KINIKSA

Every Second Counts!™

Living with Recurrent Pericarditis

2025 ANNUAL REPORT

Dear Fellow Shareholders,

In 2025, Kiniksa continued to deliver meaningful progress across our commercial and clinical portfolio, helping patients suffering from debilitating diseases with significant unmet need.

Continued ARCALYST commercial growth and disciplined capital allocation position Kiniksa for near- and long-term success. We are building the foundation for future growth through strategic investments in the commercialization of ARCALYST as well as the advancement of our pipeline of interleukin-1 alpha (IL-1α) and interleukin-1 beta (IL-1β) inhibition assets.

ARCALYST

ARCALYST, an IL-1α & IL-1β cytokine trap, is the only U.S. Food and Drug Administration (FDA)-approved therapy for the treatment of recurrent pericarditis and reduction in risk of recurrence. In the five years since launch, ARCALYST has redefined the treatment paradigm for this disease, establishing IL-1 pathway inhibition as the preferred second-line approach, ahead of corticosteroids. In August 2025, the American College of Cardiology formally recognized this evolution with the publication of its Concise Clinical Guidance, recommending IL-1 pathway inhibition after the use of NSAIDs and colchicine for patients suffering from recurrent pericarditis.

Expanding adoption of IL-1α & IL-1β inhibition with ARCALYST was the primary driver of our robust commercial performance throughout 2025. Over the course of the year, we saw meaningful increases in the breadth and depth of prescribing, treatment duration, and penetration across the recurrent pericarditis population. More than 4,150 healthcare providers have prescribed ARCALYST since launch, with approximately 29% writing more than one prescription. Importantly, the majority of new prescriptions are coming from existing prescribers, speaking to the effectiveness of our educational efforts and the growing appreciation physicians have for ARCALYST as a safe and effective treatment that can be used continuously throughout the duration of this chronic disease. Average total duration of therapy continues to grow and is approaching 3 years, in line with the median duration of disease. As a result, approximately 18% of the annual target population of 14,000 patients with multiple recurrences were actively on ARCALYST treatment as of the end of 2025. Furthermore, growing physician familiarity prescribing ARCALYST is contributing to broader use in patients on their first recurrence, who account for around 20% of ARCALYST prescriptions. The upside potential within the additional 26,000 patients each year who experience their first recurrence is large, particularly among those suffering from additional risk factors associated with longer disease duration.

ARCALYST sales grew 62% year-over-year to $677.6 million in 2025, and we believe substantial opportunity remains.

Our strong and profitable commercial collaboration positions us to enable the next phase of growth for ARCALYST. We continue to make disciplined investments to maximize our opportunity in recurrent pericarditis by efficiently reaching additional patients and physicians. Alongside our field force, we are advancing digital marketing initiatives to promote patient self-advocacy and AI-driven targeting to position our field personnel for timely engagement with physicians. We are also evaluating opportunities to further expand the impact of Pericardial Disease Centers (PDCs), where ARCALYST adoption continues to outpace that of other sites. As of the end of 2025, there were 18 PDCs across the U.S. specializing in recurrent pericarditis.

Additionally, we are committed to ongoing innovation with ARCALYST and continue to support a collaborative Phase 2 study in cardiac sarcoidosis conducted by Mayo Clinic and The Johns Hopkins University.

KPL-387

KPL-387, our independently developed monoclonal antibody that binds human interleukin-1 receptor 1 (IL-1R1) to inhibit the signaling activity of the cytokines IL-1α & IL-1β, represents a meaningful opportunity to build on our leadership in recurrent pericarditis.

As the market leader, we are leveraging our existing clinical expertise to explore additional efficacious treatment options for patients. With this program, we are advancing a validated mechanism that could address key patient needs and expand penetration into the addressable market. We believe KPL-387 could enable once-monthly dosing with a single subcutaneous self-injection in a liquid formulation, offering convenient administration using an autoinjector. In 2025, we initiated the registrational Phase 2/3 development program of KPL-387 in recurrent pericarditis, with Phase 2 data expected in the second half of 2026.

We are also conducting a supplemental Phase 2 Transition to KPL-387 Monotherapy Dosing & Administration Study to provide healthcare professionals with additional information at the time of launch to support initiating KPL-387.

Market research indicates there may be strong demand among the vast majority of surveyed patients and healthcare professionals for a highly efficacious IL-1α & IL-1β inhibitor with the target profile of KPL-387. Approximately 75% of surveyed recurrent pericarditis patients would prefer a treatment with such a target profile over currently available or other investigational therapies. Additionally, among ARCALYST-naïve patients, approximately 75% stated an increased willingness to take an injectable therapy if presented in an autoinjector. On the physician side, approximately 92% indicated a high likelihood of prescribing the KPL-387 target profile for new patients, in the context of available commercial and investigational therapies. Both patient and physician preferences highlight the potential for KPL-387 to address key needs for those with recurrent pericarditis.

In October 2025, the FDA granted Orphan Drug Designation to KPL-387 for the treatment of pericarditis, including recurrent pericarditis. We are working diligently to bring this potential treatment option to patients and are aiming to be on the market in the 2028/2029 timeframe.

KPL-1161

KPL-1161 is an Fc-modified monoclonal antibody IL-1α & IL-1β antagonist developed independently by Kiniksa that binds IL-1R1, with a target profile of once-quarterly subcutaneous dosing. We believe this profile may support treatment across a range of cardiovascular and IL-1 mediated diseases. KPL-1161 is currently in preclinical development, and we expect to initiate a Phase 1 first-in-human trial by the end of 2026.

Financial Position

Through consistent execution and prudent capital allocation, Kiniksa has maintained a robust balance sheet with positive annual cash flow. Our financial strength provides capacity to continue investing responsibly in value creation by maximizing the opportunity with ARCALYST, advancing our clinical pipeline, and pursuing business development initiatives, which remain fundamental to our strategy. Alongside our existing assets, we continue to evaluate opportunities to expand our portfolio with programs that have strong biologic rationale and validated mechanisms.

Supported by the relentless devotion of Kiniksa's employees, we are well-positioned to drive future success, generate long-term value, and help many more patients in need. Thank you for your ongoing support.

Every Second Counts!

Sincerely,

Sanj K. Patel

CEO and Chairman of the Board

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

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 International, plc

(Exact name of registrant as specified in its charter)

England and Wales	**98-1795578**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

Kiniksa Pharmaceuticals International, plc
105 Piccadilly, Second Floor
London, W1J 7NJ
England, United Kingdom
(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)

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 Ordinary Shares	KNSA	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 the last business day of the Registrant's most recently completed second fiscal quarter, June 30, 2025, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the ordinary shares on The Nasdaq Global Select Market was approximately $1,114.0 million.

As of February 20, 2026, there were 76,535,377 ordinary shares outstanding in aggregate, comprised of:

45,900,637 Class A ordinary shares, nominal value $0.000273235 per share

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

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

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

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2026 Annual Meeting of Shareholders, which the registrant intends to file with the Securities and Exchange Commission pursuant to Regulation 14A within 120 days after the end of the registrant's fiscal year ended December 31, 2025, are incorporated by reference into Part III of this Annual Report on Form 10-K.

Kiniksa Pharmaceuticals International, plc

FORM 10-K

FOR THE YEAR ENDED DECEMBER 31, 2025

TABLE OF CONTENTS

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements. All statements other than statements of historical facts contained in this Annual Report should be considered forward-looking statements, including statements regarding: our beliefs that KPL-387 will expand the recurrent pericarditis market and provide additional treatment options for patients; our beliefs about dosing and administration for our product candidates, including that KPL-387 has the potential for monthly subcutaneous self-administration in a liquid formulation and that KPL-1161 has the potential for quarterly subcutaneous dosing; our expectation to have data from the Phase 2 portion of our trial of KPL-387 in recurrent pericarditis in the second half of 2026 and that we plan to use the totality of the data to determine further development strategy; our plan to initiate a Phase 1 first-in-human clinical trial of KPL-1161 by the end of 2026; our plan to explore strategic alternatives for abiprubart; our belief that advancing KPL-387 through the clinic and into the market will further our mission of meeting patients' needs; the results we expect to receive from our commercialization efforts; the incidence and prevalence for our target patient populations; our belief that each of our product candidates holds the potential to offer differentiated therapy to patients; planned indications for our products and product candidates; our expectations regarding the value we expect to receive/pay under our current license and collaboration agreements; the plans and strategy of our competitors; our expectations around the intellectual property protection we hope to receive for our products and product candidates; the intellectual property strategy we expect to employ to protect our portfolio; our plans to apply for patent term extensions; our predictions regarding future regulations and legislation; our planned commercial strategy; our plans to rely on third-parties, such as specialty pharmacies, contract research organizations ("CROs") and contract development and manufacturing organizations ("CDMOs"); our relationships with payers; future supply for our products and product candidates; the timing and likelihood of success of our ongoing technology transfer of ARCALYST drug substance manufacturing; the expected impact of the United States' tariffs on our operations, including that we do not expect that tariffs in their current state to have a material impact on our overall business, financial condition or results of operations; plans to conduct operations through one or more of our foreign subsidiaries; the ways in which we expect to incur expenses, including through any future clinical or commercialization efforts; our expectation that our cash balance and our expected cash inflows form operations will allow us to meet our current operating plan and 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; statements regarding our expected near-term expenditures and revenue; and other similar 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 Annual 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 Annual Report and are subject to a number of risks, uncertainties and assumptions described under the sections in this Annual Report entitled "*Summary Risk Factors*", "*Risk Factors*" and "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" and elsewhere in this Annual Report.

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.

SUMMARY RISK FACTORS

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

- we may not be able to continue to commercialize ARCALYST or be successful in commercializing any future products, potentially impacting our ability to generate revenue;
- 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;
- 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;
- it may be difficult for us to realize the benefit of increasing the price of certain of our commercialized products;
- current and future healthcare legislation or executive or administrative action may have a material adverse effect on our business and results of operations;
- our business and operations are subject to extensive healthcare regulation and enforcement by various government entities, and our failure to adhere to these regulatory requirements could have a detrimental impact on our business;
- 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 significantly 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 or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities;
- we may find it difficult to enroll participants in our clinical trials in a timely manner;
- interim, preliminary and "topline" data from our clinical trials that we announce or publish from time to time may change as more participant data become available and final data may differ from such interim, preliminary and "topline" data;
- we contract with third parties, including CDMOs to manufacture our commercial supply of ARCALYST and clinical supply of our product candidates and for certain research and development; 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 are conducting a technology transfer of the manufacturing process for ARCALYST drug substance from Regeneron Pharmaceuticals, Inc. ("Regeneron") to Samsung Biologics Co., Ltd. ("Samsung"), and the analytical testing methods of ARCALYST drug substance and drug product to new contract testing labs ("CTLs"), which will be subject to significant risks and uncertainties;

- 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 or commercialize our product candidates, and our business could be substantially harmed;

- if we are unable to adequately protect our proprietary technology or obtain and maintain patent protection for our technology and patents, if the scope of the patent protection obtained is not sufficiently broad or if the terms of our patents are insufficient to protect 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 products may be materially impaired;

- 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;

- we face significant competition, 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, in-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 that 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;

- we may be adversely affected by continuing geopolitical tensions, including the introduction of tariffs or reciprocal tariffs that may be imposed by the United States and its global trading partners that could collectively cause economic uncertainty and increased costs to product development and manufacturing;

- the concentration of ownership of the voting power of our ordinary shares, including our Class B ordinary shares, and conversion rights of the holders of our Class A1 and Class B1 ordinary shares, which are held entirely 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 ordinary shares; and

- 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.

INDUSTRY AND OTHER DATA

Unless otherwise indicated, certain industry data and market data included in this Annual 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 Annual Report involve 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 Annual Report is reliable.

ARCALYST® is a registered trademark of Regeneron. Solely for convenience, trademarks, service marks and trade names referred to in this Annual Report may be listed without identifying symbols.

PART I

ITEM 1. BUSINESS.

Overview

We are a biopharmaceutical company developing and commercializing novel therapies for diseases with unmet need, with a focus on cardiovascular indications. Our portfolio of assets is based on strong biologic rationale or validated mechanisms and offers the potential for differentiation.

ARCALYST is an interleukin-1α ("IL-1α") and interleukin-1β ("IL-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 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.

ARCALYST is commercially available across the United States through a select network of specialty pharmacies. 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. In 2022, we granted Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. ("Huadong") exclusive rights to develop and commercialize ARCALYST in the Huadong Territory (as defined below). In 2023, Regeneron initiated a technology transfer of the manufacturing process for ARCALYST drug substance, and we are working to qualify Samsung as our replacement CDMO. In December 2024, we initiated a collaborative study agreement with The Mayo Clinic (together with Johns Hopkins University) to investigate the effects of ARCALYST in the treatment of cardiac sarcoidosis.

KPL-387 is an investigational, fully human immunoglobulin G2 monoclonal antibody that binds human interleukin-1 receptor 1 ("IL-1R1"), inhibiting IL-1α- and IL-1β-mediated signaling. KPL-387 is an independently developed asset that we believe may expand the recurrent pericarditis market and provide an additional treatment option for patients, with the potential to add the convenience of monthly subcutaneous self-administration with a liquid formulation.

In July 2025, we announced that the Phase 2 dose-focusing portion of the Phase 2/3 clinical trial of KPL-387 in recurrent pericarditis had begun recruiting. We expect data from the Phase 2 portion of the trial in the second half of 2026 and plan to use the totality of the data to determine further development strategy. In September 2025, we announced plans to conduct a supplemental Phase 2 transition to KPL-387 monotherapy dosing and administration study to evaluate the efficacy and safety of dosing regimens used to transition patients from standard therapies to KPL-387 monotherapy.

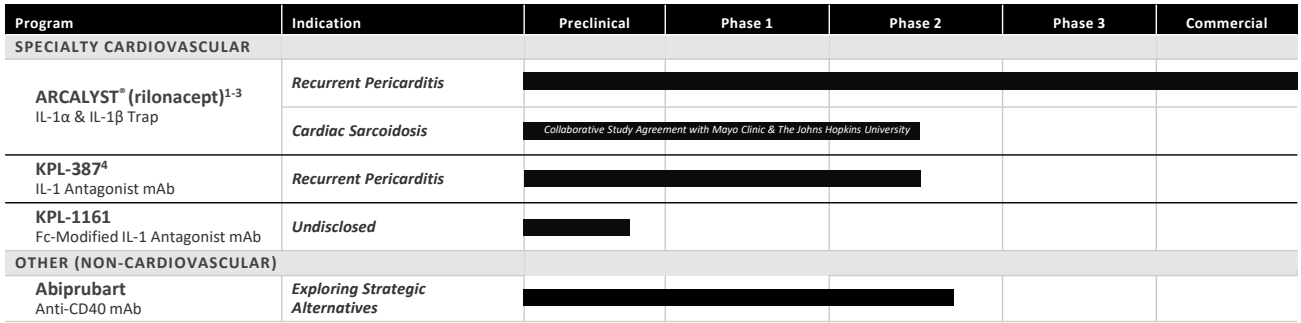
In October 2025, the FDA granted Orphan Drug Designation to KPL-387 for the treatment of pericarditis.

KPL-1161 is an independently developed, pre-clinical, Fc-modified immunoglobulin G2 monoclonal antibody that binds IL-1R1, inhibiting IL-1α- and IL-1β-mediated signaling. KPL-1161 is a modified version of KPL-387 designed to have an increased drug half-life that we believe could support quarterly subcutaneous dosing. We are currently conducting preclinical activities with respect to this asset, with an expectation to initiate a Phase 1 first-in-human clinical trial by the end of 2026.

Abiprubart is an investigational monoclonal antibody inhibitor of CD40-CD154 costimulatory interaction, which we believe to be an attractive approach to address multiple autoimmune disease pathologies. We hold an exclusive worldwide license to abiprubart from Beth Israel Deaconess Medical Center, Inc. ("BIDMC").

We previously announced a Phase 2b clinical trial of abiprubart in Sjögren's Disease. In February 2025, we announced our plans to discontinue development of abiprubart in the indication and to explore strategic alternatives for the asset.

The following table summarizes our current products, product candidates and out-licensing arrangements:



Program	Licensee	Exclusive Licensed Territory
OUT-LICENSING AGREEMENTS		
ARCALYST (rilonacept) IL-1α & IL-1β Trap	*Huadong Medicine*	*Asia Pacific Region, Excluding Japan*
Vixarelimab Anti-OSMRβ mAb	*Roche and Genentech*	*Worldwide*

(1) Approved in the United States; ARCALYST is also approved in the United States for CAPS and DIRA.

(2) The FDA granted Breakthrough Therapy designation to ARCALYST for recurrent pericarditis in 2019; the FDA granted Orphan Drug exclusivity to ARCALYST in March 2021 for the treatment of pericarditis, which includes the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and pediatric patients 12 years and older. The European Commission granted Orphan Drug designation to ARCALYST for the treatment of idiopathic pericarditis in 2021.

(3) Kiniksa has worldwide rights, excluding the Middle East and North Africa; Kiniksa granted Huadong exclusive rights in the Asia Pacific Region, excluding Japan.

(4) The FDA granted Orphan Drug designation to KPL-387 for the treatment of pericarditis, which includes recurrent pericarditis, in October 2025.

Using a data-centric approach, our team considers a wide variety of metrics to drive informed capital allocation strategies and generate value from this pipeline, including by analyzing potential additional indications for our products and product candidates, being opportunistic in our business development activities to in-license or acquire programs, considering appropriate opportunities to partner or out-license our programs and conducting internal research to discover and develop molecules to expand our portfolio.

Our Strategy

The core of our strategy is the identification, development and commercialization of therapeutic medicines for patients suffering from debilitating cardiovascular diseases with significant unmet medical need. We put patients first and live by our motto: Every Second Counts™.

Critical components of our business strategy include the following:

- **Continuing to Execute on ARCALYST Commercialization**. We have invested in a talented and specialized cardiology sales team, complemented by a successful marketing strategy, to effectively reach patients and prescribers. By expanding awareness and building the market for ARCALYST, we expect to increase disease awareness of recurrent pericarditis, improve our patients' journeys to diagnosis and treatment, establish ARCALYST as a therapy to be used earlier and for the full duration of the disease, secure patient access and support our patients throughout their therapy.

- **Advancing KPL-387 through Commercialization**. We believe KPL-387, our clinical-stage IL-1 inhibition therapy, is a potential new treatment option to address recurrent pericarditis patients' needs and expand the overall IL-1 inhibition market for recurrent pericarditis. Market research data demonstrate the demand for a drug with KPL-387's potential for streamlined preparation, dosing frequency and patient-friendly administration. We believe that advancing such a drug through the clinic and, if approved, into the market will further our mission of developing therapies for patients with critical unmet need.

- **Maximizing the Potential of our other Developmental Assets**. We are advancing a number of other assets in our pipeline, including KPL-1161. We use a data-first approach to guide our selection of indications and opportunities with an aim to maximize the potential of our portfolio. We believe that each of our product candidates holds the potential to offer differentiated therapy to patients, and we aim to unlock that potential through innovative research and development.

- **Exploring Opportunities to Drive Value and Maximize the Potential of Our Existing Portfolio.** We have and may in the future seek collaborations, licenses and other strategic relationships to assist in advancing and expanding our current programs, as appropriate. In addition, strategic out-licensing transactions may be used as a source of non-dilutive capital to support our commercial and clinical activities.

- **Working to Identify, Discover, Acquire and Develop New Therapies.** We evaluate a variety of factors for potential product candidates, technologies and discovery targets, including biologic rationale for addressing the disease, potential for regulatory approval, commercial viability, intellectual property position, prospects for favorable pricing and reimbursement and the impact of competition. We also look at assets that could potentially address multiple indications. We intend to continue to be opportunistic in our business development activities.

Our Products

ARCALYST

Overview

ARCALYST is an IL-1α and IL-1β cytokine trap. ARCALYST is currently approved in the United States for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children 12 years and older, the treatment of CAPS, including FCAS and Muckle-Wells Syndrome in adults and children 12 years and older, and the maintenance of remission in DIRA in adults and children weighing 10 kg or more. ARCALYST was sold by Regeneron in the United States for the treatment of CAPS from 2008 and the maintenance of remission in DIRA from 2020 until we assumed responsibility for sales in such indications in March 2021.

Recurrent pericarditis is the primary indication for which we are commercializing ARCALYST. It is a severe, debilitating and chronic autoinflammatory cardiovascular disease with an estimated United States prevalent population of approximately 40,000 patients seeking and receiving medical treatment. We received Breakthrough Therapy designation from the FDA for ARCALYST for the treatment of recurrent pericarditis in 2019, Orphan Drug designation from the FDA for ARCALYST for the treatment of pericarditis, which includes the treatment of recurrent pericarditis, in 2020 and 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.

In 2022, we granted Huadong exclusive rights to develop and commercialize ARCALYST in the Huadong Territory. In December 2024, we initiated a collaborative study agreement with The Mayo Clinic (together with Johns Hopkins University) to investigate the effects of ARCALYST in the treatment of cardiac sarcoidosis.

Mechanism of Action

ARCALYST is an inhibitor of IL-1α and IL-1β cytokines. Cytokines are small proteins that play important roles in intercellular signaling, and IL-1α and IL-1β have been demonstrated to play a key role in inflammatory diseases. IL-1α and IL-1β provoke potent, proinflammatory events by engaging the IL-1α and IL-1β receptor. Following tissue insult, the release of IL-1α acts as the primary initiating signal to coordinate the mobilization of immune cells to the damaged area, while IL-1β is secreted mostly by macrophages and is a prototypical cytokine of the canonical NLRP-3 inflammasome. IL-1α and IL-1β signaling results in a dramatic increase in the production of cytokines that orchestrate the proliferation and recruitment of phagocytes to the site of damage, resulting in inflammation. Moreover, IL-1α and IL-1β signaling also affects other immune system cells, such as T-cells and B-cells.

IL-1β's role in the inflammation process has been extensively studied, while, in comparison, much is still unknown about the independent function of IL-1α in disease pathology. Despite driving similar immunological outcomes, IL-1α and IL-1β differ substantially in their expression and regulation, and non-redundant roles for IL-1α or IL-1β have been demonstrated in multiple inflammatory diseases. There are disease states in which IL-1β inhibition alone does not appear to be sufficient for disease remission in the absence of IL-1α inhibition. Published studies suggest certain autoinflammatory diseases may, in fact, be pathologically driven primarily by IL-1α.

We believe that inhibiting both IL-1α and IL-1β signaling is important for treating recurrent pericarditis. In a published case study, a participant with a refractory form of recurrent pericarditis, who was well controlled on anakinra, was switched from anakinra to canakinumab, which inhibits only IL-1β, for tolerability reasons. The participant's disease returned despite further dose escalation of canakinumab. When the participant was switched back to anakinra, which inhibits ILα and ILβ, the disease promptly went back into remission. These data, together with clinical data from our pivotal Phase 3 clinical trial of ARCALYST, indicate that IL-1α and IL-1β play unique roles in recurrent pericarditis and other autoinflammatory diseases in which the pathology may be driven primarily by IL-1α. Other literature published after the June 2022 completion of the phase 3 clinical trial of ARCALYST corroborated these findings in larger populations of participants.

Beyond recurrent pericarditis, we believe there is potential for ARCALYST to address additional indications driven by IL-1α or IL-1β. We are currently engaged in a collaborative study agreement to explore ARCALYST as a treatment for cardiac sarcoidosis and are exploring strategic opportunities for further development. In particular, we believe ARCALYST may be advantageous in acute indications that may benefit from a weekly subcutaneous therapy with a proven method of action.

Background and Market Opportunity for Recurrent Pericarditis

Pericarditis is the most common disorder involving the pericardium, the two-layered sac that surrounds the heart. Pericarditis is an inflammation of this sac and is typically characterized by significant chest pain, shortness of breath, coughing and fatigue and is often misconstrued by patients as a heart attack. In addition, typical signs of pericarditis include pericardial friction rub, electrocardiogram changes or pericardial effusion, which is a buildup of fluid around the heart. Pericarditis is described as recurrent if, following an initial occurrence of pericarditis, it recurs after a symptom-free period of about four to six weeks. Pericarditis is considered chronic if symptoms of any one episode last longer than three months, typically causing significant pain and frustration. If pericarditis is left untreated, patients can develop thickening and scarring of the pericardium, potentially requiring invasive surgical stripping. Pericardial effusion, if large enough, can compress the heart extrinsically, requiring emergent drainage.

In March 2021, we received FDA approval to market ARCALYST for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children 12 years of age and older. Claims analysis, cross validated with published estimates, support a prevalent population of patients with recurrent pericarditis seeking and receiving medical treatment to be approximately 40,000 patients in the United States per year. Our commercialization efforts are focused initially on the approximately 14,000 patients in the United States who suffer from persistent underlying disease, multiple recurrences and an inadequate response to conventional therapy. Outside of our core target patient population, there are approximately 26,000 additional patients who are experiencing their first recurrence of the disease. Further, data shows that one-third of patients with multiple recurrences continue to suffer from the disease at 5 years from their

first recurrence of the disease and one-quarter continue at 8 years. We have seen that, as we expand awareness about the disease and our therapy, healthcare professionals look to prescribe ARCALYST earlier in the disease's natural history, including prescriptions to biologic-appropriate patients in their first recurrence. We expect that continuing to execute on this strategy will enable us to target this additional patient population more fully.

Current Treatment Landscape for Recurrent Pericarditis

ARCALYST, a weekly, subcutaneously injected, recombinant fusion protein that blocks IL-1α and IL-1β signaling, is the first and only FDA-approved therapy for recurrent pericarditis. A patient's initial acute episode of pericarditis is typically treated with NSAIDs or colchicine. Prior to ARCALYST's approval, episodes of recurrent pericarditis would usually have been treated in a similar manner or by adding long-term systemic corticosteroids. Both colchicine and corticosteroids often have adverse effects when used at high doses or for extended periods of time. Colchicine's adverse effects include gastrointestinal distress and neutropenia. Adverse events that may be caused by corticosteroids include glaucoma, fluid retention, hypertension, mood changes, memory changes, other psychological effects, weight gain and diabetes. Since our commercial launch of ARCALYST, we have seen a shift in the treatment paradigm, with an increasing number of healthcare professionals prescribing ARCALYST's targeted immunomodulation before using corticosteroids. Emblematic of this paradigm shift was the recently published American College of Cardiology Concise Clinical Guidance, which prioritized IL-1 inhibition therapy as a second-line treatment after failure of first-line therapy in the auto-inflammatory phenotype. We believe this reflects a growing acceptance of ARCALYST as an effective, steroid-sparing therapy for patients with unmet need in this debilitating disease.

