession or control and all Deliverables made through expiration or termination, (c) Kiniksa will pay Consultant any monies due and owing Consultant, up to the time of the effective date of termination or expiration, for Services actually performed and all authorized expenses actually incurred, (d) Consultant will promptly refund to Kiniksa any monies paid by Kiniksa in advance for Services not rendered, (e) Consultant will immediately return to Kiniksa all Confidential Information and copies thereof provided to Consultant under this Agreement except for one (1) copy which Consultant may retain solely to monitor Consultant's surviving obligations of confidentiality, (f) Consultant will immediately return to Kiniksa any and all equipment and supplies provided to Consultant under this Agreement, and (g) the terms, conditions and obligations under Sections 1.5, 1.7, 3, 4, 5.3, and 6 will survive expiration or termination for any reason.

6. Miscellaneous.

6.1 Independent Contractor. All Services will be rendered by Consultant as an independent contractor and this Agreement does not create an employer-employee relationship between Kiniksa and Consultant. Consultant will have no rights to receive any employee benefits, such as bonuses, options, health and accident insurance, sick leave or vacation which are accorded to regular employees of Kiniksa or its affiliates. Consultant will not in any way represent itself to be an employee, partner, joint venturer, or agent of Kiniksa. Consultant Client personnel shall have no authority reasonable access to make any statements, representations or commitments of any kind, or all areas as are relevant to take any action, which shall be binding on Kiniksa. In performing the Services, the amount of time devoted by Consultant on any given day will be within Consultant's control, and Kiniksa will rely on Consultant to devote the amount of time necessary to fulfill the requirements of the Agreement in an efficient and timely manner. Consultant is responsible for providing all equipment and supplies required to perform the Services. In the event Kiniksa provides to Consultant any equipment or supplies in connection with the Services, such equipment and supplies shall remain the sole property of Kiniksa, be used solely for performing the Services and, upon Kiniksa's request, Consultant shall promptly return to Kiniksa all such equipment and supplies. Upon reasonable notice, Consultant shall meet with representatives of Kiniksa or one of its affiliates at a location to be designated by the Parties. Consultant shall not in any way represent itself to be an employee, partner joint venturer, or agent of Kiniksa. Consultant shall have no authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on Kiniksa.

6.2 Taxes. Consultant will be solely and unconditionally responsible for any and all federal, state, or local taxes, social security withholding, and other self-employment tax obligations with respect to payments made to Consultant under this Agreement. Consultant will provide Kiniksa with Consultant's taxpayer identification number or social security number, as applicable.

6.3 Assignability and Binding Effect. The Services to be rendered by Consultant are personal in nature. Consultant may not assign or transfer this Agreement or any of Consultant's rights or obligations hereunder except to a corporation of which Consultant is the sole stockholder. In no event will Consultant assign or delegate responsibility for actual SBL's performance of the Services hereunder, provided that SBL may reasonably restrict Client personnel's access to any other natural person. This

Agreement will be binding upon and inure to the benefit certain areas of the Facility as it deems necessary after disclosing to Client the rationale for such restriction, and all such Client personnel shall agree to and comply with confidentiality obligations to third parties, SBL policies and their respective legal representatives, heirs, successors procedures related to safety, confidentiality, and permitted assigns.

6.4 Notices. All notices required or permitted under this Agreement must be in writing cGMP, and must be given by addressing all reasonable instructions of SBL employees at the notice to the address Facility. Client shall remain responsible at all times for the recipient compliance with the terms of this MSA and PSA by its employees and personnel.

3.4 Subcontractors. SBL may subcontract any portion of the Services solely with prior written approval from Client, which approval shall not be unreasonably withheld or delayed, to perform certain Development or Manufacturing activities on behalf of SBL with autonomy to implement and adhere to their own SOPs, which are established without SBL's involvement in approving the same (each such subcontractor for whom Client provides its approval, a "**Permitted Subcontractor**"). In the event SBL subcontracts any portion of the Services, SBL shall ensure that the Permitted Subcontractor carries out the subcontracted portion of the Services as set forth in the MSA, applicable PSA(s) and Quality Agreement, provided however that SBL shall not be responsible for [***]. Any Permitted Subcontractor must undertake in writing obligations of confidentiality and non-use regarding Confidential Information that are substantially the same as those undertaken by the Parties pursuant to this MSA prior to performing any Services. All costs associated with activities subcontracted to a Permitted Subcontractor that are specific to the Services (e.g., viral clearance, Mycoplasma, adventitious virus screen, etc.) will be passed through to Client with an additional [***] handling fee. For clarity and by way of example only, the following activities shall not be considered subcontracted Services, will not be subject to the handling fee described in this Section 3.4, will not require Client's prior written consent, and SBL shall have full responsibility for such activities as if performed by SBL: [***].

3.5 Development and Manufacturing Site. Unless otherwise agreed by Client in writing, all Services shall be performed by SBL at the Facility.

3.6 Manufacturing Documentation. SBL shall maintain Manufacturing Documentation to be true and accurate, and shall keep in strict confidence and shall not use Manufacturing Documentation for purposes other than providing or performing the Services or other obligations hereunder. SBL shall maintain all such Manufacturing Documentation for at least that period specified in the Quality Agreement. SBL will upload such Manufacturing Documentation on [***] or other similar platform and Client will be given access, including viewing and printing access. Upon written request of Client and at mutually agreeable times, Client shall have the right to review Manufacturing Documentation at the Facility as further defined in the Quality Agreement. At Client's request, SBL may provide scanned or printed copies of such Manufacturing Documentation, but Client shall be responsible for reasonable costs associated therewith. SBL shall record and maintain such Manufacturing Documentation in the language as so required in the Quality Agreement or as so required by a Regulatory Authority and in compliance with Applicable Law, provided that SBL shall, at all times, maintain a copy in the English language, if such Manufacturing Documentation is not already in the English language. To the extent necessary, SBL may redact or withhold Manufacturing Documentation provided pursuant to this MSA or any applicable PSA to protect the confidential information of its other address clients or third parties, provided that such redacted or withheld Manufacturing Documentation does not relate to the Services. The form and style of Batch documents, including, but not limited to, Batch production records, lot packaging records, equipment set up control, operating parameters, and data printouts, raw material data, and laboratory notebooks are the exclusive property of SBL. Notwithstanding anything to the contrary, SBL's SOPs not specific to Products, but related to the Facility or Services, may be provided to Client for on-site

review if reasonably requested by Client. Such SOPs cannot be removed from the SBL premises, copied, photographed or otherwise replicated without SBL's permission.

3.7 **Adverse Event Reporting and Product Complaints.** If SBL becomes aware of an adverse event or other safety issue involving Client's Products, SBL must report such matters to Client within one (1) business day of awareness to Client's Global Medical Safety team by email at [***] or phone: 1-833-Kiniksa (1-833-546-4572) in accordance with Client's standard reporting policy. If SBL becomes aware of a product complaint related to Client's Products, SBL must report such matter to Client within [***] of awareness by email at [***].

SECTION 4 SERVICE DESCRIPTIONS

4.1 **Technology Transfer.** Client shall transfer the Client Technology, Client Materials, and Cell Line to SBL in accordance with the plan, timelines and quantities agreed upon by the Parties pursuant to a PSA. In the event that Client agrees to utilize [***] for such Technology Transfer, Client agrees that (a) in the event of any relevant change that affects a Client user's authorization to use such portal, Client shall immediately notify SBL so that SBL may disable their usernames and remove / change passwords in order to secure the SBL Portal and (b) Client shall ensure that all of Client users have up-to-date antivirus software installed on the computer devices used to access such portal.

4.2 **Engineering Batch.** SBL makes no warranty that Engineering Batches will meet the Specifications or be successful, and thus under no circumstances shall SBL be obligated to re-Manufacture an Engineering Batch for [***].

4.3 **Process Validation Batch and Pre-Approval Inspection Batch.** Prior to commencement of Process Validation Batches, SBL and Client shall agree to a validation plan identifying the validation requirements of the Manufacturing Process. The costs of process validation activities are excluded from the price of Process Validation Batches and shall be paid for by Client at the price set forth in the applicable PSA, subject to Client's prior approval on the scope and nature of such validation activities. When Manufacturing Process Validation Batches and Pre-Approval Inspection Batches, SBL shall not [***].

4.4 **Facility Modification and Equipment.** Client and SBL will agree on what equipment in the Facility is necessary to perform the Services, and if Client reasonably deems it necessary to procure additional equipment beyond that which is in the Facility as of the recipient may specify applicable PSA Effective Date, SBL shall procure such equipment at Client's expense in accordance with Section 8.2.4 and SBL shall be responsible during the Term for validation, installation, maintenance, commissioning, and decommissioning at SBL's expense, unless otherwise agreed in writing under by the Parties. Thereafter, if any additional equipment is necessary, such costs shall be dealt with by Section 5 of this procedure. Notices MSA. SBL shall use Commercially Reasonable Efforts to Kiniksa negotiate pricing with the vendors of any equipment deemed necessary to procure and to procure such equipment [***]. Notwithstanding anything to the contrary in this MSA, the ownership of any and all such equipment shall remain at all times with SBL unless otherwise agreed in writing by both Parties, and SBL shall in good faith and in

accordance with its obligations under this MSA or applicable PSA, make such equipment available to perform Services for Client. If additional equipment is purchased pursuant to this Section 4.4, the Parties shall agree in writing as to whether such equipment will be used solely to perform Services for Client or may be used to perform Services for SBL clients in addition to Client.

4.5 **Additional Work.** Should the Parties mutually agree to any additional work to be added to any Scope of Work, the Service Fees for such additional work will be mutually agreed by both Parties and appropriately documented in writing at the time of adding such additional work, and depending on the nature of such additional work, the Parties shall execute a Decision Memo or an amended Scope of Work accordingly. Such Decision Memo or amended Scope of Work must include an estimate of any incremental costs and Client shall bear all additional costs and expenses associated therewith.

4.6 **Raw Materials.**

4.6.1 **Management.** SBL shall procure and maintain a reasonable quantity of Raw Materials required for the Services in accordance with the terms and conditions of this MSA and any applicable PSA. SBL shall use Commercially Reasonable Efforts to negotiate pricing with the vendors of Raw Materials and to procure Raw Materials [***]. On a per-Product basis, SBL shall prepare the categorization of the Raw Materials into (i) Common Raw Materials and (ii) Specialized Raw Materials, and send the categorization to Client for approval as soon as practicable after the Effective Date of the applicable PSA. Client shall approve the categorization in accordance with the terms and conditions of this MSA and any applicable PSA no later than [***] after the receipt of such a categorization from SBL. SBL shall not be [***]. The list of Raw Materials may be amended from time to time, subject to the Parties' mutual agreement; provided, however that, Client shall at all times be solely responsible for the costs of Raw Materials including those used in small scale runs during Technology Transfer, which are not included in the Service Fees. During Technology Transfer, the Core Team shall agree on estimates for Raw Materials anticipated to be consumed in the Manufacture of each Batch. Although SBL will make Commercially Reasonable Efforts to use no more than those amounts, SBL will not be responsible for Raw Materials used in excess of the agreed-upon estimate; provided, however, that SBL shall be responsible for any excess use, loss, spoilage, or waste of such Raw Materials to the extent caused by [***]. The Parties will mutually agree, in good faith and based on industry standard, upon strategies regarding Raw Material safety stock and sourcing from qualified vendors. In the event SBL is not able to utilize any Reserved Capacity for Manufacturing Product according to an agreed-upon forecast or manufacturing plan set forth in a PSA due to [***], then Client shall be responsible for the costs of such Reserved Capacity [***].

4.6.2 **Raw Material Specifications.** Client and SBL shall agree on the Specifications of Raw Materials, including without limitation analytical methods, supplier information including supplier site information, and other information concerning the stability, storage, and safety

thereof that are required for the Manufacturing hereunder, as further described in the Quality Agreement.

4.6.3 **Testing and Evaluation**. SBL or Permitted Subcontractors shall perform all testing and evaluation of Raw Materials as required by the Specifications for the Raw Materials and the cGMPs, as further described in the Quality Agreement, if applicable.

4.6.4 **Storage.** SBL shall secure sufficient and suitable storage for the Raw Materials; provided that such storage requirements shall be customary within SBL's industry. SBL shall exercise reasonable care to preserve and protect Raw Materials from destruction, theft, or other loss after receipt by SBL and prior to Manufacture and except for loss due to [***], Client shall be responsible for [***]. At the end of each [***] of the relevant PSA, Client shall be responsible for the loss of Raw Material to the extent such Raw Material expires or becomes obsolete because [***]. For any Raw Material that is not used during a given [***], if the Raw Material is not expired and has not become obsolete, SBL shall use Commercially Reasonable Efforts to utilize such Raw Material for other clients to the extent such Raw Material is Common Raw Material, and Client shall not be responsible for [***].