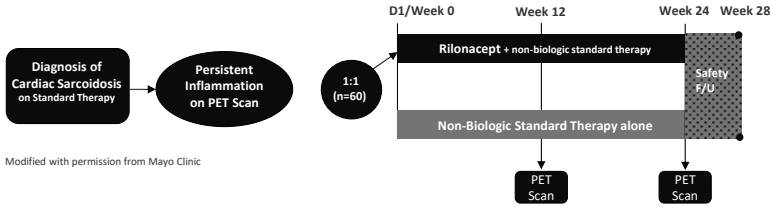
Clinical Trials and Collaborative Study Agreements

We have initiated a collaborative study agreement with The Mayo Clinic (together with Johns Hopkins University) to investigate the effects of ARCALYST in the treatment of cardiac sarcoidosis. The study is a Phase 2 PROBE-design study to evaluate the efficacy and safety of ARCALYST over 24 weeks of treatment in patients with cardiac sarcoidosis. The primary efficacy endpoint is change from baseline in number of segments with FDG uptake on cardiac FDG-PET scan at week 24. The following graphic shows the trial design and primary and secondary efficacy endpoints in more detail:

Randomized Phase 2 Trial of Rilonacept in Cardiac Sarcoidosis

Collaborative study agreement with Mayo Clinic and The Johns Hopkins University

PROBE-design study to evaluate efficacy and safety of rilonacept over 24 weeks of treatment in participants with cardiac sarcoidosis[1]



Modified with permission from Mayo Clinic

Primary Efficacy Endpoint

- Change from baseline in number of segments with FDG uptake on cardiac FDG-PET scan at Week 24

Key Secondary Endpoints

- Change from baseline in number of segments with FDG uptake at Week 12
- Change from baseline in SUV_{Max} at Week 12
- Change from baseline in SUV_{Max} at Week 24
- Change from baseline in SPRS on FDG-PET scan at Week 24

1.) Mayo Clinic is the IND-holder (IND: 172350); Clinicaltrials.gov NCT06660732.
PROBE = prospective, randomized, open label, blinded endpoint; CS = cardiac sarcoidosis; SC = subcutaneous; FDG = flurodeoxyglucose; PET = positron emission tomography; SUV_{Max} = maximum standardized uptake value; SPRS = summed perfusion rest score; qwk = every week; F/U = follow-up.

Commercial Strategy for ARCALYST

Since our commercial launch of ARCALYST for the treatment of recurrent pericarditis in 2021, we have developed a focused and targeted commercial strategy. Our specialty salesforce, which prioritizes calls on high-volume accounts and prescribers, is complemented by our medical affairs, payor and patient services teams who work to secure broad patient access to ARCALYST, educate communities, collaborate with patient advocacy groups and drive scientific understanding of recurrent pericarditis. Further, we have established an efficient marketing effort intended to educate and raise awareness of recurrent pericarditis among prescribers and patients and promote ARCALYST as the first and only FDA-approved treatment for this debilitating disease.

Using these resources, our commercialization efforts are focused on five strategic imperatives to increase the uptake and adoption of ARCALYST as well as ensuring a positive patient experience.

First, we are focused on increasing awareness of the disease and its impact on patients' lives. We believe disease awareness is essential to enable physicians to diagnose recurrent pericarditis earlier in its disease course and to treat the underlying disease, rather than to manage individual flares episodically. Our sales and marketing teams work to educate patients and prescribers about the signs, symptoms, duration and treatment of the disease, and the impact that recurrent pericarditis has on patients' lives. We have further partnered with each of NHL Hall-of-Famer Henrik Lundqvist and GRAMMY® Award-Winning Singer-Songwriter Carly Pearce as part of our Life DisRPted™ Campaign to drive awareness of recurrent pericarditis.

Second, we are working to improve the patient journey for those suffering from recurrent pericarditis. For example, in 2024 we announced our sponsorship of the American Heart Association's *Addressing Recurrent Pericarditis* initiative. This initiative is designed to facilitate knowledge-sharing across a network of healthcare providers around the United States and streamline patient access to expert care. The program currently collaborates with a number of pericardial disease centers, offering patients dedicated, expert care that is designed to shorten patients' journeys to diagnoses.

Third, we are working to establish ARCALYST as a therapy to be used in recurrent pericarditis patients as soon as appropriate after diagnosis and for the full duration of the disease. Evidence shows that, in part due to our educational efforts, prescribers are opting to prescribe ARCALYST earlier in the disease course, with real world evidence demonstrating that ARCALYST has increasingly become a second-line treatment for recurrent pericarditis, including after patients' first recurrence. In addition, patients and prescribers are opting to treat recurrent pericarditis for its full duration of disease. This supports our overall mission to help patients lead meaningful lives with minimal flares for the full breadth of the disease's natural history.

Fourth, we aim to secure broad patient access at a price that reflects ARCALYST's value as the first and only FDA-approved therapy for recurrent pericarditis. Helping to ensure affordability and access to treatment by patients is one of our core principles. To this end, we offer a suite of programs to support affordability for eligible patients who are prescribed ARCALYST.

Fifth, we have built a robust patient support program to optimize patient experiences with ARCALYST and Kiniksa. Our Kiniksa OneConnect™ program offers personalized treatment support for eligible patients prescribed ARCALYST. This program is designed to ensure patients have a positive experience from initiating ARCALYST therapy through the end of their treatment.

Our Product Candidates

KPL-387

Overview

KPL-387 is an investigational, fully human immunoglobulin G2 monoclonal antibody that binds IL1-R1, inhibiting the signaling of both IL-1α and IL-1β cytokines. KPL-387 is an independently developed asset that we believe

may expand the recurrent pericarditis market and provide an additional treatment option for patients, with the potential to add the convenience of monthly subcutaneous self-administration with a liquid formulation. In October 2025, the FDA granted Orphan Drug Designation to KPL-387 for the treatment of pericarditis.

We are currently conducting the Phase 2 dose-focusing portion of the Phase 2/3 clinical trial of KPL-387 in recurrent pericarditis, with data expected in the second half of 2026. We plan to use the totality of the data to determine further development strategy. In addition, we are conducting a supplemental Phase 2 transition to KPL-387 monotherapy dosing and administration study to evaluate the efficacy and safety of dosing regimens used to transition patients from standard therapies to KPL-387 monotherapy.

Mechanism of Action

KPL-387 binds IL-1R1, inhibiting the signaling of IL-1α and IL-1β cytokines. We believe there are diseases of the cardiovascular system where tissue inflammation may be driven by IL-1α and/or IL-1β, and we intend to consider development of KPL-387 in these indications and in others where we believe IL-1α and/or IL-1β plays a key role in disease pathophysiology.

Our Solution

We are developing KPL-387 for the treatment of recurrent pericarditis, where we believe IL-1 inhibition therapies offer significant advantages over other treatment modalities. Further, we believe an IL-1 inhibitor with the potential to combine convenient monthly dosing and a patient friendly, convenient autoinjector could meet patient needs and provide an additional treatment option for recurrent pericarditis patients.

Preclinical Development and Clinical Trials

Preclinical Development

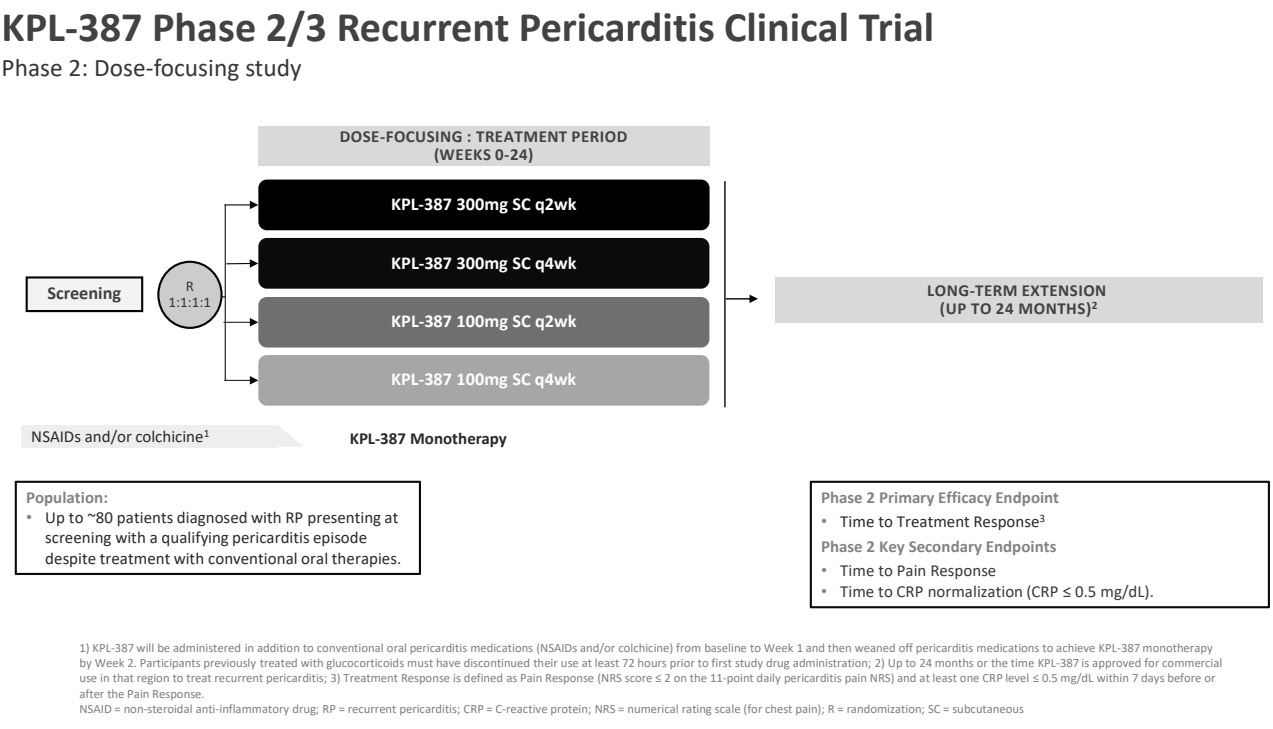
In vitro studies with KPL-387 demonstrated its ability to potently inhibit IL-6 production from peripheral blood mononuclear cells when stimulated with either Il-1α or IL-1β. *In vivo* pharmacokinetic studies of KPL-387 in non-human primates demonstrated good pharmacokinetic properties. We believe that these pharmacokinetic data, combined with the potent inhibition of IL-1 signaling that we observed *in vitro*, suggest that this therapeutic effect could be achieved with monthly subcutaneous administration in future clinical studies.

Phase 1 Clinical Trial

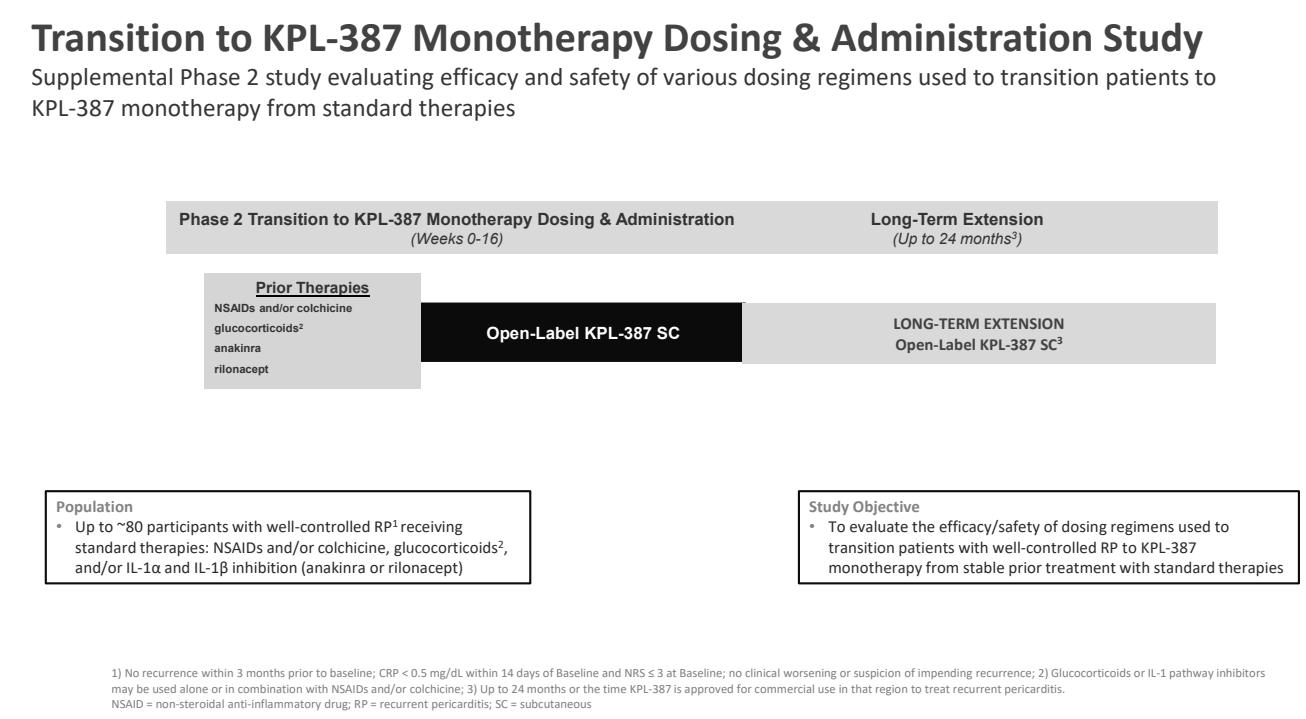
In June 2024, we initiated a Phase 1 clinical trial of KPL-387 in healthy volunteers. Topline data from the trial have shown that a single subcutaneous dose of KPL-387 maintained levels in circulation sufficient to support our belief that the drug could offer the potential for monthly subcutaneous administration in recurrent pericarditis, a chronic disease that can last for years. We aim to explore this hypothesis further during Phase 2 development.

Phase 2 Clinical Trial

In July 2025, we initiated our Phase 2/3 clinical trial of KPL-387 in recurrent pericarditis, beginning with the Phase 2 dose-focusing portion of the study. The trial is designed to enroll up to approximately 80 patients with recurrent pericarditis who present at screening with a qualifying pericarditis episode despite treatment with conventional oral therapies. The primary efficacy endpoint is time to treatment response and time to CRP normalization (CRP ≤ 0.5mg/dL). We expect data from this trial in the second half of 2026 and plan to use the totality of the data to determine further development strategy. The following graphic shows the trial design in more detail:



In addition, we are conducting a supplemental Phase 2 transition to KPL-387 monotherapy dosing and administration study to evaluate the efficacy and safety of dosing regimens used to transition patients from standard pericarditis therapies to KPL-387 monotherapy. The trial is designed to enroll up to 80 participants with well-controlled recurrent pericarditis receiving standard therapies (NSAIDS and/or colchicine, glucocorticoids and/or IL-1α and IL-1β inhibition). The following graphic shows the trial design in more detail:



KPL-1161

KPL-1161 is an independently developed, pre-clinical, Fc-modified immunoglobulin G2 monoclonal antibody that binds IL-1R1, inhibiting IL-1α- and IL-1β-mediated signaling. KPL-1161 is a modified version of KPL-387 designed to have an increased drug half-life that we believe could support quarterly subcutaneous dosing. We are currently conducting pre-clinical development of this asset and plan to initiate a Phase 1 first-in-human clinical trial of KPL-1161 by the end of 2026.

Abiprubart

Abiprubart is an investigational monoclonal antibody inhibitor of CD40-CD154 costimulatory interaction. We previously announced a Phase 2b clinical trial of abiprubart in Sjögren's Disease. In February 2025, we announced our plans to discontinue development of abiprubart in the indication and explore strategic alternatives for the asset. We previously conducted a proof-of-concept Phase 2 clinical trial of abiprubart in RA and a Phase 2b clinical trial of abiprubart in Sjögren's Disease. We believe that disrupting the CD40-CD154 co-stimulatory interaction is an attractive approach to addressing multiple autoimmune disease pathologies. We also believe that abiprubart's ability to be administered in a high-concentration subcutaneous formulation that enables monthly dosing potentially distinguishes it from other competitors.

Discovery Activities

We conduct internal discovery activities directed toward wholly owned molecules for the treatment of debilitating disease targets where we believe there to be a strong mechanistic rationale and potential for clear differentiation from existing approved agents or those in development.

Manufacturing

We do not currently own or operate any late-stage 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 of our early-stage product candidates for the majority of our clinical development efforts, as well as for the commercial manufacture of ARCALYST and our future products. Regeneron currently manufactures and supplies all of our requirements of ARCALYST for development and commercial activities pursuant to the Supply Agreement (as defined below). The Supply Agreement terminates upon the sooner of the termination of the Regeneron Agreement and the date of the completion of the transfer of technology related to the manufacture of ARCALYST drug substance. We are currently conducting a transfer of technology related to the manufacturing process of ARCALYST drug substance and the analytical testing methods of ARCALYST drug substance and drug product. As part of this process, we are working with Samsung, who will serve as the new manufacturer of ARCALYST drug substance and CTLs who will serve as the new analytical testing labs of ARCALYST drug substance and drug product. 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 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.*" Fill-finish, labeling, packaging and shipping services are conducted by additional third-party contractors.

We also have engaged CDMOs to produce our clinical product candidates. We intend to use such CDMOs for development and scale-up work for any future clinical trials and eventual commercialization of such product candidates, if approved.

We require our CDMOs to conduct manufacturing activities in compliance with current good manufacturing practice or comparable foreign requirements ("cGMP"). We have assembled a team of experienced employees and consultants to provide the necessary technical, quality and regulatory oversight of our CDMOs. We currently perform most process development internally but are reliant on CDMOs for late-stage clinical product manufacturing, process qualification, validation and commercial supply. We anticipate that the CDMOs currently manufacturing our product candidates will have the capacity to support both future clinical supply and commercial-scale production, but we do not have any formal agreements at this time with any of such CDMOs to cover commercial production. We also may elect to pursue additional CDMOs for manufacturing supplies of drug substance and finished drug product in the future.

Our reliance on third parties to manufacture certain of our products and product candidates exposes us to risks, and any technology transfer of the manufacturing process for our products or product candidates may be subject to a number of risks and uncertainties, see "*Risk Factors – Risks Related to Manufacturing and Our Reliance on Third Parties.*"

Commercial Operations

Our commercial team combines years of pharmaceutical commercial leadership experience with a passion for helping patients with significant unmet medical need. Since March 2021, we have marketed ARCALYST, our only commercial product, in the United States for recurrent pericarditis and have established our own specialty salesforce to expand our commercialization efforts nationwide. For more information, see "*Business—Our Products—ARCALYST – Commercial Strategy for ARCALYST*."

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face potential competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Our products and any product candidates that we successfully develop and commercialize may compete with existing products and new products that may become available in the future.

Competition poses a number of risks to our company, with a number of competitive factors affecting our ability to market and commercialize our products and product candidates. For more information, see "*Risk Factors—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.*"

We are aware of the following drugs currently marketed or in clinical development for the treatment of the diseases that we are targeting or may plan to target:

ARCALYST

Recurrent Pericarditis: We are not aware of any other FDA-approved therapies for recurrent pericarditis, but we are aware of several competitors developing treatments for this indication. CardiolRx is an oral cannabidiol being developed by Cardiol Therapeutics in a Phase 3 clinical trial, targeting patients who are discontinuing treatment with an IL-1 blocker. R-Pharm International is developing goflikicept, which is a cytokine trap that inhibits IL-1α/IL-1β-induced signaling. This drug is approved and marketed in Russia but with no currently active trial in the United States. Ventyx Biosciences is developing VTX2735, which is designed to inhibit the NLRP3 inflammasome, an intracellular sensor of a broad range of danger signals, that leads to the production and release of IL-1β and IL-18. In addition to their development program in CAPS, Ventyx Biosciences is conducting a Phase 2 trial of VTX2735 in recurrent pericarditis, which began in January 2025. In January 2026, Ventyx Biosciences announced that it had entered into a definitive agreement to be acquired by Eli Lilly and Company (this acquisition is expected to close in the first half of 2026). Monte Rosa Therapeutics is developing MRT-8102 (a molecular glue degrader targeting NEK-7) and has announced plans to expand their ongoing Phase 1 proof-of-concept studies in individuals at high risk for cardiovascular disease and are planning to initiate a Phase 2 study in patients with atherosclerotic cardiovascular disease. They have indicated that they continue to evaluate additional indications including recurrent pericarditis.

Dual IL-1α and IL-1β Inhibition: Other drugs, while not approved for the treatment of recurrent pericarditis, also inhibit IL-1α/IL-1β-induced signaling. Anakinra (KINERET), marketed by Swedish Orphan Biovitrum AB, is currently approved for use in RA, CAPS and DIRA, and lutikizumab (a bispecific antibody targeting IL-1α andIL-1β) is being developed by Abbvie for the treatment of hidradenitis suppurativa, ulcerative colitis, atopic dermatitis, psoriatic arthritis, rheumatoid arthritis, and Crohn's Disease.

IL-1β Inhibition Alone: There are also drugs that inhibit IL-1β-induced signaling but do not inhibit IL-1α-induced signaling. 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), Adult Onset Still's Disease (AOSD), Systemic Juvenile Idiopathic Arthritis (SJIA) and gout flares.

Other Competitors. We are also aware of several other molecules that do not directly compete with our approved indications for ARCALYST but nonetheless target IL-1α and/or IL-1β directly or indirectly. Development programs targeting IL-1α and/or IL-1β directly or indirectly via the NLRP3 inflammasome include: ZYIL-1 (by Zydus Lifesciences in amyotrophic lateral sclerosis); HT-6184 (by Halia in myelodysplastic syndromes, inflammatory pain); OLT1177 (by Olatec Therapeutics in osteoarthritis of the knee and acute gout flares); DFV-890 (by Novartis in FCAS); MAS-825 (by Novartis for the treatment of hidradenitis suppurativa and Still's disease); Selnoflast (by Roche, no indications announced); NT-00249 (by NodThera, no indications announced); NT-0796 (by NodThera in obesity); Somalix and Inzomelid (by Roche, no indications announced); VTX-3232 (by Ventyx Bioscience in Parkinson's); SSGJ-613 (by Sunshine Guojian Pharmaceuticals in acute gout); Natrunix (by XBIOTECH Inc in rheumatoid arthritis, axial

spondylarthritis); AVTX-009 (by Avalo Therapeutics in hidradenitis suppurativa); CAN-10 (by Cantargia in healthy subjects and plaque psoriasis); PCRX-202 (by Pacira Biosciences, osteoarthritis of the knee), SAR445399 (by Sanofi in hidradenitis suppurativa); LAD191/ALM27134 (by Almirall in hidradenitis suppurativa) and VENT-02 (by Ventus Therapeutics, no indications announced). There are also therapies that modulate IL-1α-induced signaling in preclinical and clinical development for diseases other than recurrent pericarditis from Johnson & Johnson and XBIOTECH USA, INC. In addition, Invea Therapeutics is developing INVA8003, a small-molecule inhibitor targeting apoptosis-associated speck-like protein containing a caspase activation and recruitment domain, with a stated intent to prioritize an indication for which injectable IL-1α and/or IL-1β therapies are already approved.

KPL-387

Since we currently expect to develop KPL-387 for the treatment of recurrent pericarditis, we believe that it will compete with the same assets as those described under "*Business—Competition—ARCALYST*", which includes a number of drugs that target IL-1α and/or IL-1β.

For recurrent pericarditis, there are a number of drugs in development that explore alternative dosing methods and frequencies to the once-weekly subcutaneous dosing method of ARCALYST, the only currently FDA-approved treatment. Both CardiolRx and VTX2735, in Phase 3 and 2 development by Cardiol Therapeutics and Ventyx Biosciences, respectively, are being investigated for oral administration. Goflikicept, currently marketed solely in Russia, though with prior clinical studies conducted in the United States, is dosed subcutaneously every two weeks following an initial loading dose. We expect that additional therapies offering even more convenient dosing and administration, including those listed in the sections above, may enter the market, including therapies that offer quarterly dosing. For KPL-387 to succeed on a commercial basis, if approved, we expect that it will need to compete against such drugs by offering a more convenient dosing regimen and/or an improved risk-benefit profile than other available options.

Abiprubart

There are various programs in clinical development antagonizing the CD40 / CD154 costimulatory pathway; however, we believe the high concentration liquid formulation of abiprubart may enable chronic subcutaneous dosing at a higher dose level than other similar drugs, which could be a key differentiator.

Amgen is developing Dazodalibep (anti-CD40L) for the treatment of Sjogren's Syndrome with Moderate to Severe Systemic Disease Activity. Sanofi S.A./ImmuNext Inc. are developing frexalimab (anti-CD40L) for the treatment of Relapsing Multiple Sclerosis, Non-relapsing Secondary Progressive Multiple Sclerosis, Systemic Lupus Erythematosus, Type 1 Diabetes and Focal segmental glomerulosclerosis. Biogen, Inc. and UCB S.A. are developing dapirolizumab pegol (anti-CD40L) for the treatment of moderately to severely active Systemic Lupus Erythematosus. Eledon Pharmaceuticals, Inc. is developing tegoprubart (anti-CD40L) for use by patients undergoing kidney transplantation. AbbVie is developing Ravagalimab (anti-CD40) for the treatment of moderately to severely active Rheumatoid Arthritis. H. Lundbeck A/S is developing Lu AG22515 (bi-specific, anti-CD40L & Albumin (scFv)2-Fab) for the treatment of moderate to severe thyroid eye disease. Tonix Pharmaceuticals, Inc is developing TNX-1500 (anti-CD40L) for use in kidney transplant recipients. Innovent Bio is developing IBI-355 (anti-CD40L, no indication announced).

License and Acquisition Agreements

Out-Licensing Agreements

Genentech Agreement

In August 2022, we entered into a license agreement (the "Genentech License Agreement") with Genentech, Inc. and F. Hoffmann-La Roche Ltd. (collectively, "Genentech"), pursuant to which we granted Genentech exclusive worldwide rights to develop, manufacture 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. In total, we have recognized $50.0 million in additional payments from Genentech related to delivery of certain drug material to Genentech and Genentech's achievement of development milestones under the Genentech License Agreement. We remain eligible to receive up to approximately $570.0 million in additional contingent payments, including specified development, regulatory and sales-based milestones, before fulfilling our upstream financial obligations to Biogen, Inc. (as further described in Note 13 to our consolidated financial statements included elsewhere in this Annual Report). 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.

Absent early termination, the Genentech License Agreement will continue until there are no more royalty or other payment obligations owed to us. Genentech has the right to terminate the Genentech License Agreement at its discretion with prior written notice and either party may terminate the Genentech License Agreement in the event of an uncured material breach of the other party or in the case of insolvency of the other party. In addition, the Genentech License Agreement will terminate upon termination of our upstream license agreement related to vixarelimab.

Huadong Collaboration Agreements

In February 2022 we entered into two collaboration and license agreements (each, a "Huadong Collaboration Agreement" and together, the "Huadong Collaboration Agreements") with Huadong, pursuant to which we granted Huadong exclusive rights to develop and commercialize ARCALYST and develop, manufacture and commercialize mavrilimumab in each case in a territory currently consisting of the following countries: People's Republic of China, Hong Kong SAR, Macao SAR, Taiwan Region, Indonesia, The Philippines, Thailand, Bangladesh, Bhutan, Brunei, Burma, Cambodia, India, Laos, Malaysia, Maldives, Mongolia, Nepal, New Zealand, Sri Lanka and Vietnam (collectively, the "Huadong Territory"). We otherwise retained our rights to ARCALYST and mavrilimumab outside the Huadong Territory.

In April 2025, we and Huadong entered into a mutual termination agreement pursuant to which we agreed to terminate the mavrilimumab Huadong Collaboration Agreement and release all claims related thereto. The ARCALYST Huadong Collaboration Agreement remains in effect.

Under the Huadong Collaboration Agreements, we received a total upfront cash payment of $22.0 million, which includes $12.0 million for the Huadong Territory license of ARCALYST and $10.0 million for the Huadong Territory license of mavrilimumab. In the fourth quarter of 2024, following the achievement of a regulatory milestone under the ARCALYST Huadong Collaboration Agreement, Huadong became obligated to make an additional cash payment of $20.0 million, which was received in the first quarter of 2025. We remain eligible to receive up to approximately $50.0 million in sales-based milestone payments for ARCALYST. Due to its termination, we do not expect to receive any future payments under the mavrilimumab Huadong Collaboration Agreement. Huadong will also be obligated to pay us tiered percentage royalties ranging from the low to mid-teens on annual net sales of ARCALYST in the Huadong Territory, subject to certain reductions tied to ARCALYST manufacturing costs and certain other customary reductions, with an aggregate minimum floor. Royalties will be payable on a country-by-country or region-by-region basis until the later of (i) 12 years after the first commercial sale of ARCALYST 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 ARCALYST in such country or region in the Huadong Territory and (iii) the expiration of the last regulatory exclusivity for ARCALYST in such country or region in the Huadong Territory.

Pursuant and subject to the terms of the Huadong Collaboration Agreements, Huadong has the exclusive right to conduct Huadong Territory-specific development activities for ARCALYST in the Huadong Territory, the first right to support global development of ARCALYST by serving as the sponsor of the global clinical trials conducted in the Huadong Territory and the exclusive right to commercialize ARCALYST in the Huadong Territory. Huadong will be

responsible for all costs of development activities and commercialization in the Huadong Territory. We and Huadong participate in a joint steering committee, which coordinates and oversees the exploitation of ARCALYST in the Huadong Territory.

We will supply certain materials to support development and commercialization activities for ARCALYST.

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

In-Licensing Agreements

License Agreement with Regeneron

In September 2017, we entered into a license agreement with Regeneron (the "Regeneron Agreement")"), pursuant to which we were 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, our pivotal Phase 3 clinical trial of ARCALYST, Regeneron transferred the biologics license application ("BLA") for ARCALYST to us. 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, we assumed the sales and distribution of ARCALYST for CAPS and DIRA in the United States.

Under the Regeneron Agreement, we paid $32.5 million in connection with upfront fees and the achievement of regulatory milestones. 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. To the extent permitted in accordance with the Regeneron Agreement, the fully-burdened costs incurred by each of us 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. 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.

The Regeneron Agreement will expire on the date on which we, our affiliates or sublicensees are no longer developing or commercializing any product containing ARCALYST. We may terminate the agreement for convenience at any time with one year's written notice. We may also terminate with three months' written notice if we reasonably determine that ARCALYST is unsafe in the indications we are pursuing. Regeneron may terminate the agreement if there is a consecutive twelve-month period during which we do not conduct any material development or commercialization activities or we do not grant a sublicense to a third party to do so, or if we challenge Regeneron's patent rights in any country in our territory. Either party may terminate the agreement in the event of a material breach

by the other party that remains uncured for 90 days (or 30 days for payment-related breaches), or by either party due to the insolvency or bankruptcy of the other party.

We have also entered into a commercial supply agreement with Regeneron (the "Supply Agreement"), under which Regeneron agreed to manufacture product for our clinical and commercial use. The Supply Agreement terminates upon the sooner of the termination of the Regeneron Agreement and the date of the completion of the transfer of technology related to the manufacture of ARCALYST drug substance.

Beth Israel Deaconess Medical Center License Agreement

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 the rights to an exclusive license to certain intellectual property rights controlled by BIDMC to make, use, develop and commercialize abiprubart under the BIDMC license agreement (the "BIDMC Agreement"). Under the BIDMC Agreement, we are solely responsible for all development, regulatory and commercial activities and costs. We are also responsible for costs related to filing, prosecuting and maintaining the licensed patent rights. Under the BIDMC Agreement, we are obligated to pay an insignificant annual maintenance fee as well as future clinical and regulatory milestone payments of up to an aggregate of $1.2 million to BIDMC. We are also obligated to pay a low single-digit royalty on annual net sales of products licensed under the agreement, if approved.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our drug candidates, manufacturing and process discoveries and other know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. We plan to protect our proprietary position using a variety of methods, which include pursuing United States and foreign patent applications related to our proprietary technology, inventions and improvements, which can include compositions of matter, drug product formulations, methods of use and methods of manufacture. We also rely on trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position.

ARCALYST

We have a field-specific exclusive license under the Regeneron Agreement to granted patents and pending applications in the United States and numerous other jurisdictions relating to ARCALYST. 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 2023. Five patents covering methods of using ARCALYST in the treatment of recurrent pericarditis have issued in the United States and have a statutory term that expires in 2038, not including any patent term adjustment. In March 2021, the FDA granted approval for ARCALYST for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children 12 years of age and older, which granted us seven years of marketing exclusivity in the United States. See "*Business—In-Licensing Agreements – License Agreement with Regeneron*" above for additional information on our rights under the Regeneron Agreement.

KPL-387

We own pending patent applications relating to KPL-387, which cover formulations and methods of manufacturing KPL-387. If issued, such patents will have statutory expiration dates in 2045, not including any patent term extensions or adjustments. As of December 31, 2025, one patent covering KPL-387 formulations has issued in the United States, expiring in 2045, not including any patent term extensions. We also own a pending patent application covering methods of using KPL-387 in the treatment of recurrent pericarditis. If issued, patents covering methods of using KPL-387 in treating recurrent pericarditis will have statutory expiration dates in 2046, not including any patent term extensions or adjustments. If we are successful in obtaining regulatory approval of KPL-387 for the treatment of recurrent pericarditis, we also expect to rely on data exclusivity and orphan exclusivity (if we satisfy the criteria for orphan drug exclusivity at the time of approval and thereafter) to protect our market position. For example, in the United States, a new biologic product receives 12 years of data exclusivity upon receiving regulatory approval. In the EU, a new

product generally receives eight years of data exclusivity and an additional two years of market exclusivity upon regulatory approval. See "*Business –Government Regulation*" below for additional information on regulatory exclusivities.

KPL-1161

We own a pending patent application relating to KPL-1161, which covers composition of matter. If issued, patents covering the composition of matter will have statutory expiration dates in 2046, not including any patent term extensions or adjustments.

Abiprubart

We own, via our acquisition of Primatope, granted patents and pending patent applications in the United States and numerous other jurisdictions relating to abiprubart. We also have an exclusive license with BIDMC to granted patents and pending patent applications in the United States and numerous other jurisdictions relating to abiprubart. These patents and patent applications cover abiprubart as a composition of matter and its use. As of December 31, 2025, the patent rights acquired from Primatope include four patents granted in the United States and 32 patents granted in other jurisdictions, including Australia, Brazil and selected countries in Europe and Asia. In addition, the patent rights acquired from Primatope include patent applications pending in the United States, Australia, Europe, Canada and selected countries in Asia. The issued composition of matter patents acquired from Primatope have statutory expiration dates in 2036, not including any patent term extensions or adjustments. As of December 31, 2025, the patent rights licensed from BIDMC include two patents granted in the United States and 58 patents granted in other jurisdictions, including Australia, Canada and selected countries in Europe and Asia. In addition, the patent rights licensed from BIDMC include patent applications pending in the United States, Europe and Canada. The issued composition of matter patents licensed from BIDMC have statutory expiration dates in 2032, not including any patent term extensions or adjustments. Patent term extension could extend the expiration date of one patent in the United States and patents in certain other jurisdictions, each in accordance with applicable law.

Other Intellectual Property

In addition to the above, we maintain certain other intellectual property, including patents, trademarks and know-how, related to our other assets, pre-clinical development and broader Kiniksa brand.

There can be no assurances that patents will issue from any of our pending patent applications or that any of our existing patents may be extended. See "*Risk Factors—Risks Related to Intellectual Property."*

In the future, if and when our drug candidates receive approval by the FDA or comparable regulatory authorities in other jurisdictions (as applicable, "regulatory authorities"), provided the legal requirements are met, we expect to apply for patent term extensions on issued patents covering those drugs, depending upon the length of the clinical trials for each drug and other factors. There can be no assurance that any of our pending patent applications will issue or that we will benefit from any patent term extension or favorable adjustment to the term of any of our patents.

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug products. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

United States Government Regulation of Biological Products

In the United States, the FDA regulates biologics under the Federal Food, Drug, and Cosmetic Act (the "FDCA") and the Public Health Service Act (the "PHSA") and their implementing regulations. Biologics are also subject to other federal, state and local statutes and regulations.

The process required by the FDA before a biologic may be marketed in the United States generally involves the following:

- Completion of extensive preclinical tests; animal studies; and toxicology, pharmacology and formulation studies in accordance with applicable regulations, including the FDA's good laboratory practice ("GLP") regulations, or similar foreign standards;

- Submission to FDA of an investigational new drug application (an "IND") which must become effective before human clinical trials may begin;

- Approval by an independent institutional review board (an "IRB") overseeing each clinical trial site, in each case before a trial may be initiated;

- Performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practices ("GCPs") and other clinical trial related regulations to evaluate the safety and efficacy of the product candidate for each proposed indication;

- Submission to FDA of a BLA for marketing approval after completion of the required pivotal clinical trials;

- Satisfactory completion of any FDA pre-approval inspections of the manufacturing facility or facilities where the product will be produced to assess compliance with cGMPs; and

- FDA review and approval of the BLA.

Preclinical Studies

Before testing any biological product candidate, including our product candidates, in humans, the product candidate must undergo rigorous preclinical testing. The preclinical development stage generally involves laboratory evaluations of the chemistry, formulation and stability of the product candidate, as well as animal trials to evaluate toxicity. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLP regulations. Before conducting a clinical trial in the United States, the sponsor must provide the results of the preclinical studies as part of an IND submitted to the FDA, along with other information, including information about chemistry, manufacturing and controls ("CMC"). An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA places the clinical trial on hold and the IND sponsor must resolve any outstanding issues before clinical trials can proceed.

Clinical Trials

Clinical trials involve the administration of the investigational product to normal healthy volunteers or participants under the supervision of qualified investigators. Clinical trials must be conducted in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials also must be conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, participant selection and inclusion/exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, an IRB representing each institution at which the clinical trial

will be conducted must review and approve the plan for any clinical trial, including, among other things, the protocol and informed consent information to be provided to clinical trial subjects or their legal representatives, to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also must monitor the clinical trial until completed.

Some clinical trials also include oversight by an independent group of qualified experts organized by the clinical study sponsor, commonly known as a Data Safety Monitoring Board (a "DSMB") or Data Monitoring Committee (a "DMC"), which may recommend continuation of a trial as planned, changes in the trial or cessation of the trial at designated check points based on access to certain data from the trial. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the participants are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to participants. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined.

- Phase 1 clinical trials generally involve a small number of participants, who are usually healthy participants (Phase 1a), although Phase 1 clinical trials can, in certain circumstances, involve patients with the target disease or condition (Phase 1b). The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, tolerability and safety of the drug.

- Phase 2 clinical trials involve studies in participants with the target disease or condition to determine the optimal dose and dosing schedule. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.

- Phase 3 clinical trials generally involve a larger number of participants at multiple, geographically dispersed clinical trial sites and are designed to provide the data necessary to demonstrate the effectiveness of the product candidate for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product candidate and provide an adequate basis for product labeling and approval.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of participants in the intended therapeutic indication, particularly for long-term safety follow up. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of a BLA.

BLA Review and Approval

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's CMC and proposed labeling, among other things, are submitted to the FDA as part of a BLA requesting marketing approval for a product for one or more indications. To support marketing approval, the data submitted from company sponsored clinical trials or potentially other alternative sources must be sufficient in quality and quantity to establish the safety, purity and potency (or efficacy) of the investigational product to the satisfaction of the FDA. In relevant cases, the BLA must include data relevant to safety, efficacy and dosing for pediatric populations. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States.

In most cases, the submission of a BLA is subject to a substantial application user fee. Within 60 days following submission of the application, the FDA reviews all BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may require the sponsor to provide additional information before accepting the BLA for filing. Once the BLA submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews a BLA to determine, among other things, whether the product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the

product's continued safety, purity and potency. Most BLAs are reviewed within ten months from the filing date or six months from the 60-day filing date for BLAs with priority review, subject in each case to extensions by the FDA.

Before approving a BLA, the FDA will typically conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether the manufacturing processes and facilities comply with cGMPs and are adequate to ensure consistent product production within required specifications. The FDA also may inspect the sponsor and one or more clinical trial sites to assure compliance with GCP requirements and integrity of the clinical data submitted to the FDA.

Additionally, the FDA may refer applications for novel biologic candidates, which present challenges in interpretation of the safety or efficacy data, to an Advisory Committee, typically a panel that includes clinicians and other experts appointed by the FDA Commissioner or a designee, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations when making decisions on approval.

The BLA approval process is lengthy and difficult, and the FDA may refuse to approve a BLA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. After the FDA evaluates a BLA, it will issue an approval letter or a Complete Response Letter ("CRL"). An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates the deficiencies in the submission and may require substantial additional testing or information for the FDA to reconsider the BLA. If and when the deficiencies have been addressed to the FDA's satisfaction, the FDA will issue an approval letter.

FDA approval authorizes commercial marketing of a drug or biologic product with specific prescribing information and for specific indications. As a condition of approval, the FDA may require, among other things, post-approval trials or testing and surveillance programs to monitor the product after commercialization or implementation of a risk evaluation and mitigation strategy ("REMS") to ensure the benefits of the product outweigh the potential risks. The FDA may prevent or limit further marketing of a product based on the results of post-marketing trials or surveillance programs, or new safety findings after market introduction. After approval, certain changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product. After the FDA grants Orphan Drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan Drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Orphan Drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to Orphan Drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity.

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. In addition, 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 the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Expedited Review and Approval

The FDA is authorized to designate certain product candidates for expedited development and review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include Fast Track designation, Breakthrough Therapy designation, accelerated approval and priority review.

To be eligible for a Fast Track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need for such disease or condition. Fast Track designation provides opportunities for more frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the BLA for a Fast Track product on a rolling basis before the complete application is submitted, if the sponsor and the FDA agree on a schedule for the submission of the application sections, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for Breakthrough Therapy designation. A product candidate can receive Breakthrough Therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

A product candidate intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA generally requires that a sponsor of a product receiving accelerated approval perform adequate and well-controlled confirmatory clinical trials to verify the predicted clinical benefit. A product that receives accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails conduct the required confirmatory trials in a timely manner or if such trials fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

The FDA may designate a product candidate for priority review if the product candidate is designed to treat a serious condition, and if approved, would provide a significant improvement in safety or effectiveness compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a biologic designated for priority review in an effort to facilitate the review. The FDA endeavors to review original BLAs with priority review designations within six months of the filing date as compared to ten months under its standard review goals.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, Fast Track designation, Breakthrough Therapy designation, accelerated approval and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

Post-approval Requirements

Once a BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs and biologics, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet and social media. Drugs and biologics may only be marketed for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports are required following FDA approval of a BLA.

In addition, FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMPs. We rely, and expect to continue to rely, on third party CDMOs for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. We, and our CDMOs are required to register our establishments with the FDA and certain state agencies. Registration with the FDA subjects us and our CDMOs to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, we and our CDMOs must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or other enforcement-related letters or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs; or mandated modification of promotional materials and labeling and the issuance of corrective information.

Biosimilars and Exclusivity

An abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA") as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (the "ACA").

Under the BPCIA, a manufacturer may submit an application for a biological product that is "biosimilar to" or "interchangeable with" a previously approved "reference product." Biosimilarity requires that the biological product be highly similar to the reference product and that there be no clinically meaningful differences in safety, purity and potency. This must be demonstrated through analytical studies, animal studies and a clinical trial or trials. In order to meet the higher hurdle of interchangeability, a sponsor must demonstrate that the biosimilar product can be expected to produce the same clinical result as the reference product, and for a product that is administered more than once, that the risk of switching between the reference product and biosimilar product is not greater than the risk of maintaining the patient on the reference product.

Under the BPCIA, a reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product.

Foreign Government Regulation

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials, marketing authorization, post-marketing requirements and any commercial sales and distribution of products approved in such jurisdictions. The product approval process ultimately varies between

countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Regulatory Framework in the European Union

Clinical Trials

Clinical trials of medicinal products in the European Union ("EU") are governed by the Clinical Trials Regulation (EU) No 536/2014 (the "CTR"), which became applicable on January 31, 2022, and repealed the Clinical Trials Directive. The CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System ("CTIS"), which contains a centralized EU portal and database. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

While the Clinical Trials Directive required a separate clinical trial application (a "CTA") to be submitted in each member state, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB respectively, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned to streamline the regulatory review. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include information concerning the trial protocol and the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized. For each clinical trial submitted in CTIS, one reporting member state will lead the assessment process for those elements of the clinical trial application that are common throughout the EU, and member states concerned by the application may raise objections to the reporting member state's assessment. Each member state is responsible for assessing the elements specific to its own territory, including ethics rules. Once the CTA is approved, clinical study development may proceed. Documents and data from the CTA are made publicly available through CTIS at time of decision about the clinical trial, subject to the redaction of personal data and confidential information.

Since January 2025, all clinical trials (including those which are ongoing but approved under the previous legal framework) are regulated by the CTR.

Medicines used in clinical trials must be manufactured in accordance with cGMP. Other national and EU-wide regulatory requirements may also apply.

Marketing Authorization

In the EU, medicinal products can only be placed on the market after obtaining a marketing authorization (an "MA"). To obtain a MA of a product candidate in the EU, we must submit a MA application (an "MAA"). The process for doing this depends, among other things, on the nature and therapeutic category of the medicinal product. There are two types of MAs that can be granted by the relevant competent authorities:

- "Centralized MAs" are issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use (the "CHMP") of the EMA, and are valid throughout the EU. The centralized procedure is compulsory for certain types of medicines, such as (i) medicines derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced-therapy medicines (such as gene-therapy, somatic cell-therapy or tissue-engineered products) and (iv) products with a new active substance indicated for the treatment of specified diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases or autoimmune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active

substance not yet authorized in the EU, or for products that represent a significant therapeutic, scientific or technical innovation or whose authorization would be in the interest of public health in the EU. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding any procedural clock stops. Clock-stops are periods during which the evaluation is paused to allow the applicant sufficient time to provide additional information in response to questions asked by the CHMP.

- "National MAs" are granted by the competent authorities of the EU member states, only cover their respective territory and are available for medicinal products that fall outside the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EU member state, this national MA can be recognized in one or more additional member states through the Mutual Recognition Procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in two or more member states through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state. Consistent with EU pharmaceutical law requirements, in order to grant the MA, the competent authorities of the EU assess the risk-benefit balance of the product against the scientific criteria relating to its quality, safety and efficacy.

MAs have an initial duration of five years. After this period, the authorization may be renewed and its validity extended, subject to a satisfactory reevaluation of the risk-benefit balance of the product.

In the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional MA for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. A conditional MA is subject to specific obligations such as generating comprehensive evidence to confirm the benefit-risk balance of the product. It is valid for one year and must be renewed annually until all conditions are fulfilled. Once outstanding data are provided and satisfactorily assessed, the conditional MA can be converted into a standard (traditional) MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the MA will cease to be renewed or may be revoked.

Data and Marketing Exclusivity

The EU also provides opportunities for marketing exclusivity. Newly authorized products that qualify as reference medicinal products – based on a complete, stand-alone dossier consisting of pharmaceutical, non-clinical and clinical trial data – receive eight years of data exclusivity, followed by additional two years of marketing exclusivity upon receiving an MA. During the data exclusivity period in the EU, biosimilar applicants are not permitted to rely on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a biosimilar MA. Once the eight-year data exclusivity has expired, a biosimilar MAA can be submitted and approved. However, no biosimilar product can be commercialized until the full ten-year exclusivity period has expired. The overall ten-year data and marketing exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Approval of a biosimilar differs from the conventional regulatory process for approving generic products because biosimilars do not meet the definition of a generic medicinal product. This is primarily due to differences in raw materials or manufacturing processes or the complex nature of biological products. Approval of a biosimilar require submission of appropriate preclinical or clinical trial results. The EMA and its advisory committees have developed detailed guidelines specifying the type of supplementary data that should be provided for different classes of biological products. These guidelines outline the evidence necessary to demonstrate that the biosimilar is comparable to the

reference product in terms of quality, safety, and efficacy. Currently, there exist no specific guidelines for complex biological products, such as gene or cell therapy medicinal products. The EMA has indicated that guidance for such complex biological products may be developed in the future, taking into account advancements in scientific knowledge and regulatory experience as they are gained.

Orphan Medicinal Products

The criteria for designating an "orphan medicinal product" in the EU, are broadly similar to those in the United States with the additional requirement in the EU to demonstrate significant benefit during the designation procedure. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a MA, entitled to ten years of market exclusivity for the approved therapeutic indication. During this ten-year orphan market exclusivity period, the competent authorities cannot accept another MAA, grant an MA or accept an application to extend a MA for a similar product for the same indication. Orphan Drug designation does not confer any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity in the EU may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, a MA may be granted to a similar product for the same indication at any time if (i) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (ii) the marketing authorization holder for the first approved product consents to a second orphan medicinal product application; or (iii) the marketing authorization holder cannot supply sufficient quantities of the approved orphan medicinal product.

Pediatrics Development

In the EU, MAAs for new medicinal products must be accompanied by the results of studies contained in a pediatric investigation plan (a "PIP") agreed with the EMA's Pediatric Committee (the "PDCO"), unless a deferral or a waiver applies. The PIP sets out the timing and measures proposed to generate the necessary data determining the conditions in which a medicinal product may be authorized to treat the pediatric population. The PDCO can grant a deferral of the obligation, allowing the requirement to carry out some or all of the measures of the PIP to be postponed until sufficient data are available to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when such data are necessary or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU member states and study results are included in the product information, regardless of whether those results would lead to approval of a pediatric indication, the product is eligible for six months' supplementary extension of the basic patent protection under a supplementary protection certificate (if one is in effect at the time of approval) or, in the case of orphan medicinal products, a two-year extension of the ten-year orphan market exclusivity may be granted under the same conditions. An extension of a supplementary protection certificate cannot be granted for orphan medicinal products, and only one of these incentives may be awarded.

PRIME Designation

In the EU, innovative products that address conditions with an unmet medical need – either because no treatment option exists or because they can offer a major therapeutic advantage over existing treatments– may be eligible for early and proactive support. Such products can benefit from a range of expedited development and review programs, including the Priority Medicines ("PRIME") scheme, which shares a common objective with the US Breakthrough Therapy designation to optimize and accelerate the development and regulatory assessment of promising therapies. The benefits of a PRIME designation include the appointment of a rapporteur before submission of an MAA, early dialogue and scientific advice at key development milestones and the potential to qualify products for accelerated review earlier in the application process. Product developers that benefit from PRIME designation may be eligible for accelerated assessment (in 150 days instead of 210 days), which may be granted for medicinal products of major interest from a public health perspective or that target an unmet medical need, but this is not guaranteed.

Post-approval Requirements

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the EU member states. The holder of an MA for a medicinal product must also comply with pharmacovigilance legislation and its related regulations and guidelines, which entail many requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of medicinal products. The holder of a MA must establish and maintain a pharmacovigilance system and appoint a qualified person for pharmacovigilance (a "QPPV") who is responsible for the establishment and maintenance of that system. MA holders required to record all suspected adverse reactions within and outside the EU and report all serious suspected adverse reactions expeditiously. In addition, MA holders are required to submit periodic safety update reports ("PSURs") or periodic benefit-risk evaluation reports to evaluate the benefit-risk balance of a medicinal product at defined time points after its authorization.

All new MAAs must include a risk management plan ("RMP"), describing the risk management system consisting of a set of pharmacovigilance activities and interventions designed to identify, characterize, prevent or minimize the risks relating to a medicinal product, including the assessment of those activities and interventions. The RMP must be updated whenever new information becomes available that significantly impacts its content. The regulatory authorities may also impose specific obligations as a condition of the MA. These risk-minimization measures or post-authorization requirements may include additional safety monitoring, more frequent submission of PSURs or the conduct of additional clinical trials or post-authorization safety studies.

Advertising and promotion of medicinal products are subject to strict legal requirements, including those governing interactions with healthcare professionals, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the specific rules are set out in national regulations and the codes of conduct of various trade associations within each member state for the rules to be enforced. As a result, the detailed requirements and enforcement practices can vary from country to country.

Failure to comply with EU and national laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of medicinal products, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials or to grant an MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Regulatory Framework in the United Kingdom

Since the end of the Brexit transition period on January 1, 2021, Great Britain (England, Scotland and Wales) has not been directly subject to EU laws. However, under the terms of the Ireland/Northern Ireland Protocol, EU laws applied to Northern Ireland. In February 2023, the EU and UK reached an agreement, known as the Windsor Framework, on the future of trade with Northern Ireland, which amends certain aspects of the Northern Ireland protocol. Pursuant to the Northern Ireland protocol, different medicinal product regulatory regimes applied in Great Britain (being England, Scotland and Wales) and Northern Ireland. In particular, Northern Ireland was bound by EU law concerning medicinal products, whereas Great Britain was not. The Windsor Framework corrects this by disapplying EU pharmaceutical law in Northern Ireland and ensuring regulatory continuity between Great Britain and Northern Ireland. In practice this means that, since these provisions took effect on January 1, 2025, medicinal products destined for sale in both Great Britain and Northern Ireland must be sold under one marketing authorization (MA), and in the same packaging and labelling.

The EU laws that have been transposed into United Kingdom (the "UK") law through secondary legislation remain applicable in Great Britain. However, under the Retained EU Law (Revocation and Reform) Act 2023, which

received royal assent on June 29, 2023, any retained EU law not expressly preserved and "assimilated" into domestic law or extended by ministerial regulations (to no later than June 23, 2026) was automatically expired and revoked by December 31, 2023. New legislation such as the EU CTR or in relation to orphan medicines is, therefore, not applicable to Great Britain. The UK government has passed a new Medicines and Medical Devices Act 2021, which introduces delegated powers in favor of the Secretary of State or an 'appropriate authority' to amend or supplement existing regulations in the area of medicinal products and medical devices. This allows new rules to be introduced in the future by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines, clinical trials and medical devices.

As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency (the "MHRA") is the UK's standalone medicines and medical devices regulator.

To be used or sold in the UK, a drug must have a valid MA granted through the national application process. National applications are governed by the Human Medicines Regulations (SI 2012/1916). Applications are made electronically through the MHRA Submissions Portal. The MHRA operates fixed submission and assessment timetables for innovative medicines applications to facilitate consultation with its statutory advisory committee, the Commission on Human Medicines ("CHM"). The MHRA assessment procedure for a MA application involves an initial evaluation, including orphan designation if applicable, and consultation with expert advisory groups as needed. By Day 90, applicants receive a consolidated request for information ("RFI"), which pauses the review clock until a complete response is submitted electronically. Responses are assessed by Day 150, with further RFIs issued for minor issues or a CHM letter for major objections. Each subsequent RFI requires a complete response within three months, and the clock is restarted upon submission. Applicants may make written or oral representations to the CHM if major objections remain. Final compliance checks are conducted once all issues are resolved, and the MHRA issues a grant or refusal letter specifying any conditions and the MA expiry date. The entire assessment process is designed to be completed within 210 calendar days, excluding any procedural clock-stops for additional information or representations. The innovative medicines timetable allows for a positive decision within 150 clock-on days if all issues are resolved following one round of questions. Where there are outstanding issues at Day 150, we will come to a final decision as soon as possible and within 210 clock-on days. The innovative medicines timetable allows for a positive decision within 150 clock-on days if all issues are resolved following one round of questions. Where there are outstanding issues at Day 150, we will come to a final decision as soon as possible and within 210 clock-on days.