4.6.5 **Handling Fee Related to Raw Material.** Raw Materials will be charged on a cost-plus basis to Client in accordance with Sections 8.1(ii) and 8.2.2.

4.7 **Client Materials.**

4.7.1 **Management.** Client shall provide, either by itself or through its third party supplier, to SBL free of charge, Client Materials in amounts reasonably necessary to carry out the Services as agreed by the Parties. SBL shall make Commercially Reasonable Efforts to import the Client Materials to the Republic of Korea in a timely manner, and Client shall provide reasonable assistance necessary for such a timely importation. Delivery conditions for the Client Materials shall be [***] (INCOTERMS 2010) provided that the [***]. During Technology Transfer, the Core Team shall agree on estimates for Client Materials anticipated to be consumed in the Manufacture of each Batch. Although SBL will make Commercially Reasonable Efforts to use no more than those amounts, SBL will not be responsible for Client Materials used in excess of the agreed-upon estimate; provided, however, that (a) SBL shall be responsible for any excessive use, loss, spoilage, or waste of such Client Materials to the extent caused by [***] and (b) notwithstanding anything to the contrary, SBL will not [***]. The Parties will mutually agree, in good faith and based on industry standard, upon strategies regarding Client Material safety stock and sourcing from qualified vendors. In the event SBL is not able to utilize any Reserved Capacity reserved for Manufacturing Product according to an agreed-upon forecast or manufacturing plan [***], then Client shall be responsible for [***].

4.7.2 **Client Material Specifications.** Client shall provide SBL with the Specifications of the Client Materials, including without limitation analytical methods, supplier information, and

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other information concerning the stability, storage, and safety thereof that are required for the Manufacturing hereunder, as may be further described in the Quality Agreement.

4.7.3 **Testing and Evaluation.** SBL shall perform testing of the Client Materials in accordance with the Quality Agreement and/or Client's written instruction prior to the performance of the Manufacturing hereunder, in order to determine whether such Client Materials meet the Specification described in the Quality Agreement (if applicable). SBL shall inform Client of (a) any damage to the Client Materials received that is visually apparent (e.g., damaged or punctured containers and temperature monitoring results outside of predetermined Specifications) within [***] days after SBL's receipt of the Client Materials and (b) any non-conformance of the Client Materials to Specification either: (i) within [***] days after the discovery of any damage or non-conformance and no later than [***] days after SBL's receipt of the Client Materials or (ii) if release testing of Client Materials is not performed until it is needed for Manufacture, within [***] days after the discovery of any damage or non-conformance and no later than [***] days after such release testing is performed; or (iii) as otherwise agreed between the Parties. If, prior to performing any Service on the Client Materials, SBL determines that such Client Materials are defective or damaged, SBL shall not perform Services using such Client Materials and shall follow Client's written instructions regarding disposal or return of such Client Materials to Client [***].

4.7.4 **Storage.** SBL shall secure sufficient and suitable storage for the Client Materials; provided that such storage requirements shall be customary within SBL's industry. SBL shall exercise reasonable care to preserve and protect the Client Materials from loss after receipt by SBL and prior to Manufacture.

4.7.5 **Handling Fee Related to Client Material.** Handling fees relating to the Client Material will be charged to Client in accordance with Sections 8.1(iii) and 8.2.3.

4.8 **Forecasts and Use of Reserved Capacity.** For each Commercial Product, the Parties shall determine a copy mutually agreeable forecasting mechanism, which shall be detailed in writing in each relevant PSA. For Clinical Product, the Parties shall agree upon the number and schedule of Batches to Kiniksa Pharmaceuticals Corp., 100 Hayden Avenue, Lexington, MA 02421, USA, Attention: Legal Department. Notices be Manufactured by SBL in the applicable PSA. In the event SBL is not able to utilize any Reserved Capacity for Manufacturing Product according to an agreed-upon forecast or manufacturing plan set forth in a PSA due to [***] then Client shall be responsible for [***].

4.9 **Purchase Orders**. For each Clinical Product or Commercial Product, Client shall notify SBL in a binding form and procedure to be agreed upon in the applicable PSA requesting a specific amount of Product to be Manufactured in the Purchase Order. The Parties acknowledge that, with or without Purchase Orders issued in advance, SBL may issue an invoice in accordance with this MSA, PSA, or Decision Memo for Services, Raw Materials, handling fees and equipment. The Parties also acknowledge that Client shall not be able to process and pay any such invoices in accordance with Section 8.3 unless and until Client issues a corresponding Purchase Order. Client shall issue such corresponding Purchase Order for any service or payment duly agreed between the Parties no later

than [***] days from entering into a written agreement specifying the scope so that the invoice can be timely processed and paid in accordance with this MSA and any applicable PSA. Notwithstanding the foregoing, the absence of a Purchase Order shall not release Client of its liability for [***].

4.10 **Product Purchase Commitment.** As further set forth in a PSA, during the Term, the Parties may agree that Client will purchase a minimum quantity of Batches of a certain Product in a given year (a "**Product Purchase Commitment**").

4.11 **Batch Failure during Manufacture**

4.11.1 If, during Manufacture of a Batch and prior to SBL's release of such Batch, the Core Team determines that all of such Batch is Non-Conforming Product (a "**Batch Failure**"), SBL shall take Commercially Reasonable Efforts to promptly re-Manufacture and deliver to Client a replacement Batch on a date to be mutually agreed by the Parties, for which Service Fees and associated costs/fees (as set forth in Section 8.1 below) shall be invoiced to and paid for by Client. Client shall ensure that SBL has adequate Client Materials to re-Manufacture such replacement Batches. The remedies contained in this Section 4.11 of this MSA shall be [***] and a Batch Failure shall not constitute a material breach of this MSA or a PSA unless SBL fails to provide the remedies contained in this Section 4.11.

4.11.2 The Parties shall conduct a root cause analysis of the Batch Failure, which shall be done through SBL's deviation process and which result will be reviewed and confirmed by the Core Team. If either the Core Team does not agree on the Batch Failure root cause, or the JSC does not agree on the results of the Core Team's Batch Failure root cause analysis, the Parties shall refer to an independent mutually agreed-on laboratory or firm with international repute, acting as a neutral arbiter, to conduct a root cause analysis of the Batch Failure. The costs of the independent laboratory [***]. The decision of the independent laboratory or firm with international repute must be in writing and will be binding on the Parties.

4.11.3 In the event of Batch Failure, SBL or Client shall be responsible for the following costs as set forth in this Section 4.11.3: (1) the SBL Service Fee to Manufacture the failed Batch; (2) SBL's costs [***]; (3) [***]; and (4) [***] which amounts are to be calculated based on the actual costs of such materials incurred by Client. To the extent the Batch Failure is caused by [***], SBL shall be responsible for (1) – (4) above, and in all other Batch Failure cases, Client shall be responsible for (1) – (4) above. Any such cost responsibility borne by SBL shall be issued as a credit against future invoices by SBL or refund to Client, at Client's option. Notwithstanding anything to the contrary, SBL shall not be responsible in the event of Batch Failure for: (a) [***] and (b) [***].

4.11.4 In the event that any of the foregoing procedures result in a replacement Batch being delivered in a different year than the year in which the original Batch was ordered for delivery by Client, the Service Fee for such re-Manufactured Batch shall be the Service Fee in effect in the year in which the original Batch was ordered.

4.12 Storage, Packaging and Delivery.

4.12.1 Service Deliverables other than Products. Storage, packaging and delivery of the deliverables designated in a PSA other than Products Manufactured shall be made in accordance with the terms and conditions of this MSA, applicable PSA, Quality Agreement and the Applicable Laws.

4.12.2 Products.

(a) Release by SBL and Acceptance by Client.

(i) Release. SBL shall perform all testing in accordance with the Specifications of the Product and release the Product in accordance with the terms and conditions of the Quality Agreement. Upon such release, SBL shall deliver to Client the Batch Related Documents, including a Certificate of Analysis and Certificate of Compliance, in accordance with the terms and conditions of the Quality Agreement.

(ii) Acceptance of Product. Client will complete the Acceptance Procedure and determine the acceptability of such Product in accordance with the terms and conditions of the Quality Agreement and notify SBL of the result within [***] days of Client's receipt of the Batch Related Documents. Upon Client's acceptance, SBL will have [***]. If there are no open investigations and Client does not reject such Product within the [***] day period, then subject to subsection (iii) below, Product will be deemed to have been given (a) three (3) business accepted by Client and SBL will have [***].

(iii) Latent Defects. If, after Client's acceptance of Product, Client finds a hidden defect which could not have been reasonably discovered through customary review of the Batch Related Documents and/or completion of the Acceptance Procedure, which constitutes a Batch Failure and/or Non-Conforming Product ("**Latent Defect**"), then Client shall promptly notify SBL within [***] days of discovery and must make a claim for such Latent Defect on or prior to the date [***], after deposit which SBL will have [***]. The Parties shall conduct a root cause analysis pursuant to Section 4.11.2 to determine whether such Batch constitutes a Batch Failure, in which case the remedies set forth in Section 4.11.3 would apply.

(iv) Non-Conforming. If, during the Acceptance Procedure, any Product is determined by Client as Non-Conforming Product, and SBL confirms such non-conformity, or such non-conformity is confirmed pursuant to Section 4.11.2, such non-conformity shall be treated as a Batch Failure, and the

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remedy set forth in Section 4.11 above shall apply to the Non-Conforming Product *mutatis mutandis*. Notwithstanding anything to the contrary, Client agrees to [***]. The remedies contained in this Section 4.12.2 shall be [***].

(b) Delivery. Shipping conditions for the Product Manufactured hereunder shall be [***] (INCOTERMS 2010), unless otherwise agreed to in the mail applicable PSA. The title to Product hereunder shall be transferred from SBL to Client when [***]. The Parties further agree as follows:

(i) After SBL's release of the Product and prior to each pick-up by Client or Client's designated carrier, SBL shall propose to Client a delivery schedule of the Product, in order for the Parties to agree on it in advance for each pick-up. SBL shall schedule Delivery with proper postage the carrier selected and paid for by Client;

(ii) SBL shall not deliver the Product until it has been instructed to by Client in accordance with the terms and conditions of the Quality Agreement. Client shall confirm specific delivery instructions with SBL prior to SBL's release; Upon SBL's release of Product, SBL shall store the Manufactured Product as described in Section 4.12.2(c) and Client shall compensate SBL for storage costs for the Manufactured Product as set forth in Section 8.1 this MSA;

(iii) SBL shall provide Client with invoice, packing lists, supporting export documents as specified by Client by separate delivery and shipment documentation instructions, together with each shipment of the Product (or such other deliverables); and

(iv) In cooperation with Client and subject to the delivery schedule agreed by the Parties, SBL shall adhere to [***] in shipping all released Product.

(c) Storage, Packaging and Shipping Container.

(i) Pursuant to the terms of this MSA and any applicable PSA, and subject to the availability of space and storage conditions, SBL shall store the Products Manufactured hereunder for the maximum period of storage as set forth in 4.12.2(c)(iii) and Client shall pay storage fees to SBL as set forth in Section 8.1 until the actual delivery date. Client will use Commercially Reasonable Efforts to take possession of Manufactured Product within the timeline set forth in the applicable PSA. During such storage, SBL shall be responsible for risk of loss and damage to Manufactured Product in the event of [***].

(ii) SBL shall store, package, label and prepare shipment according to the Specifications for the Product Manufactured hereunder, the Quality

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Agreement and the SOPs, and using storage and/or shipping containers determined in the applicable PSA.

(iii) If Client does not direct SBL to prepare Manufactured Product to be picked up by Client or Client's designated carrier with a pick-up date within [***] days of Client's receipt of the Batch Related Documents, SBL shall store the Product at the Warehouse, subject to the availability of space and storage conditions, and Client shall pay storage fees to SBL as set forth in Section 8.1 for the period of storage at the Warehouse until the actual delivery date; provided however that under no circumstances shall the period of storage in the Warehouse exceed [***] days. SBL shall be responsible for risk of loss and damage to Manufactured Product in the event of [***].

SECTION 5 CHANGES TO THE SPECIFICATIONS, ANALYTICAL METHODS, MANUFACTURING PROCESS, FACILITY OR EQUIPMENT

5.1 **Approval for Change.** Any Change shall be implemented only with mutual written agreement between the Parties acting reasonably and in good faith and in accordance with the Quality Agreement.