In addition, the MHRA 150-day accelerated review is a specialized, fast-track national MA procedure designed for innovative medicines, new active substances, and biosimilars, aiming for a decision in 150 "clock-on" days rather than the standard 210. It requires high-quality applications, typically involving one round of questions and a 60-day cool-down period for responses.

On August 30, 2023, the MHRA published detailed guidance on its recently announced new International Recognition Procedure ("IRP") for MAAs. The IRP applies from January 1, 2024, and replaces existing EU decision reliance procedure. to apply for authorizations from seven international regulators (e.g. Health Canada, Swiss Medic, FDA, EMA, among others). The IRP allows the MHRA to take into account the assessment and decision-making of the 'Reference Regulators" to perform a targeted assessment of IRP applications but retain the authority to reject applications if the evidence provided is considered insufficiently robust. There exist two recognition timetables for new IRP MAAs: IRP Route A (60 days) and IRP Route B (110 days), both starting from validation. Eligibility is determined via an applicant-completed form six weeks before submission. Recognition A applies to applications with Reference Regulator approval within the past two years, with no clock stop, but may revert to Recognition B if major objections arise. IRP Route B covers Reference Regulator approvals within the past ten years (or exceptionally older) and applies if specific criteria, such as conditional approvals, manufacturing changes, or UK-specific requirements, are met. IRP Route B allows for consultation with the CHM and aligns with CHM dates for new active substances. Applications not eligible for either timetable may be submitted as full national applications if MHRA requirements are met. IRP can be used for post-authorization measures including line extensions, variations, and renewal application.

There will be no pre-MA orphan designation. Instead, the MHRA will review applications for orphan designation in parallel to the corresponding MA application. The criteria are essentially the same as the EU rules, but have been tailored for the market, i.e., the prevalence of the condition in GB, rather than the EU, must not be more than

five in 10,000. Should an orphan designation be granted, the period or market exclusivity will be set from the date of first approval of the product in GB.

Rest of the World Regulation

For other countries outside of the EU and the United States, such as countries in Eastern Europe, Latin America, Asia or Japan, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from jurisdiction to jurisdiction. Additionally, the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Other Healthcare Laws

In the United States, activities of pharmaceutical manufacturers are subject to numerous other federal, state and local laws designed to, for example, prevent "fraud and abuse" in the delivery of and payment for healthcare; promote transparency in interactions with others in the healthcare industry; require reporting of drug prices and payment of rebates or offering of discounts to certain government programs and public and private payors; protect consumers; and regulate government payment for drugs. These laws are enforced by various federal and state enforcement authorities and non-compliance, or alleged non-compliance, with such laws could adversely affect our reputation, our business and our financial results. Similar laws exist in foreign jurisdictions, including the EU, as well.

We may be subject to various federal and state laws pertaining to health care "fraud and abuse," including anti-kickback laws (which typically prohibit soliciting, offering, receiving or paying anything of value to generate healthcare business reimbursable by third party payors, including Medicare and Medicaid) and false claims laws (which generally prohibit anyone from knowingly and willingly presenting, or causing to be presented, any false or fraudulent claims for payment for reimbursed drugs or services to third party payors, including Medicare and Medicaid). Although the specific provisions of these laws vary, their scope is generally broad and there may not be regulations, guidance or court decisions that apply the laws to particular industry practices.

Laws and regulations have also been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers, including laws that require manufacturers 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. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Given the lack of clarity in laws and their implementation, our activities could be subject to challenge.

We may need to obtain and maintain licenses for our manufacturing and distribution activities in the states in which we operate or distribute our products.

In the EU, many EU member states have adopted specific anti-gift statutes that further limit commercial practices for medicinal products, in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities and many EU member states have adopted national laws which impose requirements to disclose financial interactions with healthcare professionals to the government and public (often on an annual basis), similar to the requirements in the United States, on pharmaceutical companies. Certain countries also mandate implementation of commercial compliance programs or require disclosure of marketing expenditures and pricing information.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of approved biological products. Governments around the world are exploring cost containment programs, including price controls, reimbursement restrictions and requirements for biosimilar substitution. In the United States and markets in other countries, patients rely on third party payors to reimburse healthcare costs. Third party payors include government authorities or health care programs, managed care plans, private health insurers and other organizations.

In the United States, the process for determining whether a third party payor will provide coverage and the related coverage criteria for a biological product typically is separate from the process for setting the price of such product or for establishing the level of reimbursement that the payor will pay for the product once coverage is approved. Third party payors may limit coverage or take other action to control utilization of covered products, including restricting coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication, or place products at certain formulary levels that result in lower reimbursement levels, which results in higher cost-sharing financial obligation imposed on patients. Additionally, coverage, coverage criteria and reimbursement for products can differ significantly from payor to payor. One third party payor's decision to cover a particular biologic does not ensure that other payors will also provide coverage for the biologic or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process usually requires manufacturers to provide scientific, clinical and health economic support for the use of their products to each payor separately, which is a time-consuming process.

Third party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-benefit of biopharmaceutical products, in addition to questioning safety and efficacy. If third party payors do not consider a product to offer a favorable cost-benefit compared to other available therapies, they may not cover that product after FDA approval or, if they do, the level of payment may not be sufficient to allow a manufacturer to sell its product at a profit.

In addition, in many countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. In the EU, governments influence the price of products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Member states are free to restrict the range of pharmaceutical products for which their national health insurance systems provide reimbursement, and to control the prices and reimbursement levels of pharmaceutical products for human use. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed to by the government. Member states may approve a specific price or level of reimbursement for the pharmaceutical product, or alternatively adopt a system of direct or indirect controls on the profitability of the company responsible for placing the pharmaceutical product on the market, including volume-based arrangements, caps and reference pricing mechanisms. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits.

Government Programs and Price Reporting

We are subject to federal laws, including the Medicaid Drug Rebate Program (the "MDRP"), 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. Reporting requirements are complex and, in some instances, require reporting manufacturers to make reasonable assumptions in interpreting their obligations.

- *Medicaid.* Our products are eligible to be reimbursed by Medicaid. Medicaid is a joint federal and state program that is administered by the states for low-income and disabled beneficiaries. Under the MDRP, participating manufacturers are required to pay a rebate for each unit of product reimbursed under the state Medicaid programs. The amount of the rebate for each product is set by law and depends in part on the prices at which our products are sold to certain other purchasers and may be subject to an additional

discount if certain pricing increases more than inflation. State Medicaid programs and Medicaid managed care plans can seek additional "supplemental" rebates from manufacturers.

- *Medicare*. Medicare is a federal program that is administered by the federal government that covers individuals age 65 and over, disabled individuals and certain other eligible individuals. Medicare Part B generally covers drugs that are usually administered by physicians or other clinicians. Medicare Part B pays for such drugs under a payment methodology based on the average sales price ("ASP") of the drugs, with manufacturers reporting an ASP for their drug products. Reimbursement levels and reimbursement methodologies have come under scrutiny and may be subject to change. Medicare Part D provides coverage for self-administered drugs (i.e., drugs that do not need to be injected or otherwise administered by a physician). Medicare Part D is administered by private prescription drug plans approved by the United States government. Each drug plan establishes its own government-approved Medicare Part D formulary for prescription drug coverage and pricing, which the drug plan may modify from time-to-time. The prescription drug plans negotiate rebates with manufacturers and may condition formulary placement on the availability of manufacturer discounts. Manufacturers with marketed brand name drugs and biologics are required to provide discounts on such drugs and biologics utilized by Medicare Part D beneficiaries, under a manufacturer discount program. Additionally, as the result of recent changes under the Inflation Reduction Act of 2022 ("IRA"), drug utilization under Medicare Part B and Part D may be subject to an additional Medicare discount if the pricing increases more than inflation.

- *Federal Purchasers*. Drug products are subject to discounted pricing when purchased by federal agencies via the Federal Supply Schedule ("FSS"). FSS participation is required for a drug to be covered and reimbursed by certain federal agencies and for coverage of any manufacturer drug products under the MDRP and Medicare Part B. FSS pricing is subject to statutory reporting requirements and also is negotiated periodically with the Department of Veterans Affairs, including by reference to a manufacturer's comparable non-federal customer pricing. By statute, prices for drugs purchased by the Veterans Administration, Department of Defense (including drugs purchased by military personnel and dependents through the TRICARE retail pharmacy program), Coast Guard and the Public Health Service ("PHS") are subject to a cap on pricing (known as the "federal ceiling price") and may be subject to an additional discount if pricing increases more than the rate of inflation.

- *PHS 340B Drug Pricing Program*. To obtain coverage of drugs under the MDRP and Medicare Part B, manufacturers are required to extend discounts to certain purchasers under the PHS 340B drug pricing program. Purchasers eligible for 340B discounts include hospitals that serve a disproportionate share of financially needy patients, community health clinics and other entities that receive certain health services grants from the PHS.

Additionally, several states have either implemented or are considering implementing drug price transparency legislation. Requirements under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers and state agencies, and new product notice and reporting. A number of states may impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers who fail to comply with drug price transparency requirements. Certain other state legislation focuses on limiting the price or payment for certain drugs.

Healthcare Reform and Potential Changes to Healthcare Laws

Within the United States, federal and state governments have been active in proposing and implementing health care reform. Drug pricing and payment reform has been an ongoing focus for reform. Recent examples include federal legislation that eliminated a statutory cap on Medicaid drug rebate program rebates effective January 1, 2024. As another example, the 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 prior 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 set of negotiated Medicare maximum fair prices going into effect in 2026). The IRA has had a significant impact on the pharmaceutical industry and that impact is anticipated to continue.

Beyond the IRA, changes to Medicaid effective in 2024 eliminated the Medicaid rebate cap and changes to certain Medicare price reporting requirements for drugs beginning in 2026 will likely increase the administrative and compliance burden for manufacturers. In addition, recent legislation expanded the orphan drug exclusion in the IRA Medicare drug price negotiation program.

Under the current presidential administration, there has been significant reform activity focused on drug pricing and reimbursement. For example, an Executive Order was issued in April 2025 with multiple directives aimed at lowering drug prices, including refining the Medicare drug price negotiation program established by the IRA, accelerating competition for high-cost prescription drugs by accelerating approval of generics and biosimilars and facilitating the process for re-classifying prescription drugs as over-the-counter drugs, and increasing drug importation. In May 2025, another Executive Order was issued that directed government agencies and officials to identify most-favored nation pricing targets for prescription drugs (and looked to pharmaceutical manufacturers to make significant progress towards delivering target prices to patients), prevent foreign countries from disproportionately shifting the cost of global pharmaceutical research and development to the U.S., and facilitate direct-to-consumer purchasing programs for pharmaceutical manufacturers to sell their products to patients at the most-favored-nation price. In the wake of the Executive Orders and related executive initiatives, a number of pharmaceutical manufacturers have announced direct-to-consumer offerings with discounted prices and/or reached agreement with the federal government regarding pricing for drugs, including prices for Medicaid drugs and newly launched products. As part of the initiative, the federal government has also launched a website providing pharmaceutical direct-to-consumer channels. Federal agencies are developing new drug pricing pilot programs, such as a Medicaid model which would authorize the federal government to negotiate Medicaid supplemental rebates with participating manufacturers on behalf of state Medicaid programs, in exchange for standardized coverage criteria for participating manufacturer drugs, and proposed Medicare Part B and Part D pilot models that, if finalized as proposed, would replace existing inflation-based Medicare rebates with rebates determined on the basis of international prices, for drugs and patients subject to the model.

Other healthcare reform efforts or actions may affect access to healthcare coverage or the funding of health care benefits, although the full impact of such efforts or actions cannot be predicted. For example, the Congressional Budget Office has estimated that Medicaid provisions in the 2025 budget reconciliation legislation, including restrictions in eligibility and funding for Medicaid, as well as changes to the healthcare marketplace such as the elimination of certain subsidies, will increase the number of uninsured patients.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug and biologic pricing, reduce the cost of prescription drugs and biologics under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs and biologics.

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 copayment assistance by pharmaceutical manufacturers, value-based pricing, marketing cost disclosure and other 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, legal challenge and subsequent amendment, creating further uncertainty.

Other government actions could have an adverse effect upon, and could prevent, our products' commercial success. For example, the current presidential administration's announced tariff on branded or patented drugs may increase the cost of drug products that are imported from abroad or manufactured using products or materials imported from abroad. The timeline for implementation of this tariff has not yet been finalized. As another example, the Budget Control Act of 2011, as amended, resulted in the imposition of reductions in Medicare (but not Medicaid) payments to

providers in 2013 and remains in effect through 2032 unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

Outside the United States, there are also reform efforts. In December 2021, the EU adopted Regulation No 2021/2282 on Health Technology Assessment (the "HTA"). While the HTA entered into force in January 2022, it only became applicable to apply from January 2025 and will have a phased implementation depending on the concerned products. The HTA intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The HTA permits EU member states to use common HTA tools, methodologies and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology and making decisions on pricing and reimbursement.

In April 2023, the Commission published its long-awaited proposals to revise the EU's pharmaceutical legislation. The proposals seek to balance supporting innovation and increasing affordability and availability of medicines. The most controversial proposal is the shortening of regulatory protection periods to six (6) years of data exclusivity and two (2) years of market exclusivity (rather than the current eight (8) years data exclusivity and two (2) years market exclusivity). Other proposals include: (i) a transferable data exclusivity voucher for 'priority antimicrobials' entitling the holder to an additional one year data protection for any other centrally approved product (provided this is used within the first four years of data protection for that product) in an effort to encourage the development of new antimicrobials capable of combating antimicrobial resistance; (ii) greater flexibility for hospital pharmacies to prepare product for dispensing products in response to individual prescriptions; (iii) compulsory licenses for public health emergencies which would lead to suspension of data and market exclusivities while the compulsory license is in place; (iv) further transparency and disclosure requirements; (v) requirements for MAA to include an environmental risk assessment for the product; and (vi) streamlining regulatory procedures, reducing approval timeline by over 50 days for centrally authorized products. On December 11, 2025, the European Council (consisting of the EU member states) and the European Parliament reached an agreement on the final shape of the new rules. The agreed text now awaits formal adoption by both the Parliament and Council, after which it will be published in the Official Journal of the EU. The new Directive and Regulation will then enter into force following a transition period of 18 to 36 months, ultimately modernizing EU pharmaceutical law to better support innovation, access, and supply. The agreed framework provides among other things that new medicines benefit from eight years of data protection and one year of market protection, with possible extensions for addressing unmet medical needs or additional indications, up to a maximum of 11 years. Developers of new antibiotics may receive transferable vouchers for extra market protection, and orphan medicines can receive up to 11 years of combined protection, along with early regulatory guidance. In addition, the European Commission proposed in December 2025 the Biotech Act which seeks to strengthen the competitiveness of the biotechnology sector and facilitate the development and timely market entry of biotechnology innovations, while ensuring high standards for the protection of human health.

Other Regulations

In additional to the regulations and laws described above, our business is subject to a number of other regulations that apply broadly to companies doing business in the healthcare space, including 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 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, as amended ("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 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;

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

- United States federal, state and local laws, and similar foreign laws, regulations and standards governing the collection, use, access to, confidentiality and security of health-related and other personal information;

- 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 EU, United Kingdom and other jurisdictions, 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.

Human Capital

We aim to cultivate a highly-skilled and passionate team determined to deliver transformative therapies to the patients who need them most. As of December 31, 2025, we had 366 full-time employees, of which 351 were located within the United States and 15 were located outside of the United States.

We believe that the success and growth of our business depends in large part on our continued ability to attract, retain and motivate qualified personnel at all levels of our company.

Competitive Pay and Benefits. We provide our employees with competitive base salaries, cash bonus opportunities designed to incentivize achievement of our corporate goals, equity awards and opportunities for equity ownership through our employee share purchase plan and a robust benefit package designed to promote well-being across different aspects of our employees' lives, including comprehensive health insurance, dental and vision plans, life and other employment related insurance, retirement planning through a 401(k) plan with partial company match and paid time off.

Ethics in the Workplace. Overall, we believe that our commitment to compliance, quality and ethics throughout our business makes us a stronger and more competitive organization. We believe this attracts and retains the highest caliber of executives and employees who deliver for our patients and execute on our corporate strategy. Each employee of our company is required to confirm in writing that they understand and will comply with our policies, including but not limited to our Code of Business Conduct and Ethics, anti-harassment policy, our insider trading and compliance policy, our policies against bribery and corruption and our policies regarding interactions with healthcare professionals. Further, we believe our company benefits from a broad range of experiences and viewpoints that enable innovative approaches to our business and operations. We foster a culture where employees put compliance first and speak up on important ethical issues. Employees are required to participate in periodic and as-needed trainings to refresh their understanding of our policies and to provide additional training for new issues as and when they arise. For the clinical and manufacturing activities that we perform and oversee, we adhere to operating within the accepted GLP, GCP, cGMP and other similar regulatory guidelines.

Health and Safety. Health and safety principles are firmly rooted across our company through the integration of health and safety processes throughout our business and risk management. To foster a safe and healthy culture, we have implemented a comprehensive safety program and emergency response plan to ensure that we understand and mitigate health and safety incidents. As part of our employee health and safety program, we have a number of safety policies that employees are required to train on, conduct periodic on-site safety drills at our offices and perform periodic internal and external safety audits.

Our Corporate Information

We were initially incorporated under the laws of Bermuda in July 2015 and, in June 2024, subsequently announced the completion of the change of place of incorporation of our principal holding company from Bermuda to the United Kingdom (the "Redomiciliation"), pursuant to a scheme of arrangement approved by both the Bermuda Supreme Court and our shareholders, which caused the shareholders of our former parent company, Kiniksa Pharmaceuticals, Ltd., to become the shareholders of our current parent company, Kiniksa Pharmaceuticals International, plc.

Our registered office is located at 105 Piccadilly, Second Floor, London, W1J 7NJ, England, United Kingdom. Our executive offices are located at 100 Hayden Avenue, Lexington, Massachusetts, 02421. The telephone number for our offices is +1 (781) 431-9100. Our website address is www.kiniksa.com. The information contained on our website is not incorporated by reference into this Annual Report, and you should not consider any information contained on, or that can be accessed through, our website as part of this Annual Report.

As used herein, and unless the context otherwise requires, references to "we," "us," "our" and similar words or phrases prior to the Redomiciliation shall refer to Kiniksa Pharmaceuticals, Ltd. and from and after the Redomiciliation, to Kiniksa Pharmaceuticals International, plc. In addition, references to "ordinary shares" prior to the Redomiciliation

are to Kiniksa Pharmaceuticals, Ltd.'s common shares and from and after the Redomiciliation are to Kiniksa Pharmaceuticals International, plc's ordinary shares.

Where You Can Find More Information

We are subject to the information requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically, such as ourselves, with the SEC at *http://www.sec.gov*.

We make available free of charge on our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably possible after we electronically file such material with, or furnish it to, the SEC. Our website is located at *www.kiniksa.com*. The reference to our or the SEC's website address does not constitute incorporation by reference of the information contained at or available through such websites, and you should not consider it to be a part of this Annual Report.

Item 1A. Risk Factors.

You should carefully consider the risks described below, as well as the other information in this Annual Report, including our audited 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 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 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 sales, marketing, distribution, access and payor and patient support services capabilities 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 future.

In addition, our continued commercialization of ARCALYST or successful commercialization of any of our current or future product candidates, if approved, could be materially adversely impacted by a number of foreseen and unforeseen factors, including:

- any delays in our ability to produce sufficient quantities of ARCALYST, or any of our future products, at an acceptable cost or quality, including delays arising out of quality assurance concerns or changes in regulatory guidance, or those caused by our reliance on our third party manufacturers;
- 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;
- an inadequate number of prescribers or accounts prescribing our current and future products;
- the lack of complementary products to be supported by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- our inability to 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;
- an absence or reduction in strong scientific-based relationships to drive disease awareness and education;
- our inability to establish the unmet medical need for a given disease;
- our inability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of side effects associated with any future product;
- our inability to compete with current or future competitor products and/or biosimilars;

- the convenience and ease of administration of our products relative to alternative therapies, if any;
- alternative therapies that use the same or different mechanism of action for treating patients with recurrent pericarditis or other indications that our future products may treat;
- 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;
- limitations on the content or form of the consumer and/or prescriber-facing marketing materials that we may use;
- 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;
- publications of scientific literature, consensus papers and treatment guidelines unfavorable 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;
- 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 in the United States, which is the only country where it is currently approved for sale. We expect to use a similar strategy to sell and distribute 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 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.

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 our future products, if any, particularly in orphan or rare disease indications, will depend in part on the availability of favorable coverage and adequate reimbursement (including affordability of patient cost-sharing obligations) for ARCALYST or the future product and associated 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; restricting the breadth of coverage; implementing utilization management controls such as requiring prior authorization; limiting the amount of reimbursement for a particular product; restricting the prices that manufacturers may charge for their products and increasing the proportion of the cost for which the patient is responsible. Additional future government action to control costs is likely. 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 by similar regulatory authorities outside the United States including health technology assessment bodies in the European Union (the "EU") and the UK; 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 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. In addition, obtaining and maintaining favorable coverage and adequate reimbursement may require us to offer pricing concessions to third party payors.

We may face significant challenges in satisfying and sustaining favorable coverage and reimbursement for ARCALYST or any of our product candidates, if approved as third-party payors conduct value/benefit assessments. Payors may adopt stricter coverage criteria or select lower-cost clinical comparators, including biosimilars or competitive products (with the same or similar indications), as benchmarks for making value/benefit assessments. These actions could require patients to use alternative therapies before coverage is granted, limit pricing flexibility or even result in the denial or revocation of reimbursement. Even if we demonstrate improved efficacy, safety or convenience, competitive pricing and therapeutic category reviews may trigger aggressive pricing and coverage negotiations. Payors may also consider our products substitutable and agree to only cover the cost of an alternative product, or may remove the product from their formulary. In some cases, new competitors or biosimilars may trigger mandatory price cuts for the innovator product or broader price referencing aimed at lowering reimbursement rates for all treatments in the respective treatment category. These dynamics could significantly reduce our ability to achieve our desired pricing, limit our commercial potential and/or prevent us from realizing an appropriate return on investment. Ultimately, the evolving strategies of third-party payors to control costs and manage therapeutic categories could negatively impact our ability to continue commercializing ARCALYST or successfully launch any of our product candidates, if approved.

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 to periodically increase the price of ARCALYST 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. 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 increases that outpace inflation may also trigger additional rebate obligations, including under the Medicaid Drug Rebate Program.

In addition, the current presidential administration has taken and will likely continue to take action to limit or reduce the price of drugs and biologics. The full scope and nature of such actions, and what biopharmaceutical companies must do, remains uncertain, but any future required compliance could impede our ability to implement price increases with certain payors and purchasers.

Any price concessions will reduce our overall revenue generation and may impair the benefit of any price increases we may take. 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. 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 end coverage or impose onerous reimbursement policies. 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.

Some payors, including governmental payors, negotiate drug prices by reference to the prices we have set with other payors. Granting price concessions to one or more payors (including government payors) may limit our ability to negotiate prices with other payors or in other territories. Further, this may limit our ability to secure acceptable prices in potential new territories, which may materially limit our overall commercial growth.

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 our targeted patient population, our revenue and ability to sustain profitability may be materially adversely affected.

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

The total addressable market for 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, the country where substantially all ARCALYST sales occur, 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 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.

Within the United States, the current presidential administration has sought and is likely to continue to seek to implement "most favored nation" pricing for drugs and biologics covered under government programs. For example, proposed Medicare Part B and Part D pilot models that, if finalized as proposed, would replace existing inflation-based Medicare rebates with rebates determined on the basis of international prices, for drugs and patients subject to the model. If "most favored nation" pricing is implemented, payment for our products could be adversely affected.

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

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

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

- decreased demand for any approved products;
- injury to our reputation and significant negative media attention;
- regulatory investigations that could require costly recalls or product modifications (or withdrawal of the product from the market);
- difficulty in enrolling participants in clinical trials or withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- 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.

We are currently only authorized to market ARCALYST, our sole product, for the treatment of recurrent pericarditis in the United States, where we derive substantially all of our revenue. 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 Named Patient Program, Managed Access Program and collaborations with third parties, including Huadong. We and our collaborators are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that market, and we may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approval in many other countries, we, or our collaborators, must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials, manufacturing and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we obtain approval, 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;

- price negotiations that delay commercialization;

- 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 United States Foreign Corrupt Practices Act (the "FCPA"), the UK Economic Crime and Corporate Transparency Act 2023 or similar foreign regulations;

- different medical practices and customs in such countries affecting acceptance in the marketplace;

- import or export licensing requirements;

- tariffs, taxes and other restrictions on international trade;

- 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.

In some countries, particularly 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.

Our business and 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.

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 and abroad. Such obligations, along with continued regulatory review, may result in significant additional expense. We also will be required to report certain adverse reactions, production and quality 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 the patient population or use of our products, diminishing the addressable market or sales or both or removal of the drug from the market. 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 ordinary shares to decrease. See "*Business – Government Regulation".*

If we fail to comply with regulatory requirements; 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; if problems arise with the facility where a product is manufactured; or if a regulatory agency disagrees with the promotion, marketing or labeling of a product, such regulatory agency may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- require us to suspend sales or withdraw a product from the market;
- suspend any of our ongoing clinical trials;
- impose civil, criminal and administrative penalties, damages, disgorgement or monetary fines;
- exclude us from participating in Medicare, Medicaid or other governmental healthcare programs;
- refuse to approve pending applications or supplements to approved applications submitted by us;

- impose restrictions on our operations, including closing our CDMOs' facilities;
- 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 and regulations 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.

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 or require significant changes to the manufacturing, sales and distribution of any of our products. 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. If we or third parties acting on our behalf 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 parties are not able to maintain regulatory compliance, we may be subject to potentially significant enforcement actions.

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 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. Given the broad scope, evolving interpretation and unpredictable enforcement of these laws, our business activities could be subject to challenge in the future. For example, investigators for our clinical trials may serve as scientific advisors, speakers, advisory board members 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.

Further, the development of our marketing and sales capabilities has required, and will continue to require, significant financial and management resources. Our direct sales and marketing efforts may not be successful or may be limited by future government policies or initiatives. For example, the FDA stated in September 2025 that it intends to more aggressively enforce requirements for direct-to-consumer drug advertising and sent a significant number of warning or untitled letters to pharmaceutical companies alleging deceptive prescription drug advertising, which represents a dramatic increase in FDA actions as compared to prior years. The current administration's focus on pharmaceutical advertising heightens the risk that we may, in the future, receive a warning or enforcement action related to our advertising and marketing practices, which could adversely affect our business.

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 or will receive regulatory approval. Further, we may choose to cease development of a product candidate prior to conducting a pivotal trial for any reason, including capital conservation purposes. 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 for the product candidate entirely. In the event that a product candidate is unsuccessful in its clinical trials, fails to receive regulatory approval, is deprioritized for strategic reasons or is non-viable 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 INDs and CTAs to applicable authorities outside of the United States;
- successful completion of required nonclinical studies, including toxicology studies, pharmacological and biodistribution studies, as conducted, where applicable, under 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;
- 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.

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. 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 CTR or acceptance by other applicable regulatory authorities. Clinical testing is expensive, time consuming and uncertain as to the outcome. See "*Business – Government Regulation"* for more information on the regulations governing our clinical trials and product development.

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.

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. Factors that have and may in the future delay or prevent commencement or successful completion of clinical development of our product candidates as planned and on schedule, if at all, include but are not limited to:

- insufficient preclinical, toxicology or other data to support initiation of human trials;
- disagreements with regulatory agencies regarding trial design or implementation, including the appropriate dose levels, frequency of dosing, treatment period or endpoints in clinical trials;
- delays or failure in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- difficulties obtaining IRB or ethics committee approval at each clinical trial site;
- delays or failure in obtaining regulatory approval to commence a clinical trial or the imposition of a clinical hold by regulators;
- difficulties in enrolling suitable participants due to competition from other clinical trials in the particular indication;
- clinical trial protocol amendments impacting study criteria, endpoints or design, including amendments that either we initiate or are requested by regulatory authorities;
- difficulty collaborating with patient groups and/or investigators;
- CROs, clinical trial sites or applicable third parties failing to adhere to clinical trial requirements or comply with applicable law;
- CROs, clinical trial sites or applicable third parties failing to conform to GCPs;

- participants not completing a clinical trial or not returning for post-treatment follow-up;
- clinical trial sites withdrawing from a trial or being unable to conduct activities or participants withdrawing from clinical trials;
- participants experiencing serious adverse events, undesirable side effects or unacceptable health risks;
- participants failing to experience confirmed pre-specified events during the clinical trial within the expected timeframe, if at all;
- safety concerns outweighing potential benefits;
- regulatory changes requiring protocol amendments or new submissions;
- failure by us, our CROs or other third parties with whom we contract to timely and properly collect, analyze and/or assess clinical data;
- higher than expected clinical trial or clinical product manufacturing costs;
- strategic clinical trial reprioritization;
- errors in collecting, analyzing and assessing clinical data;
- clinical trials producing negative, inconclusive or uncompetitive results;
- failures to replicate safety, efficacy or other data from earlier preclinical studies and clinical trials conducted by us or third parties, including the trials of companies from whom we have licensed or acquired assets;
- the occurrence of unforeseen adverse events;
- trial suspensions or terminations by us, IRBs, DSMBs, DMCs, or regulators;
- insufficient production of product candidates meeting cGMP standards;
- manufacturing or supply chain delays; and
- operational disruptions affecting us, our CROs or our CDMOs and other third parties we rely on to conduct our clinical trials.

Delays in the commencement or completion of our clinical trials have occurred and may occur in the future. Consequences of delays have increased and may in the future increase our costs of developing our product candidates, delay the development and approval of our product candidates or delay or jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that cause, or lead to, difficulties and delays in the commencement or completion of clinical trials may also 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 we have patent protection or 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.

Clinical trials must be conducted in accordance with a number of national and international rules and regulations in the jurisdictions where such clinical trials are conducted. See "*Business – Government Regulations*". Further, conducting global clinical trials, as we do for certain of our product candidates, requires that we coordinate among the legal requirements and guidelines of regulatory authorities across a number of jurisdictions, including the United States, the EU, the UK and countries outside of those jurisdictions, which could require that we amend clinical trial protocols, terminate a trial in one or more jurisdictions or 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 UK may subject us to risks associated with the engagement of CROs who are unknown to the FDA, the EMA or the EU 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 UK. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted.

In addition, clinical trial rules and regulations may change. 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.

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 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;
- the availability of standard of care and/or new or existing drugs approved for the indication we are investigating;

- failure to obtain, maintain and/or timely amend participant consents;
- our ability to recruit clinical trial investigators with applicable competencies and experience;
- participants withdrawing from trials before completing their treatment or follow-up period;
- 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. Encountering difficulties in participant enrollment could cause our costs to significantly increase, and our clinical trials may be significantly delayed. Such occurrences may also delay or prevent any potential regulatory approval and commercialization, harming our business, financial condition and prospects significantly.

Undesirable side effects or adverse reactions caused by any of our product candidates may be identified that could delay or prevent their marketing approval or limit their use.

Undesirable side effects or adverse reactions caused by our product candidates could cause our CROs, an IRB or regulatory authorities to interrupt, delay or halt an ongoing clinical trial and could result in the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. Even if approved, such events could lead to restrictions to the product's label that could materially limit our ability to successfully commercialize the product. For example, many of our assets modulate the immune system and carry risks associated with immunosuppression, such as serious infections or malignancy. In addition, if other molecules in the same or related class 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 report new previously-unreported side effects, it could have an impact on the entire class of molecules, and the applicable regulatory authority may modify, suspend, or terminate our clinical trials; not authorize further clinical trials; require post-marketing clinical trial commitments or safety monitoring (e.g., REMS); or even suspend commercialization of any products or product candidates, as applicable, that contain a molecule within such class. The development of our product candidates and, if approved, commercialization of our products for new indications or new patient populations by Regeneron or Huadong (each having certain rights to develop and commercialize ARCALYST) may increase the possibility of uncovering adverse safety results not previously discovered during our own clinical development process or United States commercialization. Compassionate use of our products and product candidates, or evaluation of our products and product candidates by third parties or scientific collaborations could also uncover undesirable side effects or adverse safety results that negatively impact our clinical trials.

If any of our product candidates is associated with undesirable side effects or adverse reactions, we may choose to halt or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or adverse reactions are less prevalent, less severe or more acceptable from a risk-benefit perspective.

In addition, clinical trials by their nature utilize a sample of the potential patient population. However, with a limited number of participants and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered when a significantly larger number of patients are exposed to the product. 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;

- we may be required to create a registry or a REMS or similar risk management measures;

- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; and

- we may be subject to limitations on how we promote the product.

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

Interim, preliminary and "top-line" data from our clinical trials may differ from final data.

From time to time we may announce or publish interim, topline or preliminary data from our preclinical studies or clinical trials, which are based on an interim or preliminary analysis of the then available data from an in-progress or completed study, as applicable. Such data may be subject to change following a more comprehensive review of the data from the particular clinical trial. Interim data may change, and such change may be material, as participant enrollment continues or patients continue on treatment in the study. For preliminary or topline data, we also make assumptions, estimations, calculations and conclusions as part of our preliminary analyses, and, as a result, such data remain subject to audit and verification procedures that may result in the final data being different from the data we previously announced or published. Interim data should be viewed with caution until final data are available.

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 ordinary shares.

Risks Related to Marketing Approval and Regulatory Matters

Regulatory approval processes are lengthy, time consuming and inherently unpredictable. If we cannot 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.

Before commercializing any product, we must obtain marketing approval from regulatory authorities to sell the applicable product. 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. Approval requires the submission of extensive preclinical and clinical data and supporting information to demonstrate safety and efficacy, plus detailed manufacturing information and facility inspections. Biologic manufacturing involves living systems and highly specialized processes that are very complex and obtaining approval for such facilities is uncertain. Authorities may deny approval based on these submissions or inspections. Further, our product candidates may prove ineffective, only moderately effective or exhibit side effects or toxicities or other characteristics that may preclude our obtaining marketing approval or that prevent approval or limit commercial use. Regulatory agencies have broad discretion in the approval process and may determine our data are insufficient or request additional information or conduct additional inspections. Even trial results that we believe are promising may not meet approval standards, and

generating extra data could be difficult to generate or provide and require significant additional expense. Following approval of a product for sale, the FDA may inspect manufacturing facilities and suspend manufacturing if deficiencies are found, requiring alternative approved sites. These risks could significantly delay or prevent commercialization.

We may seek regulatory approval for our product candidates outside the United States. While requirements are similar across jurisdictions, obtaining approval in multiple countries requires compliance with varying regulatory requirements for safety, efficacy, clinical trials, sales, pricing and distribution, and success cannot be assured.

The approval process in the United States and in other jurisdictions is lengthy, costly and uncertain, often taking 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. Legislative or policy changes may delay submissions or approvals. Regulatory authorities have broad discretion in the approval process and may reject applications, deem data insufficient or require additional or clinical studies. Delays or failures in obtaining regulatory approval may occur for reasons including:

- disagreements on trial design or implementation;
- inability to demonstrate to the regulatory authorities safety or efficacy or that the clinical benefits of the product outweigh its safety risks;
- regulatory authorities requiring additional data or clinical trials, including trials to compare our products to other therapies;
- 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;
- negative or inconclusive or uncompetitive trial results, resulting in us deciding to, or regulatory authorities requiring us to, conduct additional clinical trials or to modify or cease development programs;
- clinical trials failing to meet their applicable primary or secondary endpoints, or the level of statistical significance required by regulatory authorities;
- regulatory authorities disagreeing with our interpretation of data from our preclinical studies or clinical trials;
- clinical trials generating insufficient data to support BLA, sBLA, New Drug Application, MAA or other filings;
- inability to recruit and retain sufficient numbers of suitable participants for our clinical trials;
- CRO noncompliance with data or regulatory requirements;
- regulatory authorities determine we have not sufficiently demonstrated our ability to manufacture our candidates to the requisite level of quality standards;
- 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 marketing applications;
- inadequate supply or quality of trial materials;

- undesirable side effects, toxicities or unexpected characteristics, causing trial suspension or termination by us, site investigators, IRBs or regulatory authorities; and

- regulatory policy changes.

Even if a product candidate is approved, regulatory authorities may limit indications or the patient populations approved to use the drug, impose postmarketing requirements, reject proposed pricing, make approval contingent on the performance of costly postmarketing clinical trials, approve a label that does not include the labeling claims necessary or desirable for the successful commercialization of our product or otherwise impose restrictions or requirements that may require significant additional expense or create substantial limitations on our product candidates' commercial potential.

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. 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 (such period may be shortened due to future regulatory changes). In addition, the FDA may not consider any of our approved product candidates to be reference products for competing products that were submitted for regulatory approval. If any competitor products were to enter the market, the sales of our approved products may be negatively impacted.

If we obtain marketing authorization of our current or future product candidates in a major pharmaceutical market, 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. Further, 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.

Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs or biologics intended to treat 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. See "*Business – Government Regulation*" for more information on applicable rules and regulations.

We have received Orphan Drug exclusivity in the United States for ARCALYST for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and pediatric patients 12 years and older. We have received Orphan Drug designation in the United States for KPL-387 for the treatment of recurrent pericarditis. 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. Even if we obtain Orphan Drug designation for certain product candidates for a particular orphan indication in the United States or the EU, we may not be the first to obtain marketing approval for such orphan indication due to the uncertainties associated with developing pharmaceutical products. In such cases, subject to applicable laws in those jurisdictions, Orphan Drug exclusivity may no longer be available for our product candidates, if approved, unless we can show a significant safety or efficacy advantage over the already approved orphan drug. Moreover, in the event our drug is deemed similar to the first approved orphan drug, we may be denied regulatory approval for our drug in such orphan indication for the duration of the Orphan Drug exclusivity period. Further, in order to maintain Orphan Drug exclusivity in the EU, we must demonstrate that our product or product candidate has a significant benefit over other satisfactory methods. If we are unable to do so, Orphan Drug exclusivity can be withdrawn.

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. We may also receive seven years of Orphan Drug exclusivity for KPL-387 in the same indication, should we receive FDA approval to market and commercialize the drug and satisfy the other requirements for such exclusivity. Even if Orphan Drug exclusivity is obtained, 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 because of safety, efficacy or some other 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 also 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 FDA's priority review procedures, receiving such designations does not guarantee that the BLA for such product candidates will receive priority review. See "*Business – Government Regulation*" for more information on applicable rules and regulations.

We may seek 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 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. See "*Business – Government Regulation*" for more information on the applicable rules and regulations.

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 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 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 our clinical development plans or threaten our product candidates' commercial prospects. Such an occurrence could materially impact our business, financial condition and results of operations.

We face substantial uncertainty regarding potential regulatory developments in the United States that may adversely affect our business.

The current presidential administration and federal government could adopt legislation, regulation orders or policies that adversely affect our business, including by making it more difficult to continue to market ARCALYST or by creating a more challenging and costly environment to pursue the development and commercialization of our current or future product candidates. For example, the federal government, including the FDA, may implement legislative, regulatory or policy changes regarding the standards for approving biologic products that we may be unable to satisfy or changes regarding the marketing of approved biologics that may limit or prohibit the advertising and promotion of ARCALYST and, if approved, our current or future product candidates. The impending uncertainty could present new challenges or potential opportunities as we navigate the clinical development and approval process for our product candidates.

The current presidential administration has also undertaken significant efforts to reduce the size and spending of the federal government, including at the FDA. A significant reduction in the FDA's workforce or the FDA's budget, or other disruptions at the FDA, could materially impact the FDA's ability to engage in a variety of activities that may affect our business, including routine regulatory and oversight activities. The current administration has substantially reduced the FDA's workforce and may make further reductions, which may lead to disruptions and delays in the FDA's review and oversight of our product candidates and impact the FDA's ability to provide timely feedback on our development programs. Further, reductions in workforce in divisions of the FDA responsible for overseeing the importation of pharmaceutical goods may delay our manufacturing timelines. Additionally, reductions in the FDA's

review or inspection divisions could extend review timelines, delay or prevent pre-approval inspections and limit opportunities for FDA feedback on pending applications. Any of these actions may delay or limit our ability to obtain FDA approval and commercialize our product candidates, including our ability to obtain regulatory approval for the technology transfer of ARCALYST drug substance manufacturing to Samsung.

Furthermore, the current administration has discussed several changes to the reach and oversight of the FDA, which could affect its relationship with the pharmaceutical industry, transparency in decision making and ultimately the cost and availability of prescription drugs.

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. 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 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, package and ship our products and product candidates at sufficient quality and quantity and in a timely manner in order 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 failed batches, reduced process yields or products that do not meet quality and specification requirements. As a result, we and our third party providers may be unable to manufacture sufficient supply of ARCALYST or our product candidates despite our and our CDMOs' best efforts. Failure to produce sufficient quantities of our products and product candidates that comply with all specifications could delay their development, result in supply shortages for our patients, result in lost revenue and diminish our potential profitability. This may lead to lawsuits or delay the introduction of our product candidates to the market.

Our reliance on third-party CDMOs increases the risk that we will have insufficient quantities of ARCALYST and our product candidates, or that such products may not be produced at acceptable cost, quality or 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. Any of these could impair commercialization or clinical development efforts. From time to time, we have identified events in the ARCALYST manufacturing process that have prevented the distribution of ARCALYST material as planned, though these events have not materially impacted our ability to supply ARCALYST. If we cannot source sufficient quality finished material in the future, we may stock out, fail to meet patient demand or be forced to effect a recall, any which could adversely affect our business and financial condition. Further, 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. Reagents for analytical testing have and may in the future become outdated and may require qualification before new reagents may be used. These risks may increase with higher clinical or commercial demand or if we expand ARCALYST to new indications or territories.

Regeneron is the sole manufacturer of ARCALYST drug substance and will remain so until we complete the technology transfer of the manufacturing process for ARCALYST drug substance to Samsung. Regeneron not obligated to accept our forecasts or purchase orders in certain circumstances and Regeneron may not have sufficient manufacturing capacity to meet our commercial or clinical demand for ARCALYST (including increased demand arising from our need to replace material lost to manufacturing issues). Regeneron, in turn, relies upon 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. Further, we rely on a third party CDMO to package and label ARCALYST. Our reliance on Regeneron (including its respective CDMOs) and our other CDMOs as our sole manufacturers and/or service providers means that we do not have direct control over ARCALYST 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. Many of these risks may still be present after successful completion of the technology transfer of ARCALYST drug substance manufacturing to Samsung and there is no guarantee that such technology transfer will materially diminish our ARCALYST manufacturing risk profile.

In addition, given the lead times we must provide to Regeneron and Samsung with respect to the commercial supply of ARCALYST, we must place purchase orders in advance based on projected demand. Such projections involve risks and uncertainties. We, Regeneron or Samsung may be unable to swiftly accommodate for unforeseen increases in commercial demand due to manufacturing capacity limitations. 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. As a result, we may have too little ARCALYST inventory to meet actual demand or may pay for ARCALYST supply that we will be unable to sell.

We have also contracted with 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 are party to a collaboration agreement with Huadong for ARCALYST. Until such time as Huadong is able to manufacture ARCALYST, either on its own or through a third party CDMO, we are its only source of drug supply. If our current supplier of drug substance and drug product for ARCALYST 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. A failure by our CDMOs to supply sufficient quantities of drug supply may cause us to breach our contractual obligations, triggering potential penalties, including termination of the agreement, if we fail to adequately cure such breach.

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. With respect to ARCALYST, Samsung will utilize a modified manufacturing process from that used by Regeneron, which could require lengthy development, regulatory review and approval.

Facilities used by our CDMOs to manufacture, label and package ARCALYST and our product candidates may be inspected by regulatory authorities in connection with MA submissions or based on work for other sponsors. While we oversee these CDMO activities, we do not control their manufacturing operations and rely entirely on CDMOs for compliance with cGMP and other regulatory requirements in connection with manufacturing, labeling and packaging operations. If our CDMOs fail to meet product specifications or regulatory standards, they will not be able to secure or maintain regulatory approval to operate their facilities. Although we have the contractual right to review compliance history and audit their performance, we lack direct control over CDMO operations, quality systems and personnel. Failure to obtain facility approval or the subsequent loss or withdrawal of facility approval could require us to identify alternative CDMOs, significantly impacting development timelines, regulatory approval outcomes or commercialization ability. Failure by us or CDMOs to comply with regulations could result in sanctions, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures, recalls, operating restrictions or criminal penalties, any of which could materially affect our business and product supply.

Other factors that may adversely affect manufacturing operations include natural disasters; accidents; boycotts; labor disputes; political and economic instability, such as acts of terrorism or war; changes in importation or exportation

requirements and policy; increased tariffs and/or taxes; disruptions at relevant government agencies, including the FDA, overseeing the importation of goods; or an epidemic, pandemic or other outbreak of disease. The occurrence of any such event could adversely affect our clinical and commercial supply, which would result in additional costs, impair our ability to generate revenue or otherwise 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 products and product candidates may also compete with other product candidates and approved products for access to and capacity within the limited number of cGMP-compliant CDMOs that operate manufacturing, packaging and labeling facilities. For our product candidates, we may wait to reserve capacity until we can be informed by data from the clinical trials of our product candidates, which may take several months. Any significant delay in the supply of clinical materials could considerably delay our clinical development efforts. Furthermore, given the limited capacity at many CDMOs and the long lead times needed to reserve capacity, CDMOs may require monetary commitments in connection with such reservations as well as fees for changes or cancellations or expedited operations.

Any CDMO manufacturing failure could delay or prevent, as applicable, clinical development, 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 them. Although we believe that there are several potential alternative CDMOs, 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 replacement CDMOs for ARCALYST or our product candidates, if required, is unlikely to be accomplished in a timely or cost-effective manner, if at all. Failing to procure a replacement CDMO on commercially reasonable terms could have a material adverse impact upon our business, results of operations and financial condition.

We are conducting a technology transfer with respect to the manufacturing process of ARCALYST drug substance from Regeneron to 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 worked to qualify Samsung 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 commercial manufacturing, if successful.

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 Samsung as our replacement CDMO and have selected replacement CTLs, we are still in the technology transfer process, which 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. We have yet to receive final regulatory approval to proceed. Such final approval may be substantially delayed due to the complexity of the technology transfer and related processes, an inability to successfully complete validating Samsung as a CDMO and our new CTLs, disruptions at the FDA and other factors. Such a delay could materially harm our business and operations.

In addition to the need to successfully complete the technology transfer of ARCALYST drug substance manufacturing to Samsung, the facility at which Samsung will manufacture ARCALYST will require approval by the FDA prior to the sale of ARCALYST manufactured at such facility. The FDA generally requires that any replacement CDMO be able to manufacture drug substance at sufficient levels of comparability with the materials produced by the original manufacturer. 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. We cannot guarantee that the FDA will approve the Samsung facility. Further, 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 tariffs, 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 operations.

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, meeting patient demand will depend significantly on securing sufficient safety stock from Regeneron, negotiating continued ARCALYST drug substance manufacture by Regeneron beyond its contractual obligations or some combination thereof. Purchasing safety stock requires significant upfront investment and such stock may expire or run out before completion of the technology transfer. 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. 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.

The third parties upon whom we rely for the supply of 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 KPL-387 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. For KPL-1161, we plan to manufacture drug substance in our in-house manufacturing facility and use a single supplier to manufacture drug product. While our in-house manufacturing capabilities have the limited capabilities to produce pre-clinical and early-stage clinical drug supply, we lack internal large-scale manufacturing capabilities necessary to support commercial requirements. Regeneron is currently our sole source manufacturer of ARCALYST drug substance and will remain so until we qualify Samsung as a replacement CDMO. We expect that Samsung will be our sole source manufacturer of ARCALYST drug substance following such qualification. We do not currently have arrangements in place for a redundant or second-source manufacturer of ARCALYST drug substance or drug product, or a redundant or second-source packager and labeler, in the event any of our current vendors cease or have a substantial delay in their operations or stop offering us sufficient quantities of these materials for any reason, as applicable. 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

Moreover, our ability to progress our preclinical and clinical programs or successfully commercialize our products could be materially and adversely impacted if any of the third party suppliers upon which we rely for raw

materials and preclinical and clinical stage product candidate and commercial stage product supply were to experience a significant business challenge, disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating to other customers such as regulatory or quality compliance issues, or other financial, legal, regulatory or reputational issues. Additionally, any damage to or destruction of our manufacturing facilities or equipment or those of our third party manufacturers' or suppliers' facilities or equipment may significantly impair our ability to manufacture our products and product candidates on a timely basis.

Establishing additional or replacement suppliers for the drug substance and drug product used in ARCALYST or our product candidates, if required, is unlikely to be accomplished quickly and can take several years, if at all. Furthermore, despite our efforts, we may be unable to procure a replacement supplier or do so on commercially reasonable terms, which could have a material adverse impact upon our business. Certain of the materials required in the manufacture and the formulation of our products and product candidates are derived from biological sources. Such materials are difficult to procure and may be subject to contamination or recall. Access to and supply of sufficient quantities of raw materials which meet the technical specifications for the production process is challenging and often limited to single

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 business involves the controlled storage, use and disposal of hazardous materials owned by us. 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, 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.

We rely, and expect to continue to rely, on third parties to 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 and expect to continue to rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct research, activate sites, conduct or otherwise support our preclinical studies and clinical trials for our product candidates. While we have certain contractual rights to oversee, review and audit our CROs, we have no direct control over their activities and performance. Our CROs play a significant role in the conduct of our 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 their conduct and compliance with applicable protocol, legal and regulatory requirements. 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. Although CROs may perform the services we request, we are responsible for ensuring that our CROs comply with GCPs or other regulatory requirements in providing their services and will be responsible for failing to meet these requirements. Failure to comply with applicable regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action.

Although we design the clinical trials for our product candidates, we rely on CROs to activate sites and conduct and oversee such trials. 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 CROs can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. CROs 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;
- 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. If the CROs, their subcontractors or the clinical trial sites do not perform clinical trials in a satisfactory manner, do not devote sufficient resources to a trial, 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.

If the third parties conducting our preclinical studies or our clinical trials do not perform their contractual duties, encounter any of the risks discussed above or choose to terminate their agreements with us, 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.

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. KPL-387 is being developed for recurrent pericarditis and we believe, if commercialized, would likely face additional competition from drugs that may offer, among other things, more convenient dosing methods or frequencies than what is currently available. We have not yet announced an indication(s) for KPL-1161, but expect that

it will compete with a number of drugs that inhibit IL-1 or other mechanisms. Competition may come from a range of pharmaceutical and biotechnology companies, 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. See "*Business – Competition*" for a list of our principal competition.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may further concentrate resources 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. Our competitors may also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites, trial participant enrollment and technologies complementary to our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, are more effective, have fewer or less severe side effects, are more convenient or are less expensive than ours. Clinical trials 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 before us, establishing a strong market position before we are able to enter the market. Further, our clinical trials may need to compete for participants and trial sites against other drugs in clinical development for the same indication. We believe the key competitive factors affecting the success of ARCALYST and any product candidates that we successfully develop and commercialize, are their efficacy, safety, convenience, price, the effectiveness of companion diagnostics (if any) 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 from third-parties. We cannot be certain that we will be successful in such efforts, and even if we are successful in such efforts, we cannot be certain that such discovery or transaction will be on favorable terms, or that, following any such discovery or transaction, we will be able to realize the intended benefits of it.

Research programs and business development efforts to identify new product candidates and technologies require substantial technical, financial and human resources. We may focus our efforts and resources on potential product candidates, technologies or businesses that ultimately prove to be unsuccessful. In-licensing and acquisitions of product candidates, technology or businesses often require significant payments and expenses and consume additional resources. We will need to continue to devote a substantial amount of time and personnel to research, develop and commercialize any such in-licensed or acquired product candidate or technology, or integrate any new business, and we may decide to reprioritize our efforts even after having expended resources on a particular prospect. Our research programs and business development efforts may fail to yield additional complementary or successful product candidates for clinical development and commercialization for a number of reasons, including:

- we may be unsuccessful in identifying potential product candidates or businesses with a high probability of success for development progression;

- insufficient resources or expertise to capitalize on opportunities;
- failure to agree to acceptable terms with potential licensors, partners or acquisition targets;
- incurring substantial liabilities as part of a transaction that outweigh the benefits or synergies we hope to realize; and
- being unable to leverage our expertise and development and commercial infrastructure as initially expected.

If any of these events occurs, we may not be successful in executing our growth strategy. Our growth strategy or strategic transactions may not deliver the anticipated results or we may need to spend significant resources to refine or otherwise alter our strategy.

The consummation or performance of any acquisition, business combination, collaboration or other strategic transaction in furtherance of our growth 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. We have granted Huadong exclusive rights to develop and commercialize ARCALYST in the Huadong Territory and we have entered into a license agreement with Genentech where we granted exclusive worldwide rights to develop and commercialize vixarelimab. To the extent that we decide to enter into additional transactions or arrangements, we must spend time and resources to identify appropriate collaborators, licensees or other strategic partners. Moreover, these transactions and arrangements are complex and time consuming to negotiate, document, implement and close. Further, the terms of any such transactions or arrangements that we may establish may have unfavorable tax consequences for our shareholders in the United States. Granting territory-specific rights for our products and product candidates may also 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, which may be difficult to obtain.