5.2 **Changes Required by cGMP, Regulatory Authorities or Requested by Client.** Except as otherwise expressly set forth to the contrary in the Quality Agreement, in the event that cGMP, a Regulatory Authority, Applicable Law, or any other regulatory or legal authority requires, or Client requests, a Change, SBL shall accommodate such requirements or requests, subject to the following:

(a) Client shall promptly notify SBL in writing of the required and/or requested Change(s), and provide information necessary for SBL to evaluate the effect of such Change(s), and SBL shall promptly advise Client as to any (i) additional equipment required, modifications to the Facility or equipment, and/or additional equipment and the Facility qualification and validation requirements; (ii) Manufacturing Process development, transfer, scale-up, testing, qualification, or validation requirements; (iii) regulatory requirements pursuant to such Changes; (iv) changes to the Manufacturing scheduling and/or Product delivery schedule; and (v) other impacts on the Facility or SBL's ability to manufacture products (including the Products) in the Facility, if any, which may result from such Change(s). The notification and formal approval procedure of such Changes shall be in accordance with the Quality Agreement (i.e., change control procedures) (if applicable). The Parties shall meet in a timely manner to identify and discuss such Changes as appropriate;

(b) Prior to implementation of any such Change(s), SBL shall provide Client with an Implementation Plan and Budget. Following review and approval by Client of such

Implementation Plan and Budget, followed by the Parties' written agreement pursuant to Section 16.9, SBL shall commence implementation of such Change(s);

(c) During any such implementation, SBL shall provide Client with regular updates on the progress of implementation. Subject to any timeframe imposed by Applicable Law, SBL shall exercise Commercially Reasonable Efforts to implement the Change according to the Implementation Plan and Budget's target completion date. SBL shall provide written notice to Client if SBL becomes aware of any cause that may create delay with the implementation of Changes. Following any such notice, both Parties shall discuss in good faith an amendment of the Implementation Plan and Budget; and

(d) The mutually approved written Implementation Plan and Budget shall set forth the allocation of the costs to be incurred by SBL for the implementation of any such Change(s) between the Parties, in accordance with the following principles:

(i) the costs for [***], shall be borne by SBL; provided that where the Change relates [***] in which case the costs shall be borne by Client [***];

(ii) the costs for Changes other than (i) above, and [***] shall be borne by Client; and

(iii) the costs for the Changes other than (i) and (ii) above shall be equitably allocated.

SECTION 6 REGULATORY APPROVALS AND INSPECTIONS.

6.1 **Regulatory Approvals.** To the extent applicable, SBL shall provide reasonable assistance and cooperation in order for Client to obtain and maintain the Regulatory Approvals. The costs and fees associated with such assistance and cooperation, to the extent not detailed in an applicable PSA, shall be borne by Client. As specified in the applicable PSA, the Parties shall discuss and agree on which Regulatory Approvals are to be obtained.

6.2 **Regulatory Approvals for the Facility.** To the extent applicable, SBL shall obtain and maintain all approvals, licenses, registrations or authorizations of any federal, state or local regulatory agency, department, bureau or other governmental entity (other than the Regulatory Approvals, which will be obtained or maintained by Client) that are required to Manufacture the Product at the Facility or perform the Services.

6.3 **Right of Reference**. SBL hereby grants to Client, its Affiliates and its and their sublicensees, with respect to a Product and to the extent applicable through an applicable letter of authorization or third party confidentiality agreement, where necessary, a right to reference SBL's regulatory documents (including drug master file) for the purpose of obtaining and maintaining Client's Regulatory

Approvals with respect to such Product anywhere in the world, given that SBL's confidential regulatory documents will be submitted directly by SBL to the respective Regulatory Authorities.

6.4 **Regulatory Support Activities.** Any regulatory support activities (including Pre-Approval Inspections) required and agreed to by Client to support Regulatory Approval of the Product Manufactured at the Facility shall be performed and supported by SBL as reasonably requested by Client. All such regulatory support activities are excluded from the price of Process Validation Batches, shall be approved by Client in advance, and shall be paid for by Client at the price set out in the applicable PSA. Unless otherwise agreed by the Parties, Client will have the sole right to correspond with and submit regulatory applications and other filings to Regulatory Authorities to obtain Regulatory Approvals or other approvals to import, export, conduct clinical trials with, or sell the Product, alone or in combination with other products when and as Client may deem useful and/or necessary. Accordingly, except as otherwise required by Applicable Laws and Regulatory Authorities' requirements, SBL will not correspond directly with any Regulatory Authority with respect to the Product without, in each instance, first class registered obtaining Client's prior written consent.

6.5 **Regulatory Inspections.** SBL shall notify Client according to the Quality Agreement provisions of any contacts or certified mail prepaid, inquiries by the Regulatory Authorities, including inspections, Pre-Approval Inspections, sample requests, and written correspondence and its result, related to the Product.

SECTION 7 QUALITY COMPLIANCE

7.1 **Quality Agreement.** Both Parties shall adhere to the provisions of the Quality Agreement and the Parties agree that all elements of quality assurance, quality control and the like shall be governed by the terms and conditions of the Quality Agreement. In the event of a conflict between a Quality Agreement and either any provision of this MSA or any PSA, this MSA or PSA shall control except with respect to matters directly and specifically related to Product quality or regulatory requirements in which case, the Quality Agreement will control.

7.2 **Records & Audit.**

7.2.1 **Audit by Client.** Upon Client's request, but no more than [***], SBL shall accept a formal audit of the Facility and, if reasonably requested by Client, the Warehouse, by Client and allow Client to inspect the Facility and, if reasonably requested by Client, the Warehouse, and Manufacture of the Product during provision of the Services solely to ascertain compliance by SBL with the terms of this MSA, any applicable PSA and the Quality Agreement (a "**Standard Audit**"); provided, however that in the event Client uses a third party designee, SBL must [***]. SBL will make Commercially Reasonable Efforts to require vendors or Permitted Subcontractors to accept an audit of their facilities by Client upon similar notice as described in Section 7.2.2 below. In addition to Standard Audits, Client may request a "for cause" audit [***] (a "**For Cause Audit**").

7.2.2 **Audit Notice.** For Standard Audits, Client shall provide SBL with a written notice at least [***] months prior to the initiation of the audit of the Facility and, if reasonably requested by Client, the Warehouse, which shall be conducted on

a mutually agreeable date and time, and with [***]. Client may conduct a For Cause Audit by providing SBL with a reasonable prior notice by email.

7.2.3 **Conduct of Audit.** Access to SBL's facilities shall be coordinated with SBL so as to minimize disruption to SBL's ability to perform services for its other clients. Client representatives must comply with all of SBL's cGMP, confidentiality and security procedures and protocols during such audit. SBL shall at all times cooperate and provide all the documents reasonably required by Client during such audit; provided that, to the extent necessary, SBL may withhold or redact documents to protect the confidential information of its other clients. Client shall be solely responsible for any costs and liability caused by Client's or its representatives' failure to comply with SBL's security, safety or confidentiality instructions.

SECTION 8 CONSIDERATION AND CERTAIN PAYMENT TERMS

8.1 **Consideration.** In consideration for SBL's performance of the Service and other obligations undertaken by SBL pursuant to a PSA, Client shall pay SBL (i) the Service Fees as set forth in the applicable PSA; (ii) a handling surcharge of a [***]; (iii) a handling surcharge of [***]; and (iv) [***].

8.2 **Invoices.**

8.2.1 **Service Fees.** Service Fees shall be invoiced as set forth in the applicable PSA. SBL's invoices pursuant to any applicable PSA shall be electronic, unless otherwise agreed by the Parties.

8.2.2 **Raw Materials.** SBL shall provide to Client an estimated list of Raw Materials (including quantities) needed for any particular cGMP campaign prior to the first OOF for such campaign. SBL shall submit invoices to Client for (i) the cost of Specialized Raw Materials (including any safety stock) upon receipt of the invoice from vendors/suppliers; and (ii) the cost of Common Raw Materials used [***], as applicable. In each case, for all Raw Materials, SBL shall prepare a billing summary detailing the Raw Materials used and the actual costs incurred by SBL to purchase such Raw Materials and send the same to Client in accordance with Section 8.2.5. Within [***] of receiving the billing summary for Raw Materials from SBL, Client shall either (1) accept and issue a Purchase Order, or otherwise adjust the amount of an existing Purchase Order, for the Raw Material in accordance with the billing summary or (2) reject the billing summary based on reasonable grounds, in which case SBL shall promptly re-issue a revised billing summary. Client's failure to accept or reject a billing summary within the [***] period shall be deemed an acceptance of the billing summary. The Parties shall agree upon an invoicing schedule for Raw Materials in each applicable PSA to ensure prompt issuance of invoices by SBL.

8.2.3 **Client Materials.** With respect to the Client Materials, SBL shall submit an invoice to Client for the handling surcharge described in Section 8.1 [***].

8.2.4 **Equipment.** With respect to equipment, in accordance with Section 4.4, SBL shall submit an invoice to Client upon receipt of the relevant invoice from the third party equipment vendor/supplier.

8.2.5 **Disclosure of Original Invoices.** For any Raw Materials or equipment purchased by SBL from third party vendors, Client agrees and acknowledges that SBL shall be under no obligation to disclose the original invoice or any confidential information therein from the vendors due to its confidentiality obligation with such vendors, and that not furnishing such documents shall not constitute a valid ground for rejecting SBL's billing summary or invoice. Client may, however, request a third party audit at Client's expense [***], and confirm through the auditor the sole issue of whether there is any discrepancy or inaccuracy between the vendor's invoices and SBL's billing summary or invoice (without the auditor disclosing any confidential information of the vendor to Client). Should a discrepancy or inaccuracy be found through such an audit, SBL shall be responsible for [***].

8.3 **Payment.**

8.3.1 **Mode of Payment; Foreign Exchange.** All undisputed payments to SBL due under this MSA or any applicable PSA shall be made in US$ within [***] days from the receipt of SBL's invoice in US$ by means of telegraphic transfer to the account with the bank designated by SBL in the applicable invoice without any deduction, deferment, set-off or lien. For the purpose of computing payment amounts owed by Client based on amounts incurred by SBL in a currency other than US$, such currency shall be converted into US$ using the Standard Rate published by the Bank of Korea at the opening of business on such invoice date.

8.3.2 **Taxes.** All prices and charges are exclusive of any Taxes, which shall be paid by Client. For the avoidance of doubt, the foregoing shall not include any taxes imposed on the income or profit of SBL levied on any payment to be made by Client to SBL, each of which shall be solely borne by SBL. Client shall pay or reimburse SBL for all Taxes in connection with the purchase, sale, storage, importation or exportation of any Raw Materials, Client Materials, Batches, or Product or the provision of Services, except to the extent such Taxes are recoverable by or refundable to SBL. SBL agrees to use Commercially Reasonable Efforts to assist Client in claiming exemption under double taxation or similar agreement or treaty from time to time in force to obtain a refund of any customs duties, value added taxes, and other taxes payable by SBL.

8.3.3 **Price Adjustments.** The Service Fees for activities that have not yet started in any particular calendar year will be adjusted on [***] of the following calendar year by an amount that does not exceed [***]. The relevant date for price adjustment under this Section shall be

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the issue date of SBL's invoice. For the sake of clarity, there shall be no price adjustment for Services initiated in one calendar year and completed in the following calendar year.

8.3.4 **Default Interest.** Any amount that is (i) not disputed based on reasonably justifiable grounds and (ii) not paid by a Party to the other when due under this MSA or any PSA shall bear default interest as follows: (a) at a rate of [***] per month on a daily pro rata basis for the first [***] calendar days and (b) at a rate of [***] per month on a daily pro rata basis thereafter until paid in full. In the event there is an amount which is invoiced by SBL but not paid by Client for more than [***] months after the due date, such event shall be considered a material breach of the relevant PSA. Further, notwithstanding anything to the contrary and in addition to all other remedies available to SBL, in the event that there is any undisputed amount (only good-faith dispute based on reasonably justifiable grounds shall be deemed to be in dispute) which is invoiced by SBL but not paid by Client for more than [***] days after the due date, SBL may, without any obligation to do so, suspend the provision of all or a portion of the Services under the MSA or any PSA, provided that Client shall remain liable for all Service Fees owed for the Services provided or Product Manufactured pursuant to the MSA or any PSA prior to any such suspension, and SBL shall not be responsible in any way for any Services so suspended or any Damages arising from such suspension.