Any current or future collaborations, licenses or other strategic transactions or arrangements that we enter into may not be successful. Their success 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 choose not to pursue or continue development and commercialization of licensed drugs due to 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 competing priorities, or assets or funding constraints;

- raise disputes with respect to the ownership or inventorship of intellectual property developed pursuant to our collaborations or licenses;

- fail to properly prosecute, maintain or defend our intellectual property rights, or misuse them in ways that gives rise to litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to liability;

- develop intellectual property 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;

- may own, co-own or develop intellectual property covering products that results from our arrangement with them without granting us exclusive rights, requiring us to negotiate licenses with milestone, royalty or other payment obligations (which we may be unable to negotiate on acceptable terms or at all);

- fail to achieve development, regulatory or commercial milestones, materially reducing expected collaboration revenue;

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

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

- enforce licensed intellectual property against third parties that lead such third parties to challenge the validity or enforceability of the licensed intellectual property, potentially invalidating it or rendering it unenforceable;

- fail to maintain licensed patents that are under their control, or prosecute licensed patent applications in ways that diminish their value;

- delay or refuse to pay milestone and royalty payments, which may impact our ability to satisfy upstream payment obligations, if applicable; and

- conduct sales, marketing 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 on our own or with another collaborator.

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 for our products and product candidates. We seek to do this 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 our business. We also rely on trade secrets, proprietary know-how and continuing technological innovation to develop and maintain our proprietary or 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 rights include patents and patent applications that we both own and have in-licensed. For example, we have a field-specific exclusive license under a license agreement with Regeneron to patent applications and patents relating to ARCALYST 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 we may seek to commercialize our portfolio. 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 or may be of insufficient scope to provide protection for our commercial products. Additionally, if a patent is granted in one jurisdiction, that does not mean that such a patent, or the claims set forth in that patent, will be granted in a different jurisdiction. 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. As with patents, trademarks also may be successfully opposed or challenged.

The patent position of biotechnology and pharmaceutical companies is highly uncertain, involves complex legal and factual issues, and has been the subject of much litigation. The degree of patent protection we require to commercialize our products may be unavailable or limited, failing to protect our rights or provide any competitive advantage. We cannot provide any assurances that our owned or in-licensed patents, or pending applications that mature into patents, will have claims broad enough to protect our current and 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. We are unable to obtain composition of matter patents for KPL-387's amino acid or nucleic acid sequences. We own a pending patent application covering methods of using KPL-387 in the treatment of recurrent pericarditis, which, if issued, would expire in 2046, not including any patent term extensions or adjustments. We also own additional patent applications covering various technologies related to our KPL-387 program. Additionally, we expect to rely on regulatory exclusivity, such as data exclusivity and orphan exclusivity as applicable, for KPL-387. For example, in the United States, a new biologic product receives 12 years of data exclusivity upon receiving regulatory approval. In the EU, a new product generally receives eight years of data exclusivity and an additional two years of market exclusivity upon regulatory approval. See "*Business –Government Regulation*" above for additional information on regulatory exclusivities.

In the United States, the natural (i.e., statutory) expiration of a patent is generally 20 years from the earliest filing date of a non-provisional patent application. 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 patent term extensions and adjustments, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Furthermore, the type, scope and duration of any regulatory exclusivities will vary on a country-by-country basis depending on the jurisdiction in which a product candidate is approved and the particular regulatory exclusivity for which the product is eligible as of the time of approval in such

jurisdiction. 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. Limited patent term extensions may be available in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984 (referred to as the Hatch-Waxman Act) and under similar laws in the EU and Japan. In certain countries, the term of a patent that covers a drug product may 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. 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 such cases, regulatory exclusivity, such as data exclusivity or orphan exclusivity (if available) as applicable, is expected to be relied upon for our or our licensees' products. 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 protect our patent position in the market. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights cannot be predicted with any certainty.

In addition, the patent prosecution process is expensive and time consuming, and we 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 and the scope of the claims initially submitted for examination may be significantly narrowed by the time they issue, if at all, potentially losing any competitive advantage we hope to achieve. 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. 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. Patent applications we own or license may not result in issued patents in the United States or in other countries. Even if we acquire patent protection expected to provide a competitive advantage, third parties may challenge the validity, enforceability or scope thereof, potentially narrowing, invalidating or rendering our patents unenforceable. 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 courts or patent offices, in the United States and abroad. For

example, United States patents may face challenges such as derivation, reexamination, interference, post-grant review, or *inter partes* review proceedings, while European patents may be challenged by any person in an opposition proceeding within nine months from the publication of the grant. Similar proceedings exist 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 earlier than us or our licensees, requiring us or our licensees to engage in interference or derivation proceedings at the USPTO or similar opposition actions in Europe or other regions regarding our intellectual property rights for our products, product candidates and technology to determine which party is entitled to the patent on the disputed invention. 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. 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. If a court agrees, rights to those challenged patents may be diminished or lost.

We may also face future claims from former employees or consultants of ours, our licensees or licensors asserting an ownership right in our patents or patent applications based on work they performed on our or their behalf. Although we generally require employees, consultants and collaborators with access to proprietary information to assign invention rights 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 these agreements will withstand challenges or that they will not be breached, for which remedies may be inadequate.

An adverse determination in any such 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 prevent others from using or commercializing similar or identical technology and products, without payment to us, shorten patent protection periods for our technology, products and product candidates or reduce the period of time during which our licensees are obligated to make royalty payments to us. Such challenges may also result in our inability to manufacture or commercialize our product and product candidates without infringing third party patent rights. 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 assets. Under any such license, if granted, we would most likely be subject to various payment obligations. However, we may be unable to secure such license to the third party's intellectual property on acceptable terms Even if we are successful against any contests or other claims of infringement, we may spend significant time and resources to do so. Further, if the scope or strength of our patents and patent applications is threatened, it could deter companies from collaborating with us to license, develop or commercialize current or future product candidates since they may view our intellectual property as having reduced commercial value. Further, any public announcement about the start, progress or outcome of any patent or exclusivity disputes or proceedings, in any country, may trigger significant volatility in our stock price.

Even if unchallenged, issued patents may not provide any meaningful protection or prevent competitors from designing around the patent claims by developing similar or alternative non-infringing technologies or products. For example, a competitor could create a drug that provides benefits similar to our product, or one or more of our product candidates, but has a different composition that falls outside the scope of our patent protection. If our patents lack sufficient breadth or term, or are successfully challenged, commercialization of our products could be negatively affected, harming our business.

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 certain of our products and product candidates, including ARCALYST. 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, among others. Disputes may arise between us and any of these counterparties regarding 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;
- whether our use of the licensed technology is within the scope of the rights granted to us or otherwise consistent with the agreement;
- milestone, royalty or other payment obligations;
- other parties' performance being maintained under these agreements;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor 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. If we or our sublicensees materially fail to meet our obligations under our agreements, licensors may terminate the respective agreement, requiring us to return licensed technology and possibly grant rights to our 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 assets following 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 could result in loss of exclusivity and termination of product development and commercialization efforts for our product and each of our product candidates, harming our business 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. 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 granted sub-licenses for others to develop ARCALYST and vixarelimab. Licensees must develop and commercialize drugs, make timely milestone and royalty payments, share information and indemnify us.

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.

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 and antibody-related technologies. 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. If the claims of any of these patents are asserted against us, we do not believe our proposed activities related to abiprubart would be found to infringe any valid claim of these patents. 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 products or product candidates. Regardless of when filed, we may fail to identify relevant third party patents or patent applications, or we may incorrectly conclude that a third party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes our products or 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. Contested proceedings challenging the validity of third party patents may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent.

In order to avoid infringing 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 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. Without such a license, we may cease developing or commercializing the infringing technology, product or product candidate, or be forced to redesign it and/or to cease some aspect of our business operations, which could have a material adverse effect on our business.

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. 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.

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. 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 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 in all countries throughout the world would be prohibitively expensive. Patentability requirements vary by country, especially in developing regions. Our ability to protect and enforce intellectual property may be adversely affected by changes in foreign intellectual property laws, which often provide less protection than United States intellectual property law. Many companies face significant challenges in protecting and defending intellectual property outside the United States. Further, some countries' legal systems do not favor the enforcement of patents and other intellectual property rights, particularly for United States-based companies, making it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, compulsory licensing laws in many countries require patent owners to grant licenses to third-parties, and some jurisdictions limit enforceability against certain parties, including government agencies or government contractors. As a result, we or our licensees may be unable to prevent third parties from practicing inventions covered by our patents abroad in countries outside the United States. Competitors may use our technologies to develop competing products in jurisdictions where we have not obtained patent protection, or where we have obtained patent protection, but such jurisdictions do not favor the enforcement of patents, or other intellectual property rights. In such cases, our intellectual property rights may not be effective or sufficient to prevent them from competing with us, impacting our results of operation and financial condition.

Proceedings to enforce our patent rights, even if successful, can be expensive and time-consuming. Furthermore, we cannot ensure that we or our licensees will be able to initiate or maintain protective actions in all jurisdictions in which we or they may wish to commercialize products. 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 Unitary Patent system and Unified Patent Court (the "UPC") and European Patent Package regulations (the "EU Patent Package") may present uncertainties for our ability to protect and enforce our patent rights against competitors in Europe. The UPC provides 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. Under the EU Patent Package we will have the right to opt our patents out of the UPC for a limited time, 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 patent protection, we may rely on trade secrets, know-how or technological innovation to develop and maintain our competitive position. We seek to protect proprietary technology through confidentiality and invention assignment agreements with collaborators, advisors, contractors, employees and consultants, as applicable, but unauthorized disclosure or use of our technical knowhow or other trade secrets may still occur. Further, we cannot guarantee such agreements exist with every party who had access to our confidential information or proprietary technology. We also seek to protect our proprietary information and technologies by maintaining physical security of our premises and physical and electronic security of our information technology systems. Monitoring unauthorized use and disclosure is difficult, and we cannot guarantee that the steps we have taken to protect our proprietary technologies will

be effective. We may lack adequate remedies to address any violation of these agreements or our security, especially in jurisdictions that do not favor the enforcement of intellectual property rights, resulting in loss of exclusivity. Moreover, if confidential information licensed or disclosed to us by our partners, collaborators or others is inadvertently disclosed or subject to a breach or violation, we may face liability to the owner of such information.

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 be unable 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.

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 be unable 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, particularly outside the United States where courts may be less willing to protect trade secrets.

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 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.

If our trademarks and trade names are not adequately protected, then we may be unable 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 be unable 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.

General Risk Factors

We have a history of operating losses and may require substantial additional financing in the future.

Biopharmaceutical product development is highly speculative and involves significant risk. Generating sufficient product revenue to sustain our organization will depend on a number of factors, including the continued ARCALYST commercialization, the development, approval and eventual commercialization of one or more of our current or future product candidates and the management of our costs consistent with our current operating plan. Future

capital expenditures are expected to be substantial, and we may incur operating losses in the future if expenses exceed expectations as we:

- support product development, sales, marketing and distribution capabilities, infrastructure and organization to commercialize ARCALYST and any future approved products;
- conduct research and development activities, including our Phase 2/3 clinical trial of KPL-387 in recurrent pericarditis, our ongoing Phase 1 clinical trial of KPL-387 in normal healthy volunteers, our pre-clinical investigations of KPL-1161 and prepare for our planned Phase 1 clinical trial of KPL-1161 in normal healthy volunteers;
- manufacture products and product candidates for clinical or commercial use, expand our manufacturing capabilities, identify and qualify additional or alternative manufacturers and suppliers and manage the technology transfer for ARCALYST drug substance manufacturing;
- 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 agreements;
- 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;
- address any litigation, including product liability suits, employment-relate disputes, intellectual property disputes and disputes arising out of our collaboration and license agreements;
- 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; and
- manage delays or issues with the foregoing, such as failed trials, complex or inconclusive results, safety concerns, regulatory challenges that require longer follow-up of existing trials, additional major trials, additional supportive trials in order to pursue marketing approval, pandemics or economic disruptions.

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.

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 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.

Financing our operations and activities also carries risk. The sale of additional equity or convertible securities would dilute all of our shareholders. Further, new investors could gain rights superior to our existing shareholders. The incurrence of indebtedness would result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Obtaining funds through licensing, collaboration or other strategic transactions or arrangements 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.

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

In the United States, we participate in and/or report pricing and other data in connection with the Medicaid Drug Rebate Program (the "MDRP"), Medicare Part B, the Federal Supply Schedule (the "FSS"), the PHS 340B Drug Pricing Program and a number of other federal and state government programs. For example, we have certain price and data reporting obligations under the MDRP and we have obligations to report the average sales price under the Medicare program. Under the MDRP, we are required to pay a rebate to each state Medicaid program for quantities of our products that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our products under Medicaid and for payment to be available for our products under Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS. 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.

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. For example, starting in 2026, "average sales price" regulatory changes related to "bona fide service fees" and the mandatory submission of reasonable assumptions may increase the complexity and compliance burden around Medicare Part B reporting. In addition, as the result of the Inflation Reduction Act of 2022, the "average manufacturer prices" we report under the MDRP will also be used to compute rebates under Medicare Part D triggered by price increases that outpace inflation. 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, our rebate liability or 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. The Centers for Medicare & Medicaid Services could also terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B, if applicable, for our covered outpatient drugs. We cannot assure you that our submissions will not be found to be incomplete or incorrect.

In addition, potential future legislative, regulatory or policy changes by the current presidential administration may introduce additional uncertainty for our business. These could include changes to the level of scrutiny applied by the Health Resources and Services Administration to enforce non-compliance with the 340B Drug Pricing Program, new price restrictions or price reporting requirements on products we sell to Medicaid, Medicare or other government purchasers, or other regulatory changes impacting reimbursement or competitive dynamics in multisource markets. For example, federal agencies are developing new drug pricing pilot programs under Medicare Part B and Part D that, if finalized as proposed, would replace existing inflation-based Medicare rebates with rebates determined on the basis of international prices, for drugs and patients subject to the model. Any such changes could significantly impact our business and operations.

Increasingly, states are enacting legislation requiring manufacturers to report drug pricing information. States, however, have not always clearly defined their reporting requirements, which may result in manufacturers inadvertently failing to properly disclose the required pricing information. Complying with federal and state programs and future changes to these programs can be complex and cost-and resource-intensive, and could have a material adverse effect on our business, prospects, operating results and financial condition.

Current and future healthcare legislation or executive or administrative action may have a material adverse effect on our business and results of operations.

In the United States, the UK, the EU and other jurisdictions, there have been and we expect there will continue to be a number of executive, legislative and regulatory initiatives and proposed changes to healthcare systems, drug pricing and reimbursement policies that could affect our operations.

Within the United States, federal and state governments have been active in proposing and implementing health care reform. Drug pricing and payment reform has been an ongoing focus for reform. Recent examples include federal legislation that eliminated a statutory cap on Medicaid drug rebate program rebates effective January 1, 2024. As another example, the IRA 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 prior 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 set of negotiated Medicare maximum fair prices going into effect in 2026). The IRA has had a significant impact on the pharmaceutical industry and that impact is anticipated to continue.

Beyond the IRA, changes to Medicaid effective in 2024 eliminated the Medicaid rebate cap and changes to certain Medicare price reporting requirements for drugs beginning in 2026 will likely increase the administrative and compliance burden for manufacturers. In addition, recent legislation expanded the orphan drug exclusion in Medicare drug price negotiation program.

Under the current United States presidential administration, there have been significant and wide-ranging reforms to federal policy and the federal government. Drug pricing and reimbursement reform have been a particular area of focus. For example, an Executive Order was issued in April 2025 with multiple directives aimed at lowering drug prices, including refining the Medicare drug price negotiation program established by the IRA; accelerating competition for high-cost prescription drugs by accelerating approval of generics and biosimilars and facilitating the process for re-classifying prescription drugs as over-the-counter drugs, and increasing drug importation. In May 2025, another Executive Order was issued that directed government agencies and officials to identify most-favored nation pricing targets for prescription drugs (and looked to pharmaceutical manufacturers to make significant progress towards delivering target prices to patients), prevent foreign countries from disproportionately shifting the cost of global pharmaceutical research and development to the United States and facilitate direct-to-consumer purchasing programs for pharmaceutical manufacturers to sell their products to patients at the most-favored-nation price. In the wake of the Executive Orders and related executive initiatives, a number of pharmaceutical manufacturers have announced direct-to-consumer offerings with discounted prices and/or reached agreement with the federal government regarding pricing for drugs, including prices for Medicaid drugs and newly launched products. A website sponsored by the federal government has also been launched to offer pharmaceutical direct-to-consumer channels. Federal agencies are developing new drug pricing pilot programs, such as a Medicaid model which would authorize the federal government to negotiate Medicaid supplemental rebates with participating manufacturers on behalf of state Medicaid programs, in exchange for standardized coverage criteria for participating manufacturer drugs, and the proposed Medicare Part B and Part D pilot models that, if finalized as proposed would replace existing inflation-based Medicare rebates with rebates determined on the basis of international prices, for drugs and patients subject to the model.

Other healthcare reform efforts or actions may affect access to healthcare coverage or the funding of health care benefits, although the full impact of such efforts or actions cannot be predicted with certainty. For example, the Congressional Budget Office has estimated that Medicaid provisions in the 2025 budget reconciliation legislation, including restrictions in eligibility and funding for Medicaid, as well as changes to the healthcare marketplace such as the elimination of certain subsidies, will increase the number of uninsured patients.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug and biologic pricing, reduce the cost of prescription drugs and biologics under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs and biologics.

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 copayment assistance by pharmaceutical manufacturers, value-based pricing, marketing cost disclosure and other 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, legal challenge and subsequent amendment, creating further uncertainty.

Other government actions could have an adverse effect upon, and could prevent, our products' commercial success. For example, the current presidential administration's announced tariff on branded or patented drugs may increase the cost of drug products that are imported from abroad or manufactured using products or materials imported from abroad. The timeline for implementation of this tariff has not yet been finalized. As another example, the Budget Control Act of 2011, as amended, resulted in the imposition of reductions in Medicare (but not Medicaid) payments to providers in 2013 and remains in effect through 2032 unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

The nature and extent of future healthcare or other reforms remain unpredictable. There is ongoing uncertainty regarding the nature and impact of executive, administrative or congressional actions and potential litigation. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or executive or administrative action, either in the United States, the UK, EU or elsewhere. Government policies and regulations may change, affecting our operations and business, including clinical trials, regulatory approval, pharmaceutical pricing and reimbursement. If we or third parties upon whom we rely fail 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.

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 incidents, 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, logistics providers and other contractors, consultants and service providers remain vulnerable to attack, damage or interruption from malware (e.g., ransomware), viruses, theft, natural disasters, terrorism, war, telecommunication and power failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee misuse, human error, fraud, denial or degradation of service attacks, nation-state and nation-state-supported actors or unauthorized access or use by persons within our organization, or persons with access to systems inside our organization. Attacks upon information technology systems are increasing in frequency, 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 fail to follow cybersecurity protocols, exposing us to vulnerabilities or undermining the safeguards we have put in place. Techniques to gain 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 cyberattack on a CDMO, CRO, contractor, consultant, service provider or other third party could also increase exposure by allowing criminals to exploit our relationship with such persons. Such security incidents may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or cyberattacks due to attackers increasingly using tools and techniques that are designed to circumvent controls, avoid detection and remove or obfuscate forensic evidence.

We and certain of our service providers experience periodic cyberattacks and security incidents. While we do not believe that we have experienced any current or past significant system failure, accident or security incident that has materially affected or would be reasonably likely to materially affect us, a significant event could disrupt our operations or 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 costs associated with the investigation, remediation and potential notification of a cyberattack to counter-parties and data subjects could be material. A cyberattack could result in a material disruption of our or such third party's business or operations. For example, the loss of clinical trial data could delay regulatory approvals and significantly increase costs necessary to recover or reproduce the data. To the extent that any disruption or security incident results in a loss of or damage to, inappropriate disclosure of or theft of confidential or proprietary information, the further development of our product candidates could be delayed and such proprietary information may be made available to other parties and thereby decrease the value of such information. 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 such event could adversely affect our business and revenue. Although we maintain cybersecurity insurance, coverage may be inadequate and subject to deductibles and 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 subject to data privacy and protection laws, regulations, policies and contractual obligations governing the collection, transmission, storage, processing and use of personal information and data. The global regulatory framework for data privacy and security is evolving, and interpretation and enforcement practices are likely to remain uncertain. 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 applicable laws, internal policies or contractual obligations with respect to processing personal information could result in negative publicity, government investigations, enforcement actions, third-party claims and reputational harm, any of which could materially affect our business, results of operations and financial condition.

In the United States, most healthcare professionals and research institutions from which we obtain patient health information are subject to HIPAA. We may obtain health information from third parties, such as research institutions with which we collaborate, that are subject to privacy and security requirements under HIPAA. While we are generally not directly subject to HIPAA, other than potentially with respect to providing certain employee benefits, we could be subject to criminal penalties for knowingly obtaining or disclosing protected health information maintained by a HIPAA covered entity in a manner noncompliant with HIPAA. In the event that we are subject to or affected by HIPAA, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

The United States Federal Trade Commission ("FTC") and many state Attorneys General continue to enforce federal and state consumer protection laws governing the collection, use, dissemination and security practices of personal information as it considers failing to appropriately secure consumers' personal information to be unfair acts or practices under 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 held by the company, the size and complexity of its business and the cost to improve security and reduce vulnerabilities.

Our clinical trial programs and other operations outside the United States may implicate international data protection laws, including the European Union General Data Protection Regulation 2016/679 ("GDPR"), the UK GDPR and the Swiss Federal Act on Data Protection (the "DPA"). The GDPR imposes strict requirements for processing EEA residents' personal data within the EEA and considers some of the personal data we process in respect of clinical trial participant personal data to fall under special categories requiring 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. GDPR 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 also result in regulatory investigations, reputational damage, orders to cease or change our data processing activities, enforcement notices, audits and/ or civil claims (including class actions). The UK maintains similar legislation known as the UK GDPR.

The GDPR regulates transfers of personal data subject to the GDPR to third countries with inadequate personal data protection, including the United States. Because we operate clinical trials in the EU and our operations are substantially centered into the United States, we face additional risk when transferring personal data. 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 standard contractual clauses to transfer personal data outside the EEA and the UK, including to the United States, with respect to both intragroup and third party transfers. We expect the regulatory guidance and enforcement landscape to continue to develop and may need to make certain operational changes (including revised standard contractual clauses and other relevant documentation for existing data transfers that are necessary to run our organization.

Failure or perceived failure to comply with the GDPR, the UK 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.

In addition to the above, we are also subject to other laws and regulations, such as health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws that 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. Compliance will require significant expenditures of capital and time and any claims that we have violated individuals' privacy rights or breached our contractual obligations or applicable law could result in expensive and time-consuming litigation.

Although we work to comply with our legal and contractual obligations, these requirements 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. We or our third party-contractors may fail or be alleged to have failed to comply with such statements or any other obligations we have with respect to personal information, privacy or data protection. Such failures or alleged failures could result in government investigations or enforcement actions, litigation, claims or other proceedings that could generate adverse publicity, harm our reputation, negatively impact our ability to commercialize and market products and product candidates, 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, which would adversely impact our ability to implement our business strategy and operate our business. Furthermore, replacing executive officers, senior management and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Changes in our senior management may be disruptive to our business, especially if we are unable to manage an orderly transition of responsibilities. Further, we may be unable to hire, train, retain or motivate these key personnel on acceptable terms due to intense competition among 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 (including the cost to obtain visas) could adversely affect our ability to retain skilled employees. If work permits are denied, revoked or not renewed, we may face disruptions in our 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 does not delay 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.

Our employees, principal investigators, CROs, consultants and other third party service providers may engage in fraudulent conduct or other illegal activity, including intentional, reckless or negligent conduct that violates the regulations of the FDA and other regulatory authorities, including laws related to disclosure of true, complete and accurate information to such authorities; reporting of clinical data; 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 effectively control such conduct, whether unknown or unmanaged risks or losses or in protecting us from governmental investigations, lawsuits or other adverse actions 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.

Changes in United States trade policy, including tariffs imposed by the United States and any reciprocal tariffs imposed in response, could materially impact our business and results of operations.

Changes to United States trade policy, including tariffs imposed by the United States on imported goods, as well as reciprocal tariffs that may be imposed by foreign governments, may adversely affect our business and the global macroeconomic environment. The current presidential administration has imposed or is considering imposing baseline tariffs on all other countries, reciprocal tariffs with certain countries and particularized tariffs on certain types of foreign goods, including pharmaceutical products and components manufactured outside of the United States. Such tariffs are expected to increase the price of goods imported into the United States, including pharmaceutical products and important products that are ancillary to the administration, processing or testing of pharmaceutical products.

There is substantial uncertainty with respect to what extent new (or modified) tariffs will be imposed in the long-term in the United States and other countries, or the ultimate impact such tariffs will have on us, our industry and the patients we seek to serve. Further, it is unclear to what extent subsequent trade negotiations between the United States and other countries will reduce or remove previously announced tariffs. Such unpredictability creates substantial uncertainty and poses significant planning challenges for our operations and our CDMOs' long term capital investment plans. Unlike consumer goods, pharmaceuticals face unique regulatory, technology and capacity constraints that make rapid supply chain adjustments particularly difficult and costly. Should current tariffs hold or be increased we may be unable to identify and qualify alternative sources of supply and our business may be materially and adversely affected. ARCALYST is currently manufactured in the United States, and we are in the process of moving ARCALYST drug substance manufacturing to Samsung in South Korea. While we do not expect that the current tariffs will result in a material impact to our overall business, financial condition or results of operations, a significant increase to tariffs on pharmaceutical products imported from South Korea may have a material effect on our business following the completion of such technology transfer.

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 disruptions in global financial markets. These disruptions could adversely affect our ability to manufacture, market and sell 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;
- 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;
- imposition of tariffs, 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 FCPA, its books and records provisions or its antibribery provisions and the application of anti-corruption and anti-bribery laws in applicable jurisdictions.

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

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, hurricanes, 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.

Risks Related to Ownership of Our Ordinary Shares

The concentration of ownership of our Class B ordinary shares among our senior management, and the conversion rights of our Class A1 and B1 ordinary shares, which are held entirely by entities affiliated with certain of our directors, means that certain matters submitted to our shareholders for approval may be influenced by such persons, which may have an adverse effect on the price of our Class A ordinary shares and may result in our Class A ordinary shares being undervalued.

Each Class A ordinary share is entitled to one vote per Class A ordinary share and each Class B ordinary share is entitled to ten votes per Class B ordinary share. Our Class A1 ordinary shares and Class B1 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 ordinary shares and Class B ordinary shares. As a result of the multi-class voting structure of our ordinary shares, our executive officers and certain other members of our senior management collectively control a substantial amount of the voting power of our ordinary shares and therefore are able to control the outcome of certain matters submitted to our shareholders for approval. As of December 31, 2025, the holders of Class A ordinary shares accounted for approximately 72% of our aggregate voting power and the holders of Class B ordinary shares accounted for approximately 28% of our aggregate voting power. Our executive officers and certain other members of our senior management hold Class A ordinary shares and Class B ordinary shares representing approximately 25% of our aggregate voting power as of December 31, 2025 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 ordinary shares, Class A1 ordinary shares or Class B1 ordinary shares as set forth in our articles of association. For example, as of December 31, 2025, entities affiliated with certain members of our directors could convert their Class A1 ordinary shares and Class B1 ordinary shares upon 61-days' prior written notice into Class A ordinary shares and Class B ordinary shares, respectively, which in the aggregate would result in such entities holding approximately 74% of our aggregate voting power and having the ability to control the outcome of certain matters submitted to our shareholders for approval. Due to these conversion rights, holders of our Class A1 ordinary shares and our Class B1 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 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 ordinary shares. Holders of our Class B 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 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 ordinary shares may be volatile and fluctuate substantially, which could result in substantial losses for holders of our Class A 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 Class A ordinary shares at or above the price they paid for their shares. The market price for our Class A ordinary shares may be influenced by many factors, as further discussed throughout 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 ordinary shares or that we will not experience any adverse effects that may be material to our consolidated cash flows, 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 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 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 ordinary shares could decrease, which in turn could cause the price of our Class A ordinary shares or its trading volume to decline.