SECTION 9 CONFIDENTIALITY

9.1 **Confidential Information.** Both Parties agree to maintain the Disclosing Party's Confidential Information in confidence and not to disclose the Disclosing Party's Confidential Information, in whole or in part, to any third party, and not use the Disclosing Party's Confidential Information for any purpose other than performing their obligations under this MSA or applicable PSA. The Receiving Party recognizes the proprietary nature of the Disclosing Party's Confidential Information and agrees that no right, title, ownership, license, or interest of any character in the Disclosing Party's Confidential Information other than as specifically granted herein, is conveyed or transferred to the Receiving Party. Each Party shall guard such Confidential Information using the same degree of care as it normally uses to guard its own confidential or proprietary information of like importance, but in any event no less than reasonable care. The Receiving Party shall limit disclosure of the Disclosing Party's Confidential Information to its and its Affiliates' directors, officers, employees, consultants and agents ("**Representatives**") only on a need-to-know basis, provided that, the Receiving Party shall undertake procedures such that each of its Representatives to whom the Disclosing Party's Confidential Information is disclosed understands (i) the confidential nature of the Disclosing Party's Confidential Information and (ii) that he or she is under an obligation similar to those contained herein to not disclose the Disclosing Party's Confidential Information.

9.2 **Exceptions.** Notwithstanding Section 9.1 above, Confidential Information shall not include the information that, as evidenced by written records: (a) was at the time of disclosure by the Disclosing Party hereunder publicly known or available; (b) one (1) business day after sending disclosure by the Disclosing Party hereunder, became publicly known or available by publication or otherwise, other than by an unauthorized act or omission by the Receiving Party; (c) was in the possession of the Receiving Party without

confidentiality restriction at the time of the disclosure by the Disclosing Party hereunder; (d) was lawfully received from any third party having the lawful right to make such disclosure, without obligation of confidentiality; or (e) was independently developed by the Receiving Party's directors, officers or employees without reference to the Confidential Information, as demonstrated by records contemporaneous with such development.

9.3 **Authorized Disclosures.** Disclosure of SBL's Confidential Information by Client is permitted in the event that SBL's Confidential Information is reasonably required for Client to obtain or maintain any Regulatory Approvals for the Products in any or all jurisdictions. Disclosure by the Receiving Party is permitted in the event that the Receiving Party needs to disclose such Confidential Information to comply with Applicable Law or orders issued by a Regulatory Authority or other regulatory or governmental agencies, including the FDA and the Securities and Exchange Commission or any nationally recognized overnight delivery service. securities exchange; provided that such Receiving Party shall exercise its Commercially Reasonable Efforts to limit disclosure of the Disclosing Party's Confidential Information to that which is necessary for compliance and to otherwise maintain the confidentiality of the Confidential Information. In the event that such disclosure is required in accordance with this Section 9.3, the disclosing Party shall make reasonable efforts to provide the other Party with a reasonable advance notice and to coordinate reasonably with the other Party with respect to the wording and timing of any such disclosure.

9.4 **Survival of Confidentiality Obligations.** The confidential obligations of the Receiving Party shall survive for a period of [***] years from the expiration or termination of this MSA.

6.5 **9.5** **No Modification.** **Return of the Confidential Information.** This Agreement All written, printed or other tangible manifestations of Confidential Information of the Disclosing Party disclosed under this MSA, and all copies thereof shall be returned to the Disclosing Party (or destroyed at the Disclosing Party's request) by the Receiving Party within [***] days from the written request by the Disclosing Party. All Confidential Information disclosed electronically shall be completely deleted and destroyed by the Receiving Party within [***] days from the written request by the Disclosing Party. Notwithstanding the foregoing, (i) digital backup files automatically generated by the Receiving Party's customary electronic data processing system may be changed only retained and properly stored as confidential files for the sole purpose of backup and will be deleted in accordance with the Receiving Party's retention policy, (ii) a single copy of the Confidential Information may be retained in the secured legal files of the Receiving Party for the sole purpose of determining the scope of obligations incurred by it under this MSA, and (iii) the Receiving Party may keep copies of Confidential Information for which the Receiving Party has a continuing right or license to access or use such Confidential Information; provided that the Receiving Party shall keep such Confidential Information in confidence and will use the Confidential Information solely to comply with the terms of this MSA as well as Applicable Laws.

9.6 **Public Announcements.** Subject to Applicable Law and except as otherwise provided herein, the existence and the terms of this MSA and any PSA and the transactions contemplated herein and therein shall be maintained in confidence by the Parties and their respective Affiliates, officers,

directors, employees, representatives and agents. All public announcements, notices or other communications by one Party regarding this MSA and any PSA to third parties shall require the prior written approval of the other Party, provided that in no event shall consent be required for any filings or disclosures that a Party is required to make to comply with regulation of any stock exchange or other Applicable Law, order or regulation (including SEC regulations), in which case a reasonable advance notice shall be given to the other Party.

SECTION 10 OWNERSHIP OF MATERIALS AND INTELLECTUAL PROPERTY

10.1 **Background Intellectual Property.** It is acknowledged that each Party owns or controls Background IP and nothing in this MSA shall affect such rights in Background IP. Client hereby grants SBL a non-exclusive, non-transferrable, royalty-free, [***] and fully-paid-up right and license to use Client's Confidential Information and Intellectual Property during the Term for the sole purposes of performing the Services as specified in the applicable PSA and in accordance with the terms and conditions of this MSA. Except as otherwise provided herein, the Parties shall not acquire any right, title, or interest in any Background IP of the other Party.

10.2 **Inventions.**

10.2.1 **Client Invention.** SBL shall promptly notify Client of any Client Invention(s), and shall take all reasonable measures to ensure that Client has the sole and exclusive ownership of such Client Invention(s), including without limitation ensuring that any Permitted Subcontractor assigns to SBL any rights such Permitted Subcontractor has in Client Inventions to enable the further assignment of such rights to Client. SBL agrees to assign, and to the extent legally permissible, hereby does assign to Client any and all rights, title and interests in and to any Client Invention and Client hereby accepts such assignment, and SBL shall execute and deliver any documents of assignment or conveyance to effectuate the ownership rights of Client in such Client Invention and related Intellectual Property. Client may use, and otherwise fully-exploit, any Client Invention for any purpose, including, without limitation, filing patent applications covering any Client Invention, and SBL shall provide reasonable cooperation to Client at Client's request and at the expense of Client as to all reasonable out-of-pocket expenses incurred by SBL in providing such cooperation.

10.2.2 **SBL Invention.** SBL shall promptly notify Client of any SBL Invention(s) that are incorporated into the Product or its Manufacture. SBL Inventions shall be the property of SBL and shall not be deemed to be Client Inventions or joint Inventions for the purposes of this MSA. SBL hereby grants to Client a worldwide, irrevocable, nontransferable (except to permitted assignees under this MSA), [***], royalty-free and fully-paid-up right and license under SBL Inventions to make,

use, sell, offer to sell, export and import and otherwise exploit the Product to the extent such SBL Invention is incorporated into the Product or its Manufacture.

SECTION 11 WARRANTIES.

11.1 **The Parties' General Warranties.** Each Party warrants and represents as of the Effective Date that: (i) it has the corporate power and authority to enter into this MSA and has taken all necessary action on its part required to authorize the execution, delivery and performance of this MSA; (ii) it is aware of no legal, contractual or other restriction, limitation or condition that might adversely affect its ability to enter into this MSA and perform its obligations hereunder; (iii) it is duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated; (iv) this MSA (a) has been duly executed and delivered by a writing signed by Consultant and an duly authorized representative of Kiniksa. it, and (b) is the legal, valid and binding obligation of it, enforceable against it in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws now or hereafter in effect relating to or affecting creditors' rights generally; and (v) the execution, delivery and performance of this MSA by it does not and will not (a) violate any Applicable Laws applicable to it, or (b) violate or conflict with any provision of its Articles of Incorporation or By-laws or other organizational documents.

11.2 **Client's Warranties**. Client represents and warrants to SBL that as of the Effective Date of the MSA and during the Term: (a) the formulation, composition, use, distribution, marketing, or sale of the Product shall comply with all Applicable Laws and that, during the Term, Client will perform all obligations and take other necessary actions to be in compliance with such requirements, Applicable Laws, rules and regulations, including applicable cGMPs; (b) Client will comply with all Applicable Laws, and that it will keep SBL informed of any information known to Client which would affect SBL's provision of the Services hereunder; and (c) to the best of Client's knowledge, SBL's use of the Client Materials, the portion of the Manufacturing Process other than developed by SBL, and Client Technology [***] will not infringe any third party's Intellectual Property rights.

11.3 **Anti-Corruption**. Each Party agrees, in its performance of its obligations under this MSA, to comply, and to cause its Affiliates to comply, with all Applicable Laws, including the U.S. Export Control Laws and Anti-Corruption Laws. Each Party shall not knowingly take any action that would cause the other Party to be in violation of the U.S. Export Control Laws or any Anti-Corruption Laws. Further, each Party shall immediately notify the other Party if such Party has any information or suspicion that there may be a violation of any U.S. Export Control Laws or Anti-Corruption Laws in connection with the performance of activities under this MSA.

11.4 **No Bribery**. Each Party and its employees and agents shall 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 third party for purposes of corruptly obtaining or retaining business for or with, or directing business to, any person or entity, 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.

11.5 **No Kickbacks**. Each Party and its employees and agents have not and shall 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 shall ensure that no part of any payment, commission, reimbursement or fee paid by either Party pursuant to this MSA 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 third party customer or to a Public Official or Entity.

11.6 SBL's Additional Warranties and Covenants. SBL represents, warrants and covenants that:

11.6.1 As of the Effective Date and during the Term, (i) SBL is the lawful owner, lessee, operator, or licensee of the Facility, equipment, machinery, as well as permissions required, to enable SBL to perform its obligations under this MSA, and (ii) to the best of SBL's knowledge, SBL's use of the SBL Inventions or SBL Background IP [***] will not infringe any third party's Intellectual Property rights.

11.6.2 All Product Batches, at the time of delivery to Client's designated carrier, shall (a) be Manufactured, packaged, handled and stored in compliance with Specifications, the requirements of cGMPs (except for Pilot Batches and Engineering Batches, unless otherwise agreed), the applicable PSA, the Quality Agreement and all Applicable Laws; (b) comply with the Standard Operating Procedures; (c) not include any materials not provided in the Specifications that would cause it to be adulterated or misbranded within the meaning of Sections 501 or 502 of the U.S. Federal Food, Drug and Cosmetics Act and the regulations promulgated thereunder or other Applicable Law; and (d) be transferred free and clear of any liens, claims or encumbrances of any kind.

11.6.3 It shall assign the performance of Services to personnel qualified to perform the activities set forth in a PSA and perform all obligations under this MSA and any PSA in compliance with all Applicable Laws.

11.6.4 Each Certificate of Analysis will accurately reflect the results of the tests conducted on the Batch of Product to which it relates, each Certificate of Compliance will be accurate and true, and the Batch Records will accurately reflect in all material respects the processes and procedures followed by SBL in Manufacturing the Product.

11.6.5 It will not transfer to any third party any Client Materials or Products Manufactured for Client, other than (i) for the purpose of tests at any testing lab as permitted under this MSA or any applicable PSA, (ii) to a third party designated in writing by Client, or (iii) to any Permitted Subcontractor in accordance with Section 3.4, or otherwise for the purpose of performing under this MSA or any applicable PSA.

11.6.6 It has not been (a) debarred, convicted, or is not subject to a pending debarment or conviction, pursuant to section 306 of the United States Food Drug and Cosmetic Act, 21 U.S.C. § 335a, (b) listed by any government or Regulatory Authorities as ineligible to participate in any government healthcare programs or government procurement or non-procurement programs (as

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that term is defined in 42 U.S.C. 1320a-7b(f)), or excluded, debarred, suspended or otherwise made ineligible to participate in any such program, or (c) convicted of a criminal offense related to the provision of healthcare items or services, or is not subject to any such pending action. SBL agrees to inform Client in writing promptly if SBL is subject to the foregoing, or if any action, suit, claim, investigation, or proceeding relating to the foregoing is pending, or to the best of SBL's knowledge, is threatened.

11.7 No Other Warranties. THE REPRESENTATIONS AND WARRANTIES CONTAINED IN THIS SECTION ARE EXPRESSLY IN LIEU OF AND EXCLUDE, AND THE PARTIES HEREBY EXPRESSLY DISCLAIM AND NEGATE, TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAWS, ALL OTHER REPRESENTATIONS AND WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED (ARISING BY OPERATION OF LAW OR OTHERWISE), INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, EVEN IF THAT PURPOSE IS KNOWN.

SECTION 12 INDEMNIFICATION AND INSURANCE

6.6 **12.1** **Remedies.** **Indemnification by SBL.** It SBL shall indemnify and hold harmless Client, its Affiliates, and their officers, directors, employees or agents from and against any Damages arising or resulting from any third party (which shall exclude Client Affiliates) claims to the extent such Damages are relating to, arising out of, in connection with, or resulting from claims, demands, or actions based upon [***] except to the extent that such Damages are caused by the causes as set forth in Section 12.2 for which Client is understood obliged to indemnify.