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

A significant number of our Class A ordinary shares are issuable upon conversion of our Class B, Class A1 and Class B1 ordinary shares, subject to certain limitations on conversion. As of December 31, 2025, approximately 2.1 million Class A ordinary shares directly held by our executive officers and directors, inclusive of Class A ordinary shares issuable upon conversion of our Class B, Class A1 and Class B1 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 December 31, 2025, there were approximately 12.2 million Class A ordinary shares subject to outstanding share options, PSOs, RSUs and PSUs under our equity incentive plans that may become eligible for sale in the public market to the extent permitted by the provisions of applicable vesting schedules and Rule 144 and Rule 701 under the Securities Act.

A majority of our 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 December 31, 2025, on an as-converted to Class A ordinary shares basis, these shareholders collectively held approximately 33.9 million of our Class A 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 ordinary shares (after certain restrictions on conversion or resale lapse), the market price of our Class A 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 ordinary shares, including Class A ordinary shares issuable upon conversions of our Class B, Class A1 and Class B1 ordinary shares and upon the exercise of certain rights to acquire Class A ordinary shares, or collectively registerable securities, under the Securities Act. As of December 31, 2025, on an as-converted to Class A ordinary shares basis, we have registered approximately 31.8 million Class A 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 ordinary shares basis, approximately 1.7 million Class A ordinary shares held by certain of our executive officers as of December 31, 2025. If any of these Class A 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 ordinary shares could decline.

We have anti-takeover provisions in our articles of association that may discourage a change of control.

Our 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 a limited number of reasons;

- limitations on the acquisition of more than 30% or more of our voting rights, except through certain defined permitted acquisitions;

- our multiclass ordinary share structure, which provides our holders of Class B 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 ordinary shares; and

- restrictions on the time period in which directors may be 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 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 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.

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 ordinary shares will be the sole source of gain for our shareholders for the foreseeable future.

Risks Related to Our Jurisdiction of Incorporation and Certain Tax Risks

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

Under English law, our shareholders must authorize an allotment of share capital which can be issued by our board of directors without further shareholder approval, but this authorization must be approved by our shareholders via an ordinary resolution from time to time (i.e., approval from shareholders holding more than 50% of the voting rights), with such authority capable of applying in respect of any period specified in such resolution up to a maximum of five years. At our annual meeting of shareholders in June 2025, our shareholders authorized us to issue new ordinary or preferred shares (up to a maximum of 35% of our outstanding shares on the record date for our 2025 annual meeting) for a period of five years from the date of such meeting. However, there is no guarantee that any subsequent authorizations will be approved. In the event that we do not receive such authorization, we would face significant impediments to our business and operations as we would be unable to raise capital through the issuance of equity, use equity as consideration in business development deals or honor our outstanding employee equity awards without seeking shareholder approval in each case. Such a scenario would materially harm our business due to the administrative and financial costs related thereto.

Additionally, subject to specified exceptions, 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. At our annual meeting of shareholders in June 2025, our shareholders voted to approve such a waiver for a period of five years from the date of such meeting. If, in the future, we do not receive such a waiver, this would cause a material adverse effect due to the administrative and financial costs related thereto, as a waiver of preemption rights would need to be sought from shareholders in respect of each new issuance of shares, including each instance that an employee would seek to exercise their share options.

While both the general authority to allot and waiver of pre-emption rights could be approved on an annual (or multi-year) basis by shareholders at the annual general meeting, it cannot be guaranteed.

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 companies.

In addition, English law may be subject to change in the 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. 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 against a third party). Under English law, in most cases, only Kiniksa International may be the proper plaintiff for the purposes of maintaining proceedings in respect of wrongful acts committed against it and, generally, neither an individual shareholder, nor any group of shareholders, has any 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.

Investors in the United States may find it difficult to enforce their civil liabilities against us.

It may be difficult for United States 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 United States courts based on civil liability provisions of the United States federal securities laws against us or our directors or officers, it may, depending on the jurisdiction, be difficult to enforce the judgment in the non-United States courts against us. Accordingly, United States 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 our directors and officers. The enforceability of a United States judgment in the UK will depend on the particular facts of the case as well as the laws and treaties in effect at the time. The United States and the UK 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 United States shareholders to bring an original action in the English courts to enforce liabilities based on the United States federal securities laws against us.

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

Although we are incorporated under the laws of 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 tax liability could materially adversely affect our results of operations.

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

If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arms' length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect

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

Changes and uncertainties in the tax system in the countries in which we have operations, could materially adversely affect our financial condition and results of operations, and reduce net returns to our shareholders.

We are unable to predict what tax reform may be proposed or enacted in the future by the United States, UK, Switzerland or the OECD or what effect such changes would have on our business and results of operations. Changes in tax rates, laws, practices, treaties, policies or regulations, or the change in interpretation thereof, could increase our 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 that neither the Company nor any of its subsidiaries would be classified as a PFIC for the taxable year ending December 31, 2025. Although we believe that we were not a PFIC for 2025 and do not expect to become a PFIC in 2026, there can be no guarantee that we, or 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, (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 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 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.

If we, or our subsidiaries, are classified as a PFIC for any taxable year during which a United States Holder holds our Class A 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.

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, 2025. 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 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 ordinary shares.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY

We have implemented processes to identify and assess the cybersecurity threats that could affect our business and information systems and we use various tools and methodologies to test our cybersecurity defenses on a regular basis. As part of this process, we perform regular vulnerability scans and penetration tests and engage third party experts to perform evaluations of our strengths and vulnerabilities. In addition, we perform an annual enterprise risk assessment procedure that evaluates business continuity risks, including an evaluation of cybersecurity risks. The results of these evaluations, along with recommendations for improvements and remediations to our cybersecurity program, if deemed necessary, are periodically reported to senior management and the audit committee of our board of directors, which is tasked with oversight of our cybersecurity program. Reports provided to our senior management and audit committee include updates on our cyber risks and threats, the status of projects to strengthen our information technology systems and assessments of our cybersecurity program. Our senior management and audit committee use the results from these evaluations and reports as part of their risk assessment and decision-making functions.

We require that all employees, consultants and third party contractors adhere to our cybersecurity policies. Key third party contractors undergo a qualification process under our quality management programs (including cGMP and GCP) wherein we assess, among other things, their cybersecurity risk profile. Third party contractors, such as CROs and information technology service providers, that handle sensitive data, including patient data, are subjected to increased scrutiny. Based on identified risks, we may periodically review and reassess our third party contractors on an ongoing basis.

Our cybersecurity program is overseen by our head of information technology, who has significant experience in the information technology space. Our information technology team is responsible for leading our cybersecurity strategy, policy, standards, architecture and processes. Such team is responsible for the identification and reporting of risks to our management and board, as described above. Our information technology team maintains a security operations center intended to identify anomalous activity. Further, our policies require all employees to notify our compliance, legal or information technology functions in the event of a cybersecurity incident.

We have not experienced a material data breach or failure of our cybersecurity program. Our business depends on the availability, reliability and security of our and our third party contractors' information systems, networks and data. Various risks arising out of a cyberattack, security breach or a failure on our or our third party contractors' part to

maintain an adequate cybersecurity program could adversely affect our business, financial condition and results of operations. 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."*

ITEM 2. PROPERTIES.

Our executive headquarters are located in Lexington, Massachusetts, where we have leased office and laboratory space, under a lease that expires in August 2028. We have also leased office space in London, UK, Zug, Switzerland and San Diego, California. These spaces include commercial and logistical operations, as well as office space to support our research and development operations.

ITEM 3. LEGAL PROCEEDINGS.

We are not party to any material legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Principal Market

Our Class A ordinary shares are listed on The Nasdaq Global Select Market under the symbol "KNSA."

Holders

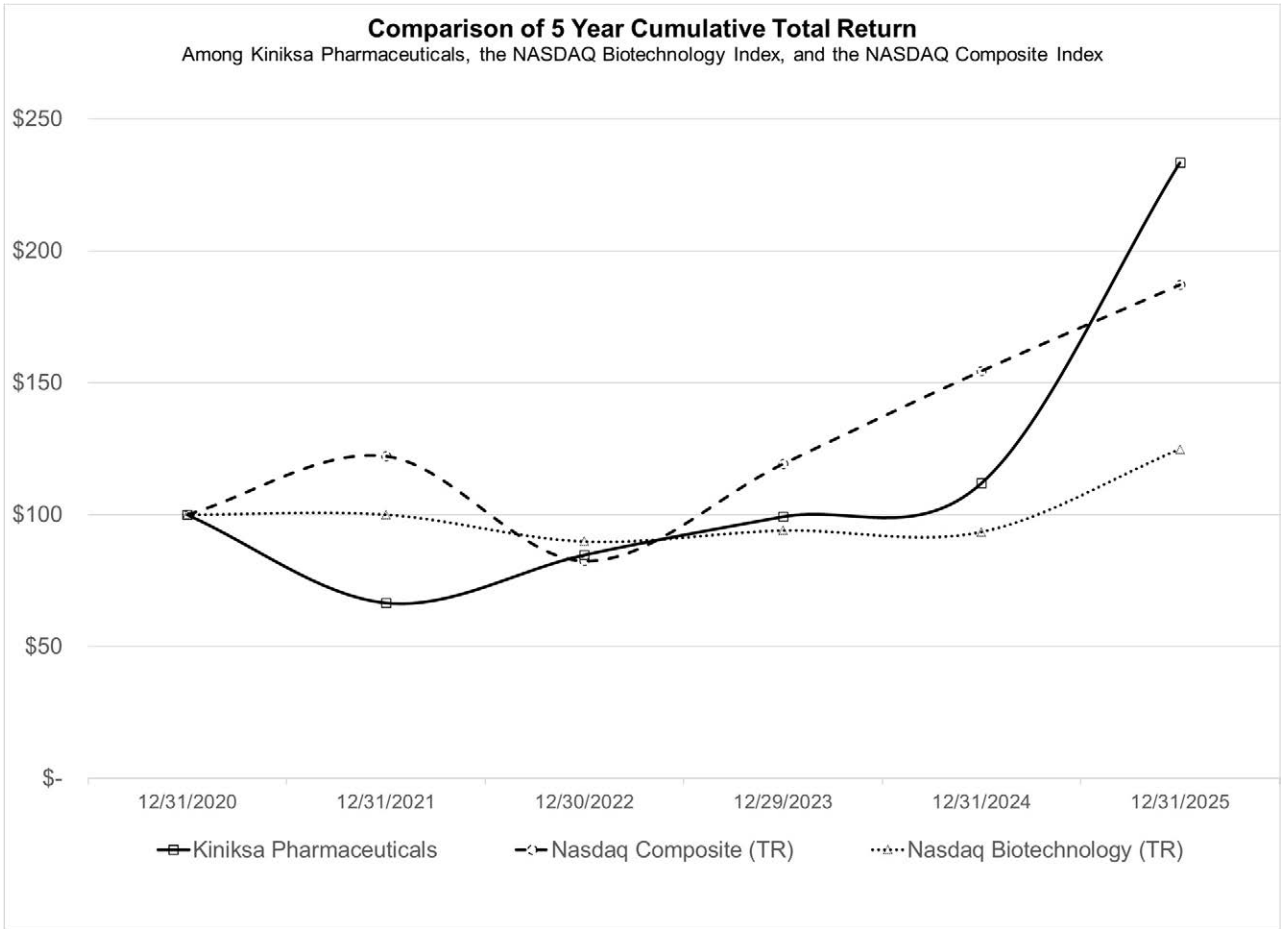
As of February 20, 2026, there were two holders of record of our Class A ordinary shares, one holder of record of our Class B ordinary shares, one holder of record of our Class A1 ordinary shares and one holder of record of our Class B1 ordinary shares. The actual number of shareholders is greater than this number of record holders, and includes shareholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. The number of holders of record also does not include shareholders whose shares may be held in trust by other entities.

Dividends Policy

We have never declared or paid any cash dividends on our ordinary shares. We intend to retain all of our future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination to declare and pay dividends to holders of our ordinary shares will be made at the discretion of our board of directors, which may take into account several factors, including general economic conditions, our financial condition and results of operations, available cash and current and anticipated cash needs, capital requirements, contractual, legal, tax and regulatory restrictions, the implications of the payment of dividends by us to our shareholders and any other factors that our board of directors may deem relevant. In addition, pursuant to the United Kingdom Companies Act 2006 a company may not declare or pay dividends unless (1) it has profits available to make the distribution and (2) the distribution must be justified by reference to relevant accounts. Under our articles of association, each of our ordinary shares is entitled to dividends if, as and when dividends are declared by our board of directors, subject to any preferred dividend right of the holders of any preferred shares.

Performance Graph

The following graph shows a comparison of the total cumulative total shareholder returns (assuming reinvestment of dividends, if any) of an investment of $100 in cash on the last trading day of 2020 to the close of the last trading day of 2025 in each of (i) our Class A ordinary shares, (ii) the Nasdaq Composite Index and (iii) the Nasdaq Biotechnology Index. The comparisons in the graph are required by the SEC and are not intended to forecast or be indicative of the possible future performance of our ordinary shares.



ITEM 6. RESERVED.

ITEM 7. 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 consolidated financial statements and related notes included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the risks identified in Part I-Item 1A "Risk Factors" section of this Annual Report and our other filings with 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 biopharmaceutical company developing and commercializing novel therapies for diseases with unmet need, with a focus on cardiovascular indications. Our portfolio of assets is based on strong biologic rationale or validated mechanisms and offers the potential for differentiation.

ARCALYST is an IL-1α and IL-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 also approved in the United States for the treatment of CAPS, including FCAS and Muckle-Wells Syndrome in adults and children 12 years and older, and the maintenance of remission in DIRA in adults and children weighing 10 kg or more. ARCALYST is commercially available across the United States through a select network of specialty pharmacies. 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. In 2022, we granted Huadong exclusive rights to develop and commercialize ARCALYST in the Huadong Territory. In 2023, Regeneron initiated a technology transfer of the manufacturing process for ARCALYST drug substance, and we are working to qualify Samsung as our replacement CDMO. In December 2024, we initiated a collaborative study agreement with The Mayo Clinic (together with Johns Hopkins University) to investigate the effects of ARCALYST in the treatment of cardiac sarcoidosis.

KPL-387 is an investigational, fully human immunoglobulin G2 monoclonal antibody that binds IL1-R1, inhibiting IL-1α and IL-1β mediated signaling. KPL-387 is an independently developed asset that we believe may expand the recurrent pericarditis market and provide an additional treatment option for patients, with the potential to add the convenience of monthly subcutaneous self-administration with a liquid formulation. In July 2025, we announced that the Phase 2 dose-focusing portion of the Phase 2/3 clinical trial of KPL-387 in recurrent pericarditis had begun recruiting. We expect data from the Phase 2 portion of the trial in the second half of 2026 and plan to use the totality of the data to determine further development strategy. In September 2025, we announced plans to conduct a supplemental Phase 2 transition to KPL-387 monotherapy dosing and administration study to evaluate the efficacy and safety of dosing regimens used to transition patients from standard therapies to KPL-387 monotherapy. In October 2025, the FDA granted Orphan Drug Designation to KPL-387 for the treatment of pericarditis.

KPL-1161 is an independently developed, pre-clinical, Fc-modified immunoglobulin G2 monoclonal antibody that binds IL-1R1, inhibiting IL-1α- and IL-1β-mediated signaling. KPL-1161 is a modified version of KPL-387 designed to have an increased drug half-life that we believe could support quarterly subcutaneous dosing. We are currently conducting preclinical activities with respect to this asset, with an expectation to initiate a Phase 1 first-in-human clinical trial by the end of 2026.

Abiprubart is an investigational monoclonal antibody inhibitor of CD40-CD154 costimulatory interaction, which we believe to be an attractive approach to address multiple autoimmune disease pathologies. We hold an exclusive worldwide license to abiprubart from BIDMC. We previously announced a Phase 2b clinical trial of abiprubart in Sjögren's Disease. In February 2025, we announced our plans to discontinue development of abiprubart in the indication and to explore strategic alternatives for the asset.

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. ARCALYST is currently only approved for sale in the United States, and, therefore, we expect to derive substantially all of our product revenue from the United States for the foreseeable future.

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 the Huadong Collaboration Agreements with Huadong, pursuant to which we granted Huadong exclusive rights to develop and commercialize ARCALYST and mavrilimumab, in the Huadong Territory. In April 2025, we entered into a mutual termination agreement with Huadong pursuant to which we agreed to terminate the mavrilimumab Huadong Collaboration Agreement and release all claims related thereto. The ARCALYST Huadong Collaboration Agreement remains in effect. For more information, see "*Business –License and Acquisition Agreements—Out-Licensing Agreements—Huadong Collaboration Agreements*".

Under the Huadong Collaboration Agreements, we received a total upfront cash payment of $22.0 million, which includes $12.0 million for the Huadong Territory license of ARCALYST and $10.0 million for the Huadong Territory license of mavrilimumab. In the fourth quarter of 2024, following the achievement of a regulatory milestone under the ARCALYST Huadong Collaboration Agreement, Huadong became obligated to make an additional cash payment of $20.0 million, which was received in the first quarter of 2025. In addition, we will be eligible to receive additional contingent sales-based milestones payments related to ARCALYST. Huadong will also be obligated to pay us tiered percentage royalties on ARCALYST ranging from the low-to-mid teens on annual net sales in the Huadong Territory, subject to certain reductions tied to ARCALYST manufacturing costs and certain other customary reductions, with an aggregate minimum floor. Royalties will be payable on a country-by-country or region-by-region basis until the later of (i) 12 years after the first commercial sale of ARCALYST 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 ARCALYST in such country or region in the Huadong Territory, and (iii) the expiration of the last regulatory exclusivity for ARCALYST 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 and do not expect to recognize any additional license and collaboration revenue following the termination of the mavrilimumab Huadong Collaboration Agreement. We have recognized $0.2 million of revenue of the $32.0 million transaction price under the ARCALYST license agreement as of December 31, 2025, and will recognize the remaining revenue as materials are shipped.

In August 2022, we entered into the Genentech License Agreement, pursuant to which we granted Genentech exclusive worldwide rights to develop and commercialize the Genentech Licensed Products. For more information, see "*Business –License and Acquisition Agreements—Out-Licensing Agreements—Genentech License Agreement*".

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 $570.0 million remains as of December 31, 2025. 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. In 2024, we completed our remaining obligations under the Genentech License Agreement and we have recognized as revenue all of the consideration received.

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 ARCALYST.

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 transfer of ARCALYST drug substance manufacturing initiated by Regeneron in March 2023, 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.

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 I, Item 1A. “Risk Factors” in this Annual 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 expect that our selling, general and administrative expenses will continue to increase in the future as we continue to expand our infrastructure related to the commercialization of ARCALYST and our other product candidates, if approved.

Other Income

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

Income Taxes

Prior to the Redomiciliation, our principal holding company was incorporated 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 previous 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 of the reporting periods in which it was incorporated there, and no net operating loss carryforwards are currently available to us for those losses. Following the Redomiciliation, our income is subject to the enacted United Kingdom statutory corporate tax rate and net operating losses incurred have an indefinite carryforward. Our wholly owned subsidiaries (including any foreign branch offices thereof) are subject to taxation in their respective countries.

In the third quarter of 2022, Kiniksa Pharmaceuticals, Ltd. ("Kiniksa Bermuda") transferred exclusive worldwide rights to develop and commercialize vixarelimab to Kiniksa Pharmaceuticals (UK), Ltd. ("Kiniksa UK"). In the fourth quarter of 2023, all rights, title and interest in, among other things, certain contracts, intellectual property rights, product filings and approvals and other information, plans and inventory owned insofar as they related exclusively or primarily to ARCALYST were allocated by Kiniksa UK to its Swiss branch office. In the first quarter of 2024, Kiniksa Bermuda transferred to Kiniksa Pharmaceuticals, GmbH ("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, KPL-387, KPL-1161 and other preclinical assets. In connection with each of the foregoing transfers and /or allocations, we recognized a step-up in basis and did not incur any material tax liabilities.

In the fourth quarter of 2024, Kiniksa UK contributed all of its rights, title and interest in, among other things, certain contracts, intellectual property rights, product filings and approvals and other information, plans and materials owned or controlled by Kiniksa UK insofar as they related exclusively or primarily to vixarelimab to Kiniksa Switzerland. In connection with the termination of Kiniksa UK rights and the contribution, we revalued the assets at fair market value and did not incur any material tax liabilities.

Results of Operations

Comparison of the Years Ended December 31, 2025, 2024 and 2023

The following table summarizes our results of operations for the years ended December 31, 2025, 2024 and 2023:

	Years Ended December 31,			2025/2024 Comparison Increase/(Decrease)		2024/2023 Comparison Increase/(Decrease)	
	2025	2024	2023	$	%	$	%
	(in thousands)			(in thousands, except percentages)			
Revenue:							
Product revenue, net	$ 677,564	$ 417,029	$ 233,176	$ 260,535	62%	$ 183,853	79%
License and collaboration revenue	—	6,210	37,083	(6,210)	(100)%	(30,873)	(83)%
Total revenue	677,564	423,239	270,259	254,325	60%	152,980	57%
Operating expenses:							
Cost of goods sold	77,673	60,910	33,407	16,763	28%	27,503	82%
Collaboration expenses	229,545	128,311	56,524	101,234	79%	71,787	127%
Research and development	96,853	111,623	76,097	(14,770)	(13)%	35,526	47%
Selling, general and administrative	196,272	168,011	129,427	28,261	17%	38,584	30%
Total operating expenses	600,343	468,855	295,455	131,488	28%	173,400	59%
Income (loss) from operations	77,221	(45,616)	(25,196)	122,837	(269)%	(20,420)	81%
Other income	11,647	9,464	8,544	2,183	23%	920	11%
Income (loss) before income taxes	88,868	(36,152)	(16,652)	125,020	(346)%	(19,500)	117%
Benefit (provision) for income taxes	(29,863)	(7,041)	30,736	(22,822)	324%	(37,777)	(123)%
Net income (loss)	$ 59,005	$ (43,193)	$ 14,084	$ 102,198	(237)%	$ (57,277)	(407)%

Product Revenue, Net

We recognized net revenue from the sale of ARCALYST of $677.6 million, $417.0 million and $233.2 million for the years ended December 31, 2025, 2024 and 2023, respectively. The increases in 2025 and 2024 were primarily driven by an increase in patient enrollment.

License and Collaboration Revenue

We did not recognize any license and collaboration revenue for the year ended December 31, 2025. We reported $6.2 million of license and collaboration revenue for the year ended December 31, 2024, primarily driven by the achievement of a $5.0 million development milestone related to a third indication under the Genentech License Agreement and $0.7 million of products sold under the ARCALYST Huadong Collaboration Agreements. We reported $37.1 million of license and collaboration revenue for the year ended December 31, 2023, related to the Genentech License Agreement primarily driven by the achievement of $25.0 million in development milestones related to two new indications, materials delivered and our ongoing recognition of the transaction price related to the in-progress Phase 2b clinical trial of vixarelimab in prurigo nodularis.

Cost of Goods Sold

We recognized cost of goods sold of $77.7 million, $60.9 million, and $33.4 million for the years ended December 31, 2025, 2024 and 2023, respectively. The increase of $16.8 million in 2025 from 2024 related primarily to

the increase in sales of ARCALYST. The increase of $27.5 million in 2024 from 2023 related primarily to the increase in sales of ARCALYST and a $12.6 million increase 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

We recognized collaboration expenses of $229.5 million, $128.3 million and $56.5 million for the years ended December 31, 2025, 2024 and 2023, respectively. The increase of $101.2 million in 2025 from 2024 relates primarily to increased revenue from sales of ARCALYST. The increase of $71.8 million in 2024 from 2023 relates primarily to an increase in revenue from the sales of ARCALYST driving higher profits under the Regeneron agreement and to a $10.0 million payment due to Regeneron related to a regulatory milestone achieved under the ARCALYST Huadong Collaboration Agreement.

Research and Development Expenses

	Years Ended December 31,			2025/2024 Comparison Increase/(Decrease)		2024/2023 Comparison Increase/(Decrease)	
	2025	2024	2023	$	%	$	%
	(in thousands)			(in thousands, except percentages)			
Direct research and development expenses by program:							
ARCALYST	$ 1,040	$ 1,080	$ 2,628	$ (40)	(4)%	$ (1,548)	(59)%
KPL-387	47,265	11,221	2,537	36,044	321%	8,684	342%
KPL-1161	4,198	581	—	3,617	623%	581	0%
Abiprubart	6,122	59,459	28,388	(53,337)	(90)%	31,071	109%
Vixarelimab	44	1,530	7,717	(1,486)	(97)%	(6,187)	(80)%
Unallocated research and development expenses:							
Personnel related (including share-based compensation)	23,943	24,302	22,462	(359)	(1)%	1,840	8%
Other	14,241	13,450	12,365	791	6%	1,085	9%
Total research and development expenses	$ 96,853	$ 111,623	$ 76,097	$ (14,770)	(13)%	$ 35,526	47%

Research and development expenses were $96.9 million for the year ended December 31, 2025, compared to $111.6 million for the year ended December 31, 2024, or a decrease of $14.8 million. Research and development expenses were $111.6 million for the year ended December 31, 2024 compared to $76.1 million for the year ended December 31, 2023, or an increase of $35.5 million.

Direct costs for our KPL-387 program were $47.3 million, $11.2 million and $2.5 million for the years ended December 31, 2025, 2024 and 2023, respectively. During the year ended December 31, 2025, expenses primarily related to the start-up of our Phase 2/3 clinical trial in recurrent pericarditis and manufacturing of clinical supply. During the year ended December 31, 2024, expenses primarily related to our Phase 1 study in normal healthy volunteers and manufacturing of clinical supply. During the year ended December 31, 2023, expenses primarily related to manufacturing of clinical supply.

Direct costs for our KPL-1161 program were $4.2 million and $0.6 million for the years ended December 31, 2025 and 2024, respectively. We did not incur any expenses related to KPL-1161 for the year ended December 31, 2023. For the years ended December 31, 2025 and 2024 expenses incurred primarily related to pre-clinical development.

Direct costs for our abiprubart program were $6.1 million, $59.5 million and $28.4 million for the years ended December 31, 2025, 2024 and 2023, respectively. During the year ended December 31, 2025 expenses incurred primarily related to the close-out of our Phase 2b clinical trial in Sjögren's Disease. During the year ended December 31, 2024 expenses incurred primarily related to a $18.5 million write-off of prepayments for future manufacturing we no

longer expect to utilize, manufacturing of clinical material, continuation of cohort four and study wind-down activities of our Phase 2 clinical trial in RA and start-up costs of our Phase 2b clinical trial in Sjögren's Disease. During the year ended December 31, 2023, expenses incurred primarily related to the manufacturing of clinical material, the continuation of the first two cohorts of the Phase 2 clinical trial of abiprubart in RA and Cohorts 3 and 4 of such trial.