12.2 **Indemnification by Client.** Client shall indemnify and agreed hold harmless SBL, its Affiliates, and their officers, directors, employees or agents from and against any Damages arising or resulting from any third party (which shall exclude SBL Affiliates) claims to the extent such Damages are relating to, arising out of, in connection with, or resulting from claims, demands or actions based upon [***] except to the extent that Kiniksa such Damages are caused by the causes as set forth in Section 12.1 for which SBL is obliged to indemnify.

12.3 **Indemnification Procedure.** The foregoing indemnification by SBL or Client shall be conditioned, if and to the extent Damages are based on or related to a third party claim, upon a Party who intends to claim indemnification under Sections 12.1 and 12.2 (the "**Indemnified Party**") (i) providing written notice to the other Party ("**Indemnifying Party**") within [***] days after the Indemnified Party has been given written notice of such third party claim, provided that absence or delay of such prior written notice will not relieve the Indemnifying Party of its obligation to indemnify except to the extent such absence or delay materially prejudices the Indemnifying Party's ability to defend the third party claim; (ii) permitting the Indemnifying Party, upon timely notice by the Indemnified Party, the opportunity to assume full responsibility (at the Indemnifying Party's cost and expense) for the investigation and defense of any such claim with counsel reasonably satisfactory to the Indemnified Party, provided, however, that the Indemnifying Party shall keep the Indemnified Party informed as to the progress of the defense of any claim and that the Indemnified Party shall cooperate in such

defense and shall make available all records, materials and witness reasonably requested by the Indemnifying Party in connection therewith; and (iii) not settling or compromising any such claim without the Indemnifying Party's prior written consent, with such consent not to be unreasonably denied or withheld.

12.4 **Insurance.** Both Parties shall obtain and maintain insurance coverage (whether through purchasing policies, self-insurance, or a combination of both) appropriate to cover their respective liabilities under this MSA, which level of coverage shall be reasonably similar to that of a company in such Party's industry of similar size and activity.

SECTION 13 DISCLAIMER OF CONSEQUENTIAL DAMAGES; LIMITATION OF LIABILITY

13.1 **Disclaimer of Consequential Damages.** [***] NEITHER PARTY WILL BE LIABLE UNDER THIS MSA FOR ANY SPECIAL, PUNITIVE, CONSEQUENTIAL, INCIDENTAL OR OTHER INDIRECT DAMAGES OF ANY TYPE OR NATURE ARISING OUT OF THIS MSA OR ANY PSA, WHETHER BASED IN CONTRACT, TORT, STRICT LIABILITY, NEGLIGENCE OR OTHERWISE, INCLUDING LOSS OF PROFITS OR REVENUES.

13.2 **Limitation of Liability.** Client agrees that SBL's aggregate total liability to Client in respect of any Damages arising under or in connection with a PSA for a given calendar year during the Term (whether in contract, tort, negligence, under indemnity or otherwise however arising) shall be capped at an amount as set forth in the applicable PSA.

SECTION 14 TERM AND TERMINATION

14.1 **Term.** This MSA will become effective as of the Effective Date and will have its own initial term of ten (10) years and shall automatically renew for successive terms of two (2) years each unless either Party gives written notice to the other Party of its intention to terminate the MSA at least eighteen (18) months prior to the end of the then current MSA term. Notwithstanding any provision to the contrary set forth in this MSA, this MSA will remain in effect for as long as any PSA is in effect. Each PSA will specify its own initial term and renewal provision.

14.2 Termination. This MSA or a PSA may be irreparably injured earlier terminated as set forth in this Section 14.2.

14.2.1 Material Breach. A Party may terminate this MSA or any PSA for a material breach by the other Party; provided, however, that the non-breaching Party shall give the breaching Party written notice of such breach and if the breaching Party fails to commence Commercially Reasonable Efforts to cure that breach within thirty (30) days after receipt of such written notice, then the non-breaching Party may terminate this MSA or such PSA by providing written notice of termination.

14.2.2 Insolvency. This MSA may be terminated by either Party upon written notice at any time during this MSA if the other Party: (a) files in any court pursuant to any statute a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such Party, or of its assets; (b) proposes a written agreement of composition for extension of its debts; (c) is served with an involuntary petition against it, filed in any insolvency proceeding which is admitted in the court; or (d) makes an assignment for the benefit of its creditors. The Party affected shall immediately notify the other Party in writing of the occurrence of any of the foregoing events.

14.2.3 Force Majeure. The Parties may terminate a PSA if they are unable to reach a mutually satisfactory solution to a Force Majeure Event in accordance with Section 16.3.

14.2.4 Other Specified Events. The Parties may additionally terminate a PSA as set forth in the applicable PSA.

14.3 Effect of Expiration or Termination.

14.3.1 Payment of Amounts Due. Expiration or termination of this MSA or PSA for any reason shall not exempt either Party from paying to the other Party any amounts owing at the time of such expiration or termination.

14.3.2 Survival. Any termination or expiration of this MSA shall not affect any outstanding obligations due hereunder prior to such termination or expiration, nor shall it prejudice any other remedies that the Parties may have under this MSA. For greater certainty, except as otherwise expressly provided, termination of this MSA, irrespective of the cause, shall not affect any rights or obligations which, from the context thereof, are intended to survive termination or expiration of this MSA, including but not limited to Sections 8 (Consideration and Certain Payment Terms), 9 (Confidentiality), 10 (Ownership of Materials and Intellectual Property), 11 (Warranties), 12 (Indemnification and Insurance), 13 (Disclaimer of Consequential Damages; Limitation of Liability), 14 (Term and Termination), 15 (Dispute Resolution), and 16 (Miscellaneous).

14.3.3 Effect of Termination. Upon termination of a PSA for any reason, SBL shall cease and refrain from performing the Services described in such PSA (including Manufacturing and supplying the Product) for Client unless otherwise provided in this Section 14.3.3, and both Parties shall pursue decommissioning activities as set forth hereunder:

(a) Settlement of Payment. SBL shall be compensated no later than [***] days after a breach termination for:

(i) all Service Fees incurred up to the date of this Agreement; that money damages would not be an adequate remedy termination including the Service Fees for any such breach; and that Kiniksa will be entitled completing the Manufacture of Product-in-process, subject however to Section 14.3.3(b) below;

seek equitable relief,**(ii)** all costs incurred through the date of termination, including injunctive relief the costs of procuring Raw Materials used or purchased for use in connection with Services; and specific performance,

(iii) any unreimbursed procurement fee of additional equipment that SBL has purchased on behalf of Client pursuant to Section 4.4.

(b) **Delivery**. Unless [***], SBL shall continue manufacturing Product-in-process as of the date of termination and deliver the fully manufactured Product to Client in accordance with the schedule then agreed upon by the Parties. As soon as practically possible after the termination and provided that [***], SBL shall deliver to Client or its designee(s) and Client or its designee(s) shall accept (1) any Raw Material purchased for use in connection with Services, (2) any Client Material then in possession of SBL; provided however that the Parties may mutually agree instead to destroy or discard such Raw Material or Client Material, in which case SBL shall promptly destroy or dispose of the same without having making any further use of such materials. Any costs incurred in connection with such a delivery or destruction, as the case may be, shall be [***]; provided that, for all other cases, the Parties shall negotiate in good faith the allocation of all such costs and expenses.

(c) **Termination by SBL pursuant to post Clauses 14.2.1 or 14.2.2**. In the event of termination by SBL pursuant to Clauses 14.2.1 or Clause 14.2.2, the outstanding binding obligations to purchase Product as of the date of termination shall survive termination of such PSA, including but not limited to a bond, Firm Period, Purchase Order, and Minimum Purchase Commitment, and Client shall be responsible for the costs incurred in connection with delivery or disposal of Raw Materials, Client Material, or equipment during decommissioning activities.

(d) **Termination by Client pursuant to Clauses 14.2.1 or 14.2.2**. In the event of termination by Client pursuant to Clauses 14.2.1 or Clause 14.2.2, Client shall be released from any outstanding binding obligations to purchase Product as of the date of termination including but not limited to any obligation pursuant to a remedy for any such breach, Firm Period, Purchase Order, and such remedy will not be Kiniksa's exclusive remedy for any breach Minimum Purchase Commitment, except the decommissioning activities set forth in this Section 14.3.3 of this Agreement. MSA which shall be binding on both Parties.

(e) **Termination by either Party based on Clause 14.2.3**. In the event of termination pursuant to Section 14.2.3, the Parties shall negotiate in good faith and based on industry standards for the handling and delivery of the fully Manufactured Product, Product-in-process, Client Materials, and Raw Materials and the allocation of costs and expenses between the Parties.

14.3.4 **Effect of Expiration.** Upon expiration of a PSA at the end of the initial term or any renewed term of such PSA, SBL shall cease and refrain from performing the Services described in such PSA (including Manufacturing and supplying the Product), and Section 14.3.3 (a) and (b) above shall apply *mutatis mutandis*, and both Parties shall negotiate in good faith the allocation of related costs and expenses for such decommissioning activities.

SECTION 15 DISPUTE RESOLUTION

6.7 15.1 Severability. Informal Discussions Any. Except as otherwise provided herein, in the event of any controversy or claim arising out of or relating to this MSA or any applicable PSA, or the rights or obligations of the Parties hereunder or thereunder, the Parties shall first try to settle their differences amicably between themselves through the Core Team and then JSC level. Thereafter, either Party may initiate informal dispute resolution on the Executive level by sending written notice of the dispute to the other Party, and, within [***] days after such notice, appropriate Executives of the Parties shall attempt resolution by good faith negotiations. If such representatives are unable to resolve promptly such disputed matter within the said [***] days, either Party may refer the matter by written notice to the Chief Executive Officer of the other Party, or his/her designee, and the Chief Executive Officer of such Party, for discussion and resolution. If such individuals or their designees are unable to resolve such dispute within [***] days of such written notice, either Party may initiate arbitration proceedings in accordance with the provisions of this Agreement which are determined Article 15.

15.2 Arbitration. If the Parties do not fully settle a dispute pursuant to Section 15.1, and a Party wishes to pursue the matter, each such dispute, controversy or claim shall be invalid or unenforceable finally resolved by binding arbitration in accordance with the Commercial Arbitration Rules of the International Chamber of Commerce ("ICC"), and judgment on the arbitration award may be entered in any court having jurisdiction will thereof to enforce the arbitration award. The arbitration shall be ineffective conducted by a panel of three persons experienced in the pharmaceutical business, and within [***] days after initiation of arbitration, each Party shall select one person to act as arbitrator and the two Party-selected arbitrators shall select a third arbitrator within [***] days of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the ICC. The place of arbitration shall be New York, New York, United States and all proceedings and communications shall be in English. Either Party may apply to the extent arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this MSA, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of such invalidity that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or unenforceability any other type of damages not measured by a Party's direct compensatory damages, and in such jurisdiction, without rendering invalid all cases, any decision or unenforceable determination by the remaining provisions hereof and without affecting arbitrators shall comply with Article 13, as applicable. The Parties agree that, in the validity event of a good faith dispute over the nature or enforceability quality of any performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other terms of this Agreement in such jurisdiction, or the terms of this Agreement in any other jurisdiction. The parties will substitute for the invalid or unenforceable provision a valid judicial determination.

15.3 Costs and enforceable provision that conforms as nearly as possible with the original intent Fees. Each Party shall bear its own attorneys' fees, costs, and disbursements arising out of the parties.

6.8 Waivers. No waiver of any term, provision or condition of this Agreement in any one or more instances will be deemed to be or construed as a further or continuing waiver of any other term, provision or condition of this Agreement. Any such waiver must be evidenced by arbitration, and shall pay an instrument in writing executed by Consultant or, in the case of Kiniksa, by an officer authorized to execute waivers.

6.9 Entire Agreement. This Agreement (including any exhibits or schedules attached hereto) constitutes the entire agreement equal share of the parties with regard fees and costs of the arbitrators. Absent the filing of an application to correct or vacate the subject matter, arbitration award as permitted by Applicable Law, each Party shall fully perform and with satisfy the exception arbitration award within [***] days after the service of any written agreement between the parties relating to the disclosure or exchange of confidential information, supersedes all previous written or oral representations, agreements and understandings between the parties award on the subject matter. such Party.

6.10

SECTION 16 MISCELLANEOUS

16.1 Notices. Any notice required or permitted under this MSA shall be in writing with duly authorized signature and made to the following addresses:

If to Client:

Kiniksa Pharmaceuticals (UK), Ltd.
Swiss branch office
Grafenaustrasse 5
6300 Zug, Switzerland
Attention: Legal Department

With a copy to:

Kiniksa Pharmaceuticals Corp.
100 Hayden Ave.
Lexington, MA 02421, USA
Attention: Legal Department

If to SBL:

Samsung BioLogics Co., Ltd.
300, Songdo bio-daero, Yeonsu-gu
Incheon 21987, South Korea
Attention: SBL Legal Team

Either Party may change its designated address by notice to the other Party in the manner provided in this Section 16.1.

Any notice shall be deemed to have been delivered on [***] if delivered personally, or on the [***] day after being delivered by a national or internationally recognized overnight or two-day courier service, or on the [***] day of posting if sent by registered or certified mail with return receipt requested and postage prepaid.

16.2 Governing Law. This Agreement and all acts and transactions pursuant hereto and the rights and obligations of the parties hereto MSA shall be governed, construed and interpreted in accordance with the laws of the State of New York, United States and all rights and remedies shall be governed by such laws without giving effect

regard to principles of conflicts of law. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to the transactions contemplated by this MSA.

16.3 Effect of Force Majeure Event. The Affected Party shall not be liable to the other Party for failure to perform or delay in performing its obligation under this MSA or any applicable PSA when such failure or delay is due to Force Majeure Event.

The Affected Party agrees to give the other Party prompt written notice of the occurrence of any Force Majeure Event, the nature thereof, and the extent to which the Affected Party will be unable fully to perform its obligations under this MSA or applicable PSA. If a Force Majeure Event continues for more than one hundred eighty (180) consecutive days, the Parties shall negotiate a mutually satisfactory solution to the problem, if reasonably practicable. The Parties shall discuss the possibility of terminating this MSA or applicable PSA if the Parties fail to reach a mutually satisfactory solution to the Force Majeure Event.

16.4 Assignment.

16.4.1 The rights and obligations under this MSA or any applicable PSA may not be Assigned or transferred by a Party, by operation of law or otherwise, without the express prior written consent of the other Party, which shall not be unreasonably withheld or delayed; *provided, however*, that Client may, without such consent but upon prior written notice to SBL, Assign this MSA or any PSA and its rights and obligations hereunder or thereunder (a) to any of its Affiliates, or (b) in connection with the transfer or sale of all or substantially all of the portion of its business to which this MSA and/or PSA relates through an asset sale or exclusive (sub)license or as resulting from any merger or consolidation of Client with or into a third party; provided however that in each case of (a) and (b), such Affiliate, acquirer or purchaser, as applicable, is (i) creditworthy (or otherwise provides financial security for the performance of its obligations under this MSA and/or PSA reasonably satisfactory to SBL) and (ii) is not, as its primary business, engaged as a contract development and manufacturing organization (i.e., developing and/or manufacturing products on behalf of third party clients). For clarity, if consent to Assignment is necessary, then withholding consent in the event of the potential assignee's refusal to agree in writing to assume all rights and obligations under this MSA or a PSA shall not be deemed unreasonable. Any attempted Assignment in violation of this Section shall be deemed null and void for all purposes. This MSA will be binding upon and inure to the benefit of the parties and their respective legal representatives, heirs, successors and permitted assigns.

16.4.2 In the event of an Assignment, the Party Assigning this MSA or any applicable PSA or all rights and obligations hereunder or thereunder shall be responsible for any and all additional costs and expenses reasonably related to such an Assignment, including but not limited to any additional Services that need to be performed by SBL, in which case such Services must be included in a PSA.

16.5 No Grant of License. Nothing in this MSA shall affect, or grant any right to, patents, know-how or other intellectual property owned by either Party prior to the principles commencement of conflicts this MSA unless otherwise expressly provided in this MSA.

16.6 No Right to Use Names. Except as expressly provided herein, no right, expressed or implied, is granted by this MSA to use in any manner the name of law. either of the Parties or any other trade name, symbol, logo or trademark of the other Party in connection with the performance of this MSA, without the prior written consent of the other Party.

16.7 Independent Contractors. The Parties hereto are independent contractors and nothing contained in this MSA shall be deemed or construed to create a partnership, joint venture, employment, franchise, agency or fiduciary relationship between the Parties.

6.11 16.8 Counterparts. Integration. This Agreement MSA constitutes the entire agreement between the Parties relating to the subject matter of this MSA and supersedes all previous oral and written communications between the Parties with respect to the subject matter of this MSA.

16.9 Decision Memo; Amendment; Waiver. A Decision Memo may be entered into by the Core Teams or JSCs with a binding effect, with it being understood that, (i) in the event of a conflict between a Scope of Work, or Decision Memo and a later executed Decision Memo, the later executed Decision Memo shall prevail and (ii) a Decision Memo may never amend or modify this MSA or any PSA. Except as otherwise expressly provided herein, no alteration of or modification to this MSA or any PSA shall be effective unless made in writing and executed by an authorized representative of both Parties. No course of dealing or failing of either Party to strictly enforce any term, right or condition of this MSA in any number instance shall be construed as a general waiver or relinquishment of counterparts, each such term, right or condition. The observance of which will any provision of this MSA may be deemed an original waived (either generally or any given instance and all either retroactively or prospectively) only with the written consent of which together the Party granting such waiver.

16.10 **Severability.** The Parties do not intend to violate any Applicable Laws. However, if any sentence, paragraph, clause or combination of this MSA is in violation of any law or is found to be otherwise unenforceable, such sentence, paragraph, clause or combination of the same shall constitute one be deleted and the same instrument. Signatures delivered via facsimile or electronic means remainder of this MSA shall be remain binding, provided that such deletion does not alter the basic purpose and treated as if they were original signatures. structure of this MSA.

16.11 **Construction.** The Parties mutually acknowledge that they have participated in the negotiation and preparation of this MSA. Ambiguities, if any, in this MSA shall not be construed against any Party, irrespective of which Party may be deemed to have drafted this MSA or authored the ambiguous provision.

6.12 **16. Headings. Interpretation.** The section captions and headings to this MSA are included solely for convenience only, and are to be of reference and will not control no force or affect the meaning effect in construing or interpretation of interpreting any of the provisions of this Agreement. MSA. Unless context otherwise clearly requires, whenever used in this MSA: (a) the words "include" or "including" shall

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be construed as incorporating, also, "but not limited to" or "without limitation"; (b) the words "hereof," "herein," "hereby" and derivative or similar words refer to this MSA; (c) all references to the word "will" are interchangeable with the word "shall" and shall be understood to be imperative or mandatory in nature. All references to days, months, quarters or years are references to calendar days, calendar months, calendar quarters, or calendar years. Whenever any matter hereunder requires consent or approval, such consent or approval shall not be unreasonably withheld or delayed.

16.13 **Counterparts.** This MSA and any PSA may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, duly authorized representatives of the Parties have executed this MSA as of the Effective Date.

KINIKSA PHARMACEUTICALS (UK), LTD.

Signature: /s/ Vincent Lévêque
Name: Vincent Lévêque
Title: Branch Manager of Swiss branch office

SAMSUNG BIOLOGICS CO., LTD.

Signature: /s/ John Rim
Name: John Rim
Title: CEO & President

Exhibit A: POWER OF ATTORNEY

[***]

Exhibit 10.13

SAMSUNG BIOLOGICS CO., LTD.

PRODUCT SPECIFIC AGREEMENT – COMMERCIAL PRODUCT DRUG SUBSTANCE

This Product Specific Agreement (this "**PSA**") is made effective as of June 21, 2024 (the "**PSA Effective Date**") by and between Kiniksa Pharmaceuticals (UK), Ltd., a private company organized under the laws of England and Wales with a Swiss branch office located at Grafenaustrasse 5, 6300 Zug, Switzerland ("**Client**") and Samsung BioLogics Co., Ltd., a Korean corporation having its principal place of business at 300, Songdo bio-daero, Yeonsu-gu, Incheon, 21987, Republic of Korea ("**SBL**"). Client and SBL are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**".

WHEREAS, Client and SBL entered into a Master Services Agreement effective June 21, 2024 (the "**MSA**") and whereas pursuant to Section 2.1 of the MSA, the Parties wish to enter into this PSA whereby SBL will provide certain Services as detailed herein;

NOW, THEREFORE, the Parties agree as follows:

1. **Relationship to the MSA**. All capitalized terms not defined in this PSA will have the meanings given to them in the MSA. This PSA is hereby incorporated by reference into the MSA.

2. **Definitions**

   a. "**Annual Forecast**" means, for any particular Year, Client's annual projection of its requirement for delivery of Batches of Commercial Product during such Year. For the avoidance of doubt, the Parties acknowledge and agree that while the PPQ Batches and PAI Batches may be used for commercial purposes, they are excluded from any Annual Forecast.

   b. "**Campaign**" means a series of Batches of the Product that are produced in sequence at the Facility followed by validated cleaning of such equipment and purification suite, and for the purposes of counting the number of Product batches in a Campaign in a given period, the start date of such Campaign shall be the determining factor. A Campaign will be deemed to end upon the completion of such cleaning.

   c. "**Firm Period**" means (a) the first [***] of the [***]Year Forecast accepted by SBL, and the first [***] of the Quarterly Forecast accepted by SBL, during which period the Forecast shall be [***] firm and binding on both Parties and (b) the [***] of the [***]Year Forecast accepted by SBL, during which period the Forecast shall be [***] as described in Section 5(d)(i)(4) below.

   d. "[***]**Year Forecast**" has the meaning set forth in Section 5(d)(i)(1).

   e. "**New Batch**" means any Batch of Commercial Product that is requested to be delivered in the Quarter newly entering the Quarterly Forecast (i.e., the Quarter that was not covered by the prior Quarterly Forecast).

   f. "**Product Purchase Commitment Shortfall**" means the difference between the Product Purchase Commitment for any particular Year and the number of Batches of Commercial Product actually purchased by Client in such Year.

   g. "**Quarterly Forecast**" means Client's projection of its requirement for delivery of Batches of Commercial Product in each Quarter over a period of [***] quarters, on a rolling basis. For

the avoidance of doubt, the Parties acknowledge and agree that while the PPQ Batches and PAI Batches may be used for commercial purposes, they are excluded from any Quarterly Forecast. For the sake of clarity, the Quarterly Forecast is intended to specify delivery date(s) for the amount of Commercial Product specified in the first [***] of the [***]Year Forecast.

h. "**Year**" means each one (1) year period that begins on January 1 and ends on December 31.

3. **General Information**.

a. Commercial Product: Arcalyst (rilonacept) Commercial Product Formulated Drug Substance.

b. Commercial Product Indications: As of the PSA Effective Date, indicated in the United States for Cryopyrin-Associated Periodic Syndromes (CAPS), Deficiency of Interleukin-1 Receptor Antagonist (DIRA), and Recurrent Pericarditis (RP)

c. Cell Line: [***]

d. Manufacturing Facility: [***]

4. **Raw Materials**.

a. **Client Materials**.

i. List: See Exhibit A: Client Materials

ii. Handling Fee: [***] of the invoice of third party suppliers from whom Client purchased the Client Materials.

iii. Timing of provision of Client Materials to SBL: [***].

b. **Raw Materials**. As set forth in Section 4.6.1 of the MSA, the Parties shall finalize the categorization of Raw Materials to be used in performing the Services of this PSA into (i) Common Raw Materials, and (ii) Specialized Raw Materials, which list shall form part of this PSA as Exhibit B.

i. Handling fee for Common Raw Materials to be procured by SBL at Client's expense: [***]

ii. Handling fee for Specialized Raw Materials (typically resins, media, and specialized filters) to be procured by SBL at Client's expense: [***]

iii. Handling fee for [***]

The foregoing handling fees shall cover costs related to Raw Material handling, including but not limited to testing, registration and storage.

5. **Technology Transfer, Manufacturing, and Supply Services**. SBL shall perform the Services as set forth in this Section 5.

a. **Services.** SBL shall provide the Services as set forth in Exhibit D in accordance with this PSA.

b. **Service Fees and Invoicing**. In consideration for SBL's performance of the Services pursuant to this Section 5, Client shall pay the Service Fees as set forth in Exhibit C.

Additional Service Fees and costs may be detailed in an amendment to this PSA or in accordance with the MSA. Service Fees shall be invoiced as follows:

Service	Timing of Invoicing
Project Management	Invoiced [***]
IN WITNESS WHEREOF, duly authorized representatives Batches	[***] invoiced at OOF of the parties Batch and [***] invoiced upon SBL's release of the Batch
Services other than Batch Manufacturing and Project Management	[***] invoiced upon initiation of the Service and [***] invoiced after SBL's completion of the Service with "initiation" and "completion" being acknowledged in writing by Client
Specialized Raw Materials	Invoiced to Client [***]. When negotiating with vendors to purchase Specialized Raw Materials, SBL shall use Commercially Reasonable Efforts to keep any deposits or upfront payments as low as possible
Common Raw Materials	The cost of the Common Raw Materials will be charged [***] and will be invoiced [***] upon its consumption

A. **Excess Production**. If, in the course of manufacturing pursuant to a Client Purchase Order, SBL manufactures more than the amount ordered in the Client's Purchase Order due to the mutually agreed manufacturing plan (i.e., Client wishes to do at scale production with a back-up batch), then Client shall either revise its original Purchase Order to account for the additional batch(es) or issue a new Purchase Order to cover the additional batch(es).

B. **Technology Transfer**. In the course of performing Technology Transfer required under this PSA, Client may [***]

C. **Forecasts / Purchase Orders**

i. [***] Year Forecast

1. By [***] of each Year of the PSA term, Client shall provide to SBL a rolling Annual Forecast for the next [***] Years (the "**[***] Year Forecast**"). For the sake of clarity, (A) Client provided to SBL the first [***] Year Forecast on [***] and (B) Client does not have executed to specify any quantities in the [***] Year Forecast for time periods beyond December 31, 2031 (i.e., the [***] Year Forecast may not always cover a full [***] year period).

2. Within [***] days of receipt of any [***] Year Forecast, SBL shall provide a written acceptance or comments. Upon SBL's written acceptance, the applicable Firm Period shall be firm and binding as to the total number of Batches of Commercial Product that are to be delivered in each Year of the Firm Period.

3. If SBL provides comments on the [***] Year Forecast (rather than acceptance), then the Parties shall further discuss in good faith to agree on the [***] Year Forecast that can be accommodated based on SBL's available capacity.

4. The [***] Year of each [***] Year Forecast shall be partially binding on Client as follows: when the [***] Year of any [***] Year Forecast becomes the [***] Year of the next [***] Year Forecast, such [***] Year must forecast between [***] of the [***] Year of the previous [***] Year Forecast. For clarity, both SBL and Client agree that the [***] Year Forecasts will include quantities measured only in [***]. By way of example only, [***].

5. Each [***] Year Forecast issued by Client shall be consistent with the Product Purchase Commitment and the previously issued [***] Year Forecast in terms of Batches of Commercial Product forecasted for each Year falling in the Firm Period of the [***] Year Forecast.

6. Notwithstanding anything to the contrary, upon Client's request, SBL shall use Commercially Reasonable Efforts to Manufacture Batches in excess of the number of Batches set forth in any Firm Period, subject to SBL's existing commitments.

ii. Quarterly Forecast

1. At least [***] days prior to start of each Quarter of the PSA term during which SBL is Manufacturing Commercial Product, Client shall provide to SBL a rolling Quarterly Forecast that begins with such Quarter.

2. The Quarterly Forecast shall set forth the Batches of Commercial Product that are requested by Client to be delivered in each Quarter of the Quarterly Forecast. Quarterly Forecasts shall be consistent with the then-current [***] Year Forecast when requesting Batches to be delivered in a Quarter falling in the Firm Period of any [***] Year Forecast. If there is a conflict between

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any Quarterly Forecast and any [***] Year Forecast regarding a binding amount, the [***] Year Forecast shall supersede unless agreed to in writing by SBL.

iii. Delivery Schedule and Purchase Orders

1. Each time Client submits a Quarterly Forecast to SBL pursuant to Section 5(d)(ii), SBL and Client shall discuss in good faith the Manufacturing schedule for each New Batch. The Parties shall discuss in good faith for up to [***] days and shall agree upon a Manufacturing schedule for the New Batches covered by the Quarterly Forecast, upon which Client shall issue a binding Purchase Order for each New Batch, consistent with the Parties' agreement and the Quarterly Forecast. The Purchase Order shall detail the New Batches requested, and estimated delivery date(s) for such New Batches, which delivery date shall be finalized upon SBL's release of the New Batches pursuant to Section 4.12 of the MSA.

2. When deciding a Manufacturing schedule for the New Batches, the Parties agree that (a) all Manufacturing shall be on a [***] Campaign per Year basis, and (b) if there is more than [***] Campaign per Year scheduled as a result of a Quarterly Forecast, then Client will be subject to a product changeover fee of $[***] per additional Campaign. If the Parties agree to add additional Batches to a Campaign that was already scheduled pursuant to a previous Quarterly Forecast, Client shall re-issue the previously issued Purchase Orders to align with such new agreement, but will not be subject to a product changeover fee. SBL will use Commercially Reasonable Efforts to accommodate additional Batches into a Campaign that was already scheduled pursuant to a previous Quarterly Forecast. The Service Fee for any Batch in an additional Campaign in a single Year will be calculated based on the number of Batches in such additional Campaign.

3. The Parties agree and acknowledge that actual yields of Formulated Drug Substance per Batch may vary, even when Manufactured in accordance with the Manufacturing Process. For the sake of clarity, the Service Fee per Batch identified in Exhibit C will not vary based on the actual yield of Formulated Drug Substance produced in accordance with the Manufacturing Process.

D. Reserved Capacity and Product Purchase Commitment

i. Reserved Capacity during Technology Transfer. As part of the Reserved Capacity for Client, SBL shall reserve in the Facility the following manufacturing slots solely on behalf of Client to carry out the Services described below and SBL agrees not to offer such Reserved Capacity to any third parties:

1. [***] ;

2. [***]; and

3. [***].

Within [***] days after the PSA Effective Date, Client shall issue Purchase Orders for the [***], which are not covered by the first [***] Year Forecast submitted by Client pursuant to Section 5(d)(i) above. Such Purchase Orders shall be fully binding on a minimum take or pay basis.

ii. Product Purchase Commitment for Commercial Product.

1. Client's Product Purchase Commitment for Years [***] is [***] Batches of Commercial Product.

2. Client's Product Purchase Commitment for Years [***] is [***] Batches of Commercial Product.

iii. Product Purchase Commitment Shortfall. During each of Years [***], both inclusive, Client shall pay SBL, on a minimum take or pay basis, for the greater of (a) [***], and (b) [***].

iv. Product Purchase Commitment Shortfall. During each of Years [***], Client shall pay to SBL the Service Fees for a Commercial Campaign and the costs of Raw Materials actually incurred by SBL (and associated handling fees and reimbursable expenses or costs) in preparation for a Commercial Campaign, that are applicable to any Product Purchase Commitment Shortfall, if any, provided that Client's obligation to pay for such Raw Materials shall be [***]. For any Year for which a Product Purchase Commitment Shortfall payment is owed to SBL, SBL shall invoice Client for the Product Purchase Commitment Shortfall on December 31 of such Year, and Client shall pay such invoice in accordance with Section 8.3 of the MSA.

v. Delay in Use of Reserved Capacity.

The Parties acknowledge that the Technology Transfer process for Product may not always proceed in accordance with the expected schedule and that there may be hurdles to overcome including, without limitation, delays in Raw Material procurement, unexpected results during processes and methods transfer, and additional studies needed to achieve comparability. The Parties agree to collaborate in good faith to overcome such hurdles with the intention of SBL successfully manufacturing Commercial Product for Client.

Notwithstanding anything to the contrary in the MSA or this PSA, Client is not responsible for any delay in using the Reserved Capacity within each timeframe set forth in this PSA to the extent such delay is due to [***]. If there is a delay in Client's timing for the use of the Reserved Capacity [***]. For clarity and notwithstanding the above, the delay in Client's use of the Reserved Capacity due to subsection (c) above shall be allowed [***].

If the FDA does not approve SBL as a manufacturer for Batches of Commercial Product (other than the Regulatory Approvals, which will be obtained or maintained by Client) due to [***], Client shall not be

responsible for any Reserved Capacity that was dedicated to Manufacturing Commercial Batches.

vi. Mitigation. Notwithstanding any provision to the contrary in the MSA or this Agreement PSA, if Client is unable to use its Reserved Capacity [***]. Notwithstanding any provision to the contrary set forth in the MSA or this PSA, the Parties agree and acknowledge that, in order to protect Confidential Information including that of other stakeholders such as SBL's other clients and to avoid challenges, costs, and risks associated with producing evidence and details thereof, SBL shall be under no obligation to provide any evidence or details of a resale or none thereof, and instead, the Parties shall, based on mutual trust and relying on each other's duty of good-faith, neither demand nor investigate evidence of resale or no resale by SBL.

6. **Batch Failure**. The Parties shall be responsible for the costs related to Batch Failure pursuant to Section 4.11 of the MSA (Batch Failure during Manufacture).

7. **Regulatory Approvals**. The Regulatory Approvals covered by this PSA are post approval changes (as described in Exhibit D).

8. **Storage**.

a. Storage of Formulated Drug Substance following the time period of [***] days after Client's receipt of Batch Related Documents shall be charged to Client at the rate of $[***] per pallet at [***] °C per month.

b. The Parties will discuss whether SBL should store certain materials considered necessary to support Development or Manufacturing Services. If Client determines that storage of certain materials is no longer necessary, this determination will be captured in a Decision Memo and such materials will either be destroyed by SBL or provided to Client at Client's expense.

9. **Limitation of Liability**. Each Party's maximum aggregate liability to compensate the other Party for all Damages under this PSA will be set on a per Year basis and for the Year in which the cause of such liability lies or exists (whether in contract, tort, strict liability, statute, or otherwise) and shall be limited to [***], except that (i) for either Party's indemnification obligations to the other Party under Article 12 of the MSA (Indemnification), the maximum aggregate liability shall be limited to [***] and (ii) for either Party's fraud, gross negligence or willful misconduct, the maximum aggregate liability shall be limited to [***].

10. **Term**. This PSA will commence as of the PSA Effective Date. Date and will continue in full force and effect until the later of (a) the completion of all Services contemplated by this PSA or (b) December 31, 2031, unless earlier terminated in accordance with the termination provisions of the MSA. Prior to the expiration of this PSA, the Parties shall use Commercially Reasonable Efforts to negotiate in good faith and enter into a new Product Specific Agreement that would govern SBL's provision of Manufacturing Services as required by Client for the Commercial Product for Years after 2031.

The Parties have entered into this PSA as of the PSA Effective Date by their respective duly authorized representatives.

EXHIBIT A

1. Services:

Consultant will provide advice on matters relating to (a) Kiniksa's pipeline development strategy and (b) the review and design of Kiniksa's clinical trial protocols.

During the Term, Consultant shall provide Services for an average of eight (8) to ten (10) hours per week.

2. Compensation:

As compensation for the Services, Kiniksa shall pay Consultant as follows:

(a) $45,000.00 USD within thirty (30) days of the Effective Date; and

(b) Restricted Stock Units (RSUs), representing the right to receive Class A common shares of Kiniksa with a combined value equal to $45,000.00 USD as of market closing on the Effective Date, rounded down to the nearest whole share. Such RSUs will vest immediately on the Effective Date.

Consultant shall bear Consultant's own day-to-day expenses, such as expenses for telephone calls, faxes and mail, that Consultant incurs in providing Services. For all other out-of-pocket expenses, Kiniksa agrees to reimburse Consultant for those expenses that Kiniksa has authorized in advance.

Compensation for Services shall not exceed a total value of $90,000.00 USD during the Term without the prior written approval from Kiniksa.

Exhibit A: Client Materials

[***]

Exhibit B: Specialized Materials

[***]

Exhibit C: Service Fees

[***]

Exhibit D: Estimated Timeline & DS Scope of Work (10,000L)

[***]

Exhibit 31.1

CERTIFICATIONS

I, Sanj K. Patel, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Kiniksa Pharmaceuticals International, plc;

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.

Exhibit 10.2

[***] 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.

KINIKSA PHARMACEUTICALS, LTD.
2018 INCENTIVE AWARD PLAN

PERFORMANCE-BASED RESTRICTED SHARE UNIT GRANT NOTICE

Capitalized terms not specifically defined in this

Performance-Based Restricted Share Unit Grant Notice (the "***Grant Notice***") have the meanings given to them in the 2018 Incentive Award Plan (as amended from time to time, the "***Plan***") of Kiniksa Pharmaceuticals, Ltd. (the "***Company***").

The Company has granted to the participant listed below ("***Participant***") the performance-based Restricted Share Units described in this Grant Notice (the "***PSUs***"), subject to the terms and conditions of the Plan and the Performance-Based Restricted Share Unit Agreement attached as **Exhibit A** and the Performance-Based Restricted Share Unit Vesting Schedule attached as **Exhibit B** (together with **Exhibit A**, the "***Agreement***"), all of which are incorporated into this Grant Notice by reference.

Participant:	
Grant Date:	
Grant Number:	
Number of PSUs (at Target) (the "***Target Award***"):	
Vesting Schedule:	As set forth on **Exhibit B** hereto.

By Participant's signature below, Participant agrees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has reviewed the Plan, this Grant Notice and the Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, this Grant Notice and the Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement.

KINIKSA PHARMACEUTICALS, LTD.

By: _____

Name:

Title:

PARTICIPANT

[Participant Name]

_____

July 25, 2024

/s/ Sanj K. Patel

PERFORMANCE-BASED RESTRICTED SHARE UNIT AGREEMENT

Capitalized terms not specifically defined in this Agreement have the meanings specified in the Grant Notice or, if not defined in the Grant Notice, in the Plan. Sanj K. Patel

GENERAL

1.1 Award of PSUs Chief Executive Officer and Dividend Equivalents.

(a) The Company has granted the PSUs to Participant effective as of the grant date set forth in the Grant Notice (the "***Grant Date***"). Each PSU represents the right to receive one Share or, at the option of the Company, an amount of cash, in either case, as set forth in this Agreement. Participant will have no right to the distribution of any Shares or payment of any cash until the time (if ever) the PSUs have vested.

(b) The Company hereby grants to Participant, with respect to each

PSU, a Dividend Equivalent for ordinary cash dividends paid to substantially all holders of outstanding Shares with a record date after the Grant Date and prior to the date the applicable PSU is settled, forfeited or otherwise expires. Each Dividend Equivalent entitles Participant to receive the equivalent value of any such ordinary cash dividends paid on a single Share. The Company will establish a separate Dividend Equivalent bookkeeping account (a "***Dividend Equivalent Account***") for each Dividend Equivalent and credit the Dividend Equivalent Account (without interest) on the applicable dividend payment date with the amount of any such cash paid. The PSUs, together with the Dividend Equivalents, are referred to in this Agreement as this "***Award***".

1.2 Incorporation of Terms of Plan. The PSUs are subject to the terms and conditions set forth in the Grant Notice, including this Agreement, and the Plan, which is incorporated herein by reference. In the event of any

inconsistency between the Plan and the Grant Notice, the terms of the Plan will control.

1.3 Unsecured Promise. The PSUs and Dividend Equivalents will at all times prior to settlement represent an unsecured Company obligation payable only from the Company's general assets.

ARTICLE II VESTING; FORFEITURE AND SETTLEMENT

2.1 Earned PSUs. The PSUs shall become "Earned PSUs" following the end of the Performance Period (as such term is defined in **Exhibit B** to the Grant Notice) to the extent earned in accordance with **Exhibit B**, subject to the Compensation Committee Chairman of the Board (the "***Compensation Committee***") determining, in its sole discretion, the level of achievement of the applicable Performance Criteria. Directors

(Principal Executive Officer)

2.2 Vesting; Forfeiture; Change in Control.

(a) Except as provided in

Section 2.2(c) below, the Earned PSUs, if any, will vest on the Determination Date (as such term is defined in **Exhibit B**). Dividend Equivalents (including any Dividend Equivalent Account balance) will be earned, vest or be forfeited, as applicable, upon the earning, vesting or forfeiture of the PSU, as applicable, with respect to which the Dividend Equivalent (including the Dividend Equivalent Account) relates.

(b) In the event of Participant's Termination of Service for any reason, all unvested PSUs will immediately and automatically be cancelled and forfeited, except as otherwise determined by the Administrator or provided in this Section 2.2(b) or in a binding written agreement between Participant and the Company. In the event of a Participant's Termination of Service (i) by the Company or a Subsidiary without Cause or, (ii) for any Participant who is party to a binding written agreement with the Company or a Subsidiary that contains a definition of "Good Reason"

and that is in effect at the time of such Termination of Service, by Participant for Good Reason (as defined in such agreement), the PSUs shall not be cancelled upon such Termination of Service and instead shall remain outstanding and eligible to become Earned PSUs in accordance with the terms of **Exhibit B** and to vest on the Determination Date, with the number of Earned PSUs,

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Exhibit 31.2

CERTIFICATIONS

I, Mark Ragosa, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Kiniksa Pharmaceuticals International, plc;

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.

4.2 Recovery of Compensation. Participant acknowledges that this Award (including any proceeds, gains or other economic benefit Participant actually or constructively receives in connection with this Award or the sale of Shares delivered pursuant to this Award) will be subject to the Company's Policy for Recovery of Erroneously Awarded Compensation and any other policy or policies of the Company or a Subsidiary that

provides for forfeiture, disgorgement or clawback with respect to incentive compensation that includes awards under the Plan.

4.3 Notices. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant at Participant's last known mailing address, email address or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.

4.4 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

4.5 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as

necessary to conform to Applicable Laws.

4.6 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

4.7 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement, the PSUs and the Dividend Equivalents will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.

4.8 Entire Agreement. The Plan, the Grant Notice and this Agreement constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

4.9 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be

severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

4.10 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the PSUs and Dividend Equivalents, and rights no greater than the right to receive cash or the Shares as a general unsecured creditor with respect to the PSUs and Dividend Equivalents, as and when settled pursuant to the terms of this Agreement.

4.11 Not a Contract of Employment. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Subsidiary or interferes with or restricts in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without Cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

4.12 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

* * * * *

July 25, 2024

/s/ Mark Ragosa

PERFORMANCE-BASED RESTRICTED SHARE UNIT VESTING SCHEDULE Mark Ragosa
Chief Financial Officer

Capitalized terms not specifically defined in this **Exhibit B** have the meanings specified in the Grant Notice or **Exhibit A** thereto or, if not defined in the Grant Notice or **Exhibit A**, in the Plan.

1. General. [***] percent ([***]%) of the Target Award will be eligible to be earned subject to the terms and conditions of Section 3 of this **Exhibit B** based on Arcalyst Revenue (the "***Revenue PSUs***") and the remaining [***] percent ([***]%) of the Target Award will be eligible to be earned subject to the terms of conditions of Section 4 of this **Exhibit B** based on Total Shareholder Return (as measured by TSR Percentile Rank) (the "***TSR PSUs***"). Arcalyst Revenue and Total Shareholder Return (as measured by TSR Percentile Rank) shall be the Performance Criteria under the Award.

2. Definitions. The terms set forth below, as used in this **Exhibit B**, shall the following meanings:

(a) "***Arcalyst Revenue***" shall mean [***].

(b) "***Determination Date***" shall mean the date on which the Compensation Committee determines the number

of Earned PSUs, which date shall occur not later than thirty (30) days after the close of the Performance Period, or, in the event that the Performance Period ends as a result of a Change in Control, not later than the consummation of the Change in Control.

(c) "***Performance Period***" shall mean the period beginning on the Performance Period Start Date and ending on the Performance Period End Date.

(d) "***Performance Period End Date***" shall mean December 31, 2026 or, if earlier, the date of the consummation of a Change in Control.

(e) "***Performance Period Start Date***" shall mean January 1, 2024.

(f) "***Nasdaq Biotech Index Companies***" shall mean the companies making up the Nasdaq Biotechnology Index as of the Performance Period Start Date.

(g) "***Total Shareholder Return***" shall mean the change in value expressed as a percentage of a given dollar amount invested in a company's most widely publicly traded stock over the Performance Period, taking into account both stock price appreciation (or depreciation) and the reinvestment of dividends (including the cash value of non-cash dividends) in such stock of the company. The sixty (60) calendar-day average closing price of the Shares and the stock of the Nasdaq Biotech Index Companies (i.e., the average closing prices over the period of trading days occurring in the sixty (60) calendar days prior to the Performance Period Start Date and ending on the Performance Period Start Date and the average closing prices over the period of trading days occurring in the final sixty (60) calendar days ending on the Performance Period End Date) will

be used to value the Shares and the stock of the Nasdaq Biotech Index Companies. Dividend reinvestment will be calculated using the closing price of a Share or the stock of the applicable Nasdaq Biotech Index Company on the ex-dividend date or, if no trades were reported on such date, the latest preceding date for which a trade was reported. If a company that is included in the Nasdaq Biotech Index as of the Performance Period Start Date ceases to be publicly traded during the Performance Period, or if it publicly announced that any such company will be acquired, whether or not such acquisition occurs during the Performance Period, such company shall not be treated as a Nasdaq Biotech Index Company for purposes of the determinations herein and such company's Total Shareholder Return shall not be included for purposes of the calculations herein.

(h) "***TSR Percentile Rank***" shall mean the percentage of Total Shareholder Return values among the Nasdaq Biotech Index Companies at the Performance Period End Date that are equal to or lower than the Company's Total Shareholder Return at the Performance Period End Date, provided that if the Company's Total Shareholder Return falls between the Total Shareholder Return of two of the Nasdaq Biotech Index Companies the TSR Percentile Rank shall be adjusted by interpolating the Company's Total Shareholder Return on a straight-line basis between the Total Shareholder Return of the two Nasdaq Biotech Index Companies that are closest to the Company's. For purposes of the TSR Percentile Rank calculation, the Company will be excluded from the group of Nasdaq Biotech Index Companies.

3. Earning of Revenue PSUs. No portion of the Revenue PSUs shall become earned unless Arcalyst Revenue, expressed as a percent of Target, is at or above [***] percent ([***]%). If Arcalyst Revenue is at or above [***] percent ([***]%) of Target, the number of Revenue PSUs that become Earned PSUs shall be equal to the number of Revenue PSUs multiplied by the "Applicable Percentage" set forth in the table below. In the event that Arcalyst Revenue falls between two of the percentages listed in the table below, the Applicable Percentage shall be interpolated on a straight-line basis and the percentage of the number of Revenue PSUs earned shall be based on such interpolated percentage. If Arcalyst Revenue is at or above [***] percent ([***]%) of Target, the Applicable Percentage shall be two hundred percent (200%).

Target Arcalyst Revenue ($000s)	$[***] ("***Target***") (Principal Financial Officer)

Arcalyst Revenue (% of Target)	**Applicable Percentage**
≥ [***]%	200%
[***]%	[***]%
[***]%	[***]%
[***]%	[***]%
< [***]%	0%

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 International, plc (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 June 30, 2024 (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.

July 25, 2024 /s/ Sanj K. Patel

4. Earning of TSR PSUs. No portion Sanj K. Patel

Chief Executive Officer and Chairman of the TSR PSUs shall become earned unless the TSR Percentile Rank is at or above the [***] ([***]) percentile. If the TSR Percentile Rank is at or above the [***] ([***]) percentile, the number Board of TSR PSUs that become Earned PSUs shall be equal to the number of TSR PSUs multiplied by the "Applicable Percentage" set forth in the table below. In the event that TSR Percentile Rank falls between two of the percentile ranks listed in the table below, the Applicable Percentage shall be interpolated on a straight-line basis and the percentage of the number of TSR PSUs earned shall be based on such interpolated percentage. If TSR Percentile Rank is at or above the [***] ([***]) percentile,

the Applicable Percentage shall be two hundred percent (200%). If the Company's Total Shareholder Return is negative, in no event shall the Applicable Percentage exceed [***] percent ([***]%). Directors

TSR Percentile Rank	**Applicable Percentage**

(Principal Executive Officer)

≥ [***] Percentile	200%
[***] Percentile	[***]%
[***] Percentile	[***]%
[***] Percentile	[***]%
< [***] Percentile	0%

5. Change in Control. In the event that the Performance Period ends as a result of a Change in Control, the portion (if any) of the Revenue PSUs and the TSR PSUs earned shall be determined by the Compensation Committee as of such Change in Control based on the extent to which the Performance Criteria have been achieved as of the Change in Control, with the TSR PSUs earned based on the TSR Percentile Rank using the per-Share price as determined in connection with the Change in Control.

6. Determinations by the Compensation Committee. At the end of the Performance Period, the Compensation Committee shall determine the extent to which, if any, the Performance Criteria have been met and the number of PSUs that are earned hereunder. Any PSUs that are earned hereunder are referred to as "***Earned PSUs***". No PSUs shall be earned and shall vest until the Compensation Committee determines that the Performance Criteria have been met and determines the extent to

which they have so been met. Any Earned PSUs, determined separately for the Revenue PSUs and the TSR PSUs, shall be rounded down to the nearest whole number of Shares and any fractional Earned PSUs shall be disregarded. All determinations under this **Exhibit B** shall be made by the Compensation Committee and will be final and binding on Participant.

* * * * *

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.

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 International, plc (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 June 30, 2024 (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.

April 25, 2024

/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.

April July 25, 2024 /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, 2024 (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.

April 25, 2024 /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, 2024 (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.

April 25, 2024

/s/ Mark Ragosa

Mark Ragosa
Chief Financial Officer
(Principal Financial Officer)

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