Direct costs for our vixarelimab program were less than $0.1 million, $1.5 million and $7.7 million for the years ended December 31, 2025, 2024 and 2023, respectively. During the year ended December 31, 2024, expenses incurred were primarily related to the wind-down activities of our Phase 2b clinical trial in prurigo nodularis. During the year ended December 31, 2023 expenses incurred primarily related to our ongoing Phase 2b clinical trial of vixarelimab in prurigo nodularis.

Unallocated research and development expenses were $38.2 million, $37.8 million and $34.8 million for the years ended December 31, 2025, 2024 and 2023, respectively. The increase of $0.8 million in unallocated research and development expenses in 2025 from 2024 was primarily due to an increase in pre-clinical development. The increase of $3.0 million in unallocated research and development expenses in 2024 from 2023 was primarily due to an increase in personnel to support our clinical trials. Personnel-related costs for the years ended December 31, 2025, 2024 and 2023 included share-based compensation of $6.6 million, $6.1 million and $5.5 million, respectively.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $196.3 million, $168.0 million and $129.4 million for the years ended December 31, 2025, 2024 and 2023, respectively. The increase of $28.3 million in 2025 from 2024 was primarily due to an increase of $23.1 million in personnel-related costs largely attributable to an increase in headcount and an increase in sales and marketing expenses of $5.5 million. The increase of $38.6 million in 2024 from 2023 was primarily due to an increase of $18.9 million in personnel-related costs and an increase in sales and marketing expenses of $13.5 million, largely attributable to a full year of expenses associated with the expansion of our salesforce in 2023 and an increase in professional fees of $2.8 million largely attributable to the Redomiciliation. Personnel-related costs for the years ended December 31, 2025, 2024 and 2023 included share-based compensation of $28.2 million, $22.9 million and $19.8 million, respectively.

Other Income

Other income was $11.6 million, $9.5 million and $8.5 million for the years ended December 31, 2025, 2024 and 2023. The year-over-year increases were driven primarily by higher interest income generated by increased average holdings of cash, cash equivalents, and short-term investments.

Benefit (Provision) for Income Taxes

For the year ended December 31, 2025, we recorded an income tax provision of $29.9 million relating primarily to income earned in Switzerland, the United States, and the UK; valuation allowance on Swiss losses and revaluation of Swiss deferred tax assets for enacted rate changes; offset by benefits related to share-based compensation, and United States federal and state R&D Credits.

For the year ended December 31, 2024, we recorded an income tax provision of $7.0 million relating primarily to income earned in Switzerland and the United States, offset by Foreign-Derived Intangible Income ("FDII") deduction and United States federal and state R&D Credits utilized.

For the year ended December 31, 2023, we recorded an income tax benefit of $30.7 million relating to a non-cash deferred tax benefit of $33.8 million primarily associated with Kiniksa UK's allocation of its ARCALYST assets to its Swiss branch office and the release of the valuation allowance on United States deferred tax assets offset by the establishment of a partial valuation allowance on our UK deferred tax assets. The net benefit in the net deferred tax asset was offset by current income tax expense of $3.1 million primarily associated with income earned in the UK and the United States.

Liquidity and Capital Resources

As of December 31, 2025, our principal source of liquidity was cash, cash equivalents and short-term investments, which totaled $414.1 million. Our net income (losses) were $59.0 million, ($43.2) million and $14.1 million for the years ended December 31, 2025, 2024 and 2023, respectively. We expect our cash balance and our expected cash inflows from operations to allow us to meet our current operating plan.

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 $24.6 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 $10.5 million, $3.5 million of which are due within one year. In connection with our ongoing technology transfer of ARCALYST drug substance manufacturing, we have entered into a Master Services Agreement and a Product Specific Agreement with Samsung. Our commitments under such agreements, which includes the purchase of raw materials and related service fees, obligates us to minimum payments of $147.7 million, $18.9 million of which are due within one year. As December 31, 2025, we have capitalized $20.9 million of production cost into inventory as semi-finished goods related to drug substance manufactured at Samsung. We have additionally entered into agreements with several CDMOs to provide us with preclinical and clinical trial materials for our non-ARCALYST assets, which obligate us to minimum payments of $3.4 million, all of which are due within one year. We have long-term incentive plans for our employees that may result in cash award payments of $23.1 million, based upon the achievement of certain regulatory milestones, none of which are expected to be achieved in the next year.

Under various agreements with third parties, we are entitled to receive upfront payments, milestone payments, and royalties, each based upon specified milestones. In 2024, we received $15.0 million in development milestone payments from Genentech related to a second and third indication under the Genentech License Agreement. In 2025, we received a $20.0 million milestone payment related to Huadong’s achievement of a regulatory milestone under the ARCALYST Huadong Collaboration Agreement, $10.0 million of which was paid to Regeneron in 2025 as part of the Regeneron Agreement.

These agreements impact our short-term and long-term liquidity and capital needs. As of December 31, 2025, we had cash, cash equivalents and short-term investments of $414.1 million.

Cash Flows

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

	Years Ended December 31,		
	2025	2024	2023
		(in thousands)	
Net cash provided by operating activities	$ 137,985	$ 25,689	$ 13,301
Net cash provided by (used in) investing activities	(188,993)	37,672	(29,557)
Net cash provided by financing activities	33,023	12,266	1,495
Net increase (decrease) in cash and cash equivalents	$ (17,985)	$ 75,627	$ (14,761)

Operating Activities

Net cash provided by operations was $138.0 million for the year ended December 31, 2025, compared to $25.7 million for the year ended December 31, 2024. 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 $5.0 million.

Net cash provided by operations was $25.7 million for the year ended December 31, 2024, compared to $13.3 million for the year ended December 31, 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 $20.0 million.

Investing Activities

Net cash used in investing activities was $189.0 million for the year ended December 31, 2025, compared to net cash provided by investing activities of $37.7 million for the year ended December 31, 2024 as part of managing our cash and short-term investment portfolio mix as we deployed higher levels of investable cash into treasury securities with longer-terms.

Net cash provided by investing activities was $37.7 million for the year ended December 31, 2024, compared to net cash used in investing activities of $29.6 million for the year ended December 31, 2023 as part of managing our cash and short-term investment portfolio mix.

Financing Activities

During the years ended December 31, 2025, 2024 and 2023, net cash provided by financing activities was $33.0 million, $12.3 million and $1.5 million, respectively, consisting of proceeds from the exercise of employee share options and our 2018 Employee Share Purchase Plan (the "2018 ESPP").

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 collaboration, licensing or other strategic transactions. Further, we may incur 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. For more information on our near and long-term funding requirements, see "*Risk Factors – General Risk Factors – We have a history of operating losses and may require substantial additional financing in the future.*"

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 collaboration, licensing or other 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 I, Item 1A. "*Risk Factors*" in this Annual Report.

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.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements included elsewhere in this Annual Report, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

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

We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. Once a contract is determined to be within the scope of ASC 606, we determine the performance obligations that are distinct. We recognize as revenues the amount of the transaction price that is allocated to each respective performance obligation when the performance obligation is satisfied or as it is satisfied. Generally, our performance obligations are transferred to customers at a point in time, typically upon receipt of the product by the customer.

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

Product Revenue, Net

Net revenue from product sales is recognized at the transaction price when the specialty pharmacy or specialty distributors obtains control of our products, 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 us as our 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.

As of December 31, 2025, a 10% change in our product revenue allowance and reserve would not result in a material change in our net revenue.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. 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. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of these estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors, including research laboratories, in connection with preclinical development activities;
- CROs and investigative sites in connection with preclinical studies and clinical trials;
- third parties in the connection with the achievement of milestones due under license acquisition and other similar agreements; and
- CDMOs in connection with drug substance and drug product formulation and manufacturing of materials.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of participants and the completion of clinical trial milestones. Non-refundable prepayments determined to be used within one year for goods or services that will be used or rendered for future research and development activities are recorded as prepaid expenses. Non-refundable prepayments or minimum balance requirements associated to clinical trials determined to not be used within one year are classified as other long-term assets. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services

performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

As of December 31, 2025, we have accrued $6.6 million of estimated research and development expenses.

Income Taxes

We file tax returns based upon our interpretation of tax laws and regulations, and we record estimates in our financial statements based upon these interpretations at the applicable tax rates in the jurisdictions in which we operate. Our tax returns are routinely subject to examination by taxing authorities, which could result in future tax, interest, and penalty assessments. Inherent uncertainties also exist in estimates of many tax positions due to the complexity of tax laws. We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained upon examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate resolution. The amount of unrecognized tax benefits is adjusted for changes in facts and circumstances such as changes to existing tax law, the issuance of regulations by taxing authorities, new information obtained during a tax examination, or resolution of a tax examination. We believe our estimates for uncertain tax positions are both appropriate and sufficient to pay assessments that may result from examinations of our tax returns; however, given the uncertainty of positions that could be taken by taxing authorities during the examinations of our tax returns, the ultimate outcome of any tax matters may result in liabilities that are greater than amounts accrued. We recognize both accrued interest and penalties related to unrecognized tax benefits in income tax expense.

We account for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in our tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the benefit (provision) for income taxes. We assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe, based upon the weighting of both positive and negative evidence available, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected, cumulative recent earnings and considering prudent and feasible tax planning strategies. Significant judgment is required in assessing both positive and negative evidence available and, to the extent that a reversal of any portion of our valuation allowance against our deferred tax assets is deemed appropriate, a tax benefit will be recorded in our income tax benefit (provision) in the period of such reversal.

We believe our estimates for our uncertain tax positions and the valuation allowances against certain deferred tax assets recognized in our financial statements are appropriate based upon our assessment of the factors mentioned above.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our annual consolidated financial statements included elsewhere in this Annual Report.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Interest Rate Risk

We are exposed to market risk related to changes in interest rates. As of December 31, 2025, our cash, cash equivalents and short-term investments consisted of money market funds and United States Treasury securities. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of United

States interest rates. Such interest rates have and in the future may be subject to significant volatility. However, because of the short-term nature of the instruments in our portfolio, an immediate 100 basis point change in market interest rates would not have a material impact on the fair market value of our investment portfolio or on our financial position or results of operations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those financial statements is found in Item 15.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated, as of the end of the period covered by this Annual Report, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. 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 December 31, 2025.

In designing and evaluating our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), 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.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act.

Our management conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2025 using the criteria set forth in "Internal Control – Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on this assessment, our management concluded that, as of December 31, 2025, our internal control over financial reporting was effective.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2025 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

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 fourth quarter of the year ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

Trading Arrangements.

During the three months ended December 31, 2025, certain of our directors and officers entered into, modified or terminated contracts, instructions or written plans for the purchase or sale of our ordinary shares that are intended to satisfy the affirmative defense conditions specified in Rule 10b5-1(c) under the Exchange Act, as described below:

				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	Chairman and CEO	Adoption	October 31, 2025	X		December 31, 2026	564,182
John Paolini	EVP, Chief Medical Officer	Adoption	November 18, 2025	X		November 19, 2026	98,424

(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 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Except to the extent provided below, the information required to be disclosed by this Item will be set forth in our proxy statement for our 2026 Annual Meeting to be filed with the SEC within 120 days of December 31, 2025, and is incorporated into this Annual Report by reference.

We have adopted a written code of business conduct and ethics that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer and controller, or persons performing similar functions. Our code of business conduct and ethics is available in the "Investors" section of our website at *www.kiniksa.com* under "Corporate Governance". We intend to post on our website all disclosures that are required by law or the Nasdaq rules concerning any amendments to, or waivers from, any provision of the code. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this Annual Report.

ITEM 11. EXECUTIVE COMPENSATION.

The information required to be disclosed by this Item will be set forth in our proxy statement for our 2026 Annual Meeting to be filed with the SEC within 120 days of December 31, 2025, and is incorporated into this Annual Report by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS.

The information required to be disclosed by this Item will be set forth in our proxy statement for our 2026 Annual Meeting to be filed with the SEC within 120 days of December 31, 2025, and is incorporated into this Annual Report by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information required to be disclosed by this Item will be set forth in our proxy statement for our 2026 Annual Meeting to be filed with the SEC within 120 days of December 31, 2025, and is incorporated into this Annual Report by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required to be disclosed by this Item will be set forth in our proxy statement for our 2026 Annual Meeting to be filed with the SEC within 120 days of December 31, 2025, and is incorporated into this Annual Report by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a)(1) Financial Statements.

See the "Index to Consolidated Financial Statements" on page F-1 below for the list of financial statements filed as part of this report.

(a)(2) Financial Statement Schedules.

All schedules have been omitted because they are not required or because the required information is given in the Consolidated Financial Statements or Notes thereto set forth below beginning on page F-1.

(a)(3) Exhibits. See Exhibit Index.

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
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 the Class A Ordinary Shares	8-K12B	001-38492	4.1	6/28/24	
4.2	Second Amended and Restated Investors' Rights Agreement, dated as of February 9, 2018	S-1	333-224488	4.2	4/27/18	
4.3	Description of Kiniksa Pharmaceuticals International, plc Securities	8-K12B	001-38492	4.2	6/28/24	
10.1†	Asset Purchase Agreement, dated September 7, 2016, by and between the Registrant and Biogen MA Inc., as amended	S-1	333-224488	10.6	4/27/18	
10.2††	Amendment No. 2, dated August 2, 2022, to the Asset Purchase Agreement, dated September 7, 2016, by and between the Registrant and Biogen MA Inc.	10-Q	001-38492	10.2	11/3/22	
10.3†	License Agreement, dated September 25, 2017, by and between the Registrant and Regeneron Pharmaceuticals, Inc.	S-1	333-224488	10.7	4/27/18	
10.4††	Amendments Nos. 1 and 2 to the License Agreement, dated September 25, 2017, by and between Kiniksa Pharmaceuticals Ltd. and Regeneron Pharmaceuticals, Inc.	10-Q	001-38492	10.2	5/6/21	
10.5†	License Agreement, dated as of December 21, 2017, by and between the Registrant and MedImmune, Limited	S-1	333-224488	10.8	4/27/18	
10.6†	Amendment No. 1 to the License Agreement, effective as of July 9, 2020, by and between Kiniksa Pharmaceuticals, Ltd. and MedImmune Limited	8-K	001-38492	10.1	7/15/20	
10.7††	Exclusive License Agreement, dated as of November 1, 2013, by and between The Beth Israel Deaconess Medical Center and Primatope Therapeutics Inc.	10-K	001-38492	10.38	2/24/22	
10.8††+	Collaboration and License Agreement (Rilonacept), by and between Kiniksa Pharmaceuticals (UK), Ltd. and Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd., dated as of February 21, 2022	10-Q	001-38492	10.2	5/5/22	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.9†††+	License Agreement, dated August 2, 2022, by and among Kiniksa Pharmaceuticals (UK), Ltd., Genentech, Inc. and F. Hoffmann-La Roche Ltd.	10-Q	001-38492	10.1	11/3/22	
10.10††	Commercial Supply Agreement, dated February 26, 2021, by and between Kiniksa Pharmaceuticals (UK) Ltd. and Regeneron Pharmaceuticals, Inc.	10-Q	001-38492	10.1	5/6/21	
10.11	Clinical Supply Agreement, dated as of September 27, 2017, by and between the Registrant and Regeneron Pharmaceuticals, Inc.	S-1	333-224488	10.9	4/27/18	
10.12†	Master Services Agreement, dated June 25, 2024, by and between Kiniksa Pharmaceuticals (UK), Ltd. and Samsung Biologics Co., Ltd.	10-Q	001-38492	10.12	7/25/24	
10.13†	Product Specific Agreement, dated June 25, 2024, by and between Kiniksa Pharmaceuticals (UK), Ltd. and Samsung Biologics Co., Ltd.	10-Q	001-38492	10.13	7/25/24	
10.14	Sublease Agreement, dated as of March 13, 2018, by and between Kiniksa Pharmaceuticals Corp. and Shire Human Genetic Therapies, Inc.	S-1	333-224488	10.10	4/27/18	
10.15	First and Second Amendment to Sublease Agreement, dated as of June 26, 2018 and July 17, 2018, respectively, by and between Kiniksa Pharmaceuticals Corp. and Shire Human Genetic Therapies, Inc.	10-Q	001-38492	10.10	8/6/18	
10.16	Third Amendment to Sublease Agreement, dated as of November 7, 2018, by and between Kiniksa Pharmaceuticals Corp. and Shire Human Genetic Therapies, Inc.	8-K	001-38492	10.1	11/13/18	
10.17	Recognition and Attornment Agreement and Amendment of Sublease by and between Kiniksa Pharmaceuticals Corp. and 92 Hayden Avenue Trust dated as of November 6, 2020	8-K	001-38492	10.1	11/10/20	
10.18	Fifth Amendment of Sublease, dated July 27, 2022, by and between Kiniksa Pharmaceuticals Corp. and 92 Hayden Avenue Trust	10-Q	001-38492	10.3	11/3/22	
10.19	Sixth Amendment of Sublease, dated May 24, 2023, by and between Kiniksa Pharmaceuticals Corp. and 92 Hayden Avenue Trust	10-Q	001-38492	10.1	8/1/23	
10.20#	Amended and Restated Employment Agreement, dated as of May 29, 2018, by and between Kiniksa Pharmaceuticals Corp. and Sanj K. Patel	10-Q	001-38492	10.7	8/6/18	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.21#	Employment Agreement, effective as of January 1, 2025, by and between Kiniksa Pharmaceuticals Corp. and John F. Paolini	10-K	001-38492	10.22	2/25/25	
10.22#	Employment Agreement, effective as of January 1, 2025, by and between the Company and Mark Ragosa	10-K	001-38492	10.23	2/25/25	
10.23#	Employment Agreement, effective as of January 1, 2025, by and between Eben Tessari and Kiniksa Pharmaceuticals Corp.	10-K	001-38492	10.24	2/25/25	
10.24#	Employment Agreement, effective as of July 1, 2025, by and between Michael Megna and Kiniksa Pharmaceuticals Corp.	10-Q	001-38492	10.1	10/28/25	
10.25#	Employment Agreement, effective as of January 1, 2025, by and between Kiniksa Pharmaceuticals Corp. and Ross Moat	10-K	001-38492	10.26	2/25/25	
10.26+#	Consulting Agreement by and between Kiniksa Pharmaceuticals International, plc and Dr. Richard Levy					*
10.27#	Form of Indemnification Agreement for Directors	8-K12B	001-38492	10.1	6/28/24	
10.28#	Form of Indemnification Agreement for Officers	8-K12B	001-38492	10.2	6/28/24	
10.29#	2015 Equity Incentive Plan	8-K12B	001-38492	10.3	6/28/24	
10.30#	2018 Incentive Award Plan and forms of award agreements thereunder	10-Q	001-38492	10.9	7/29/25	
10.31#	2018 Incentive Award Plan; Subplan for UK Employees and forms of award agreements thereunder	8-K12B	001-38492	10.5	6/28/24	
10.32#	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	
10.33#	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	
10.34#	Form of 2024 Performance Share Unit Grant Notice and 2024 Performance Share Unit Award Agreement	10-Q	001-38492	10.2	4/25/24	
10.35#	Form of 2025 Performance Share Unit Grant Notice and 2025 Performance Share Unit Award Agreement	10-Q	001-38492	10.1	4/29/25	
10.36#	2018 Employee Share Purchase Plan	8-K12B	001-38492	10.8	6/28/24	
10.37#	Offering Document under the 2018 Employee Share Purchase Plan	8-K12B	001-38492	10.9	6/28/24	
10.38#	KPL-387 Long-Term Incentive Plan for Executive Officers	8-K	001-38492	10.1	4/23/25	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
10.39#	Form of Milestone 1 Cash Award Grant Notice and Agreement under the KPL-387 Long-Term Incentive Plan	8-K	001-38492	10.2	4/23/25	
10.40#	Form of Milestone 2 Cash Award Grant Notice and Agreement under the KPL-387 Long-Term Incentive Plan	8-K	001-38492	10.3	4/23/25	
10.41#	Form of Milestone 1 PSU Award Grant Notice and Agreement under the KPL-387 Long-Term Incentive Plan	8-K	001-38492	10.4	4/23/25	
10.42#	Form of Milestone 2 PSU Award Grant Notice and Agreement under the KPL-387 Long-Term Incentive Plan	8-K	001-38492	10.5	4/23/25	
10.43#	Form of Milestone 1 Option Award Grant Notice and Agreement under the KPL-387 Long-Term Incentive Plan	8-K	001-38492	10.6	4/23/25	
10.44#	Form of Milestone 2 Option Award Grant Notice and Agreement under the KPL-387 Long-Term Incentive Plan	8-K	001-38492	10.7	4/23/25	
10.45#	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	
10.46#	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	10.11	6/28/24	
10.47#	Non-Employee Director Compensation Program					*
10.48#	Restricted Share Agreement, dated as of September 16, 2015, by and between the Registrant and Sanj K. Patel	S-1	333-229394	10.25	1/28/19	
19.1	Insider Trading Compliance Program	10-K	001-38492	19.1	2/28/24	
21.1	Subsidiaries of the Registrant					*
23.1	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm					*
31.1	Rule 13a-14(a) / 15d-14(a) Certification of Chief Executive Officer					*
31.2	Rule 13a-14(a) / 15d-14(a) Certification of Chief Financial Officer					*
32.1	Section 1350 Certification of Chief Executive Officer					**
32.2	Section 1350 Certification of Chief Financial Officer					**

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
97.1	Policy for Recovery of Erroneously Awarded Compensation	10-K	001-38492	97.1	2/28/24	
101.INS	Inline XBRL Instance 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 as Inline XBRL and contained in Exhibit 101).					

* Filed herewith
** Furnished herewith
*** Submitted electronically herewith
Indicates management contract or compensatory plan
† Confidential treatment of certain provisions has been granted by the SEC pursuant to Rule 406 under the Securities Act of 1933, as amended
†† 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)

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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 INTERNATIONAL, PLC

Date: February 24, 2026

By: /s/ Sanj K. Patel
Sanj K. Patel
Chief Executive Officer and Chairman of the Board of Directors

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Sanj K. Patel Sanj K. Patel	Chief Executive Officer and Chairman of the Board of Directors (principal executive officer)	February 24, 2026
/s/ Mark Ragosa Mark Ragosa	Chief Financial Officer (principal financial officer)	February 24, 2026
/s/ Michael R. Megna Michael R. Megna	Chief Accounting Officer (principal accounting officer)	February 24, 2026
/s/ Felix J. Baker Felix J. Baker	Lead Independent Director	February 24, 2026
/s/ Stephen R. Biggar Stephen R. Biggar	Director	February 24, 2026
/s/ M. Cantey Boyd M. Cantey Boyd	Director	February 24, 2026
/s/ G. Bradley Cole G. Bradley Cole	Director	February 24, 2026
/s/ Richard S. Levy Richard S. Levy	Director	February 24, 2026
/s/ Thomas R. Malley Thomas R. Malley	Director	February 24, 2026
/s/ Tracey L. McCain Tracey L. McCain	Director	February 24, 2026
/s/ Kimberly J. Popovits Kimberly J. Popovits	Director	February 24, 2026
/s/ Barry D. Quart Barry D. Quart	Director	February 24, 2026

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Kiniksa Pharmaceuticals International, plc

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Kiniksa Pharmaceuticals International, plc and its subsidiaries (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations and comprehensive income (loss), of shareholders' equity and of cash flows for each of the three years in the period ended December 31, 2025, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2025, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Product Revenue, Net

As described in Notes 2 and 4 to the consolidated financial statements, the Company's product is sold through a third party logistics provider that distributes primarily through a network of authorized specialty pharmacies and specialty distributors. The Company's net revenue from such product sales is recognized at the transaction price when the specialty pharmacy or specialty distributors obtain control of the Company's products, which occurs at a point in time, typically upon shipment of the product from the third party logistics provider. The Company's 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. For the year ended December 31, 2025, the Company recognized $677.6 million of product revenue, net.

The principal consideration for our determination that performing procedures relating to product revenue, net, is a critical audit matter is a high degree of auditor effort in performing procedures related to the Company's recognition of product revenue, net.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the recognition of product revenue, net. These procedures also included, among others (i) testing revenue recognized for a sample of revenue transactions by obtaining and inspecting source documents, such as invoices, customer purchase orders, shipping documents, and cash receipts; and (ii) testing a sample of discounts and allowances transactions related to chargebacks and rebates by obtaining and inspecting source documents, which included support for contractual arrangements, units sold, and rebate payments.

Accrued Research and Development Costs

As described in Notes 2 and 9 to the consolidated financial statements, the Company has entered into various research and development-related contracts with companies both inside and outside of the United States. When billing terms under these contracts do not coincide with the timing of when the work is performed, management is required to make estimates of outstanding obligations to those third parties as of the end of the reporting period. Total accrued research and development expenses related to these estimated research and development obligations were $6.6 million as of December 31, 2025. Accrual estimates are based on a number of factors, including management's assessment of progress towards completion of the research and development activities, invoicing to date under the contracts, communication from the research institution or other companies of any actual costs incurred during the period that have not yet been invoiced, and the costs included in the contracts. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period.

The principal considerations for our determination that performing procedures relating to accrued research and development costs is a critical audit matter are (i) the significant judgment by management when developing the estimate of the accrued research and development costs and (ii) a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating audit evidence for the factors related to management's assessment of progress towards completion of the research and development activities, invoicing to date under the contracts, and communication from the research institution or other companies of any actual costs incurred during the period that have not yet been invoiced.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to accrued research and development costs, including controls over the review of contracts, accumulating information on actual costs incurred during the period, and assessment of progress towards completion of the research and development activities. These procedures also included, among others (i) testing management's process for developing the estimate of accrued research and development costs; (ii) evaluating the appropriateness of the methodology used by management to develop the estimate; (iii) evaluating the reasonableness of the factors related to management's assessment of progress towards completion of the research and development activities, invoicing to date under the contracts, and communication from the research institution or other companies of any actual costs incurred during the period that have not yet been invoiced by testing, on a sample basis, specific tasks and the associated cost incurred for services the Company has not yet been invoiced for or otherwise notified of the actual cost at December 31, 2025, and (iv) testing the completeness and accuracy of underlying data used by management.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
February 24, 2026

We have served as the Company's auditor since 2016.

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

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 165,596	$ 183,581
Short-term investments	248,478	60,046
Accounts receivable, net	15,594	41,724
Inventory	54,895	26,364
Prepaid expenses and other current assets	42,614	20,084
Total current assets	527,177	331,799
Property and equipment, net	1,943	662
Operating lease right-of-use assets	9,807	10,376
Other long-term assets	11,307	10,315
Intangible asset, net	15,250	16,250
Deferred tax assets	198,149	211,151
Total assets	$ 763,633	$ 580,553
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 2,028	$ 2,039
Accrued collaboration expenses	70,015	48,157
Accrued expenses	42,020	32,355
Operating lease liabilities	2,987	1,993
Other current liabilities	22,134	16,077
Total current liabilities	139,184	100,621
Non-current liabilities:		
Non-current deferred revenue	31,811	31,811
Non-current operating lease liabilities	6,510	7,862
Other long-term liabilities	18,522	1,823
Total liabilities	196,027	142,117
Commitments and contingencies (Note 16)		
Shareholders' equity:		
Class A ordinary shares, par value of $0.000273235 per share; 45,659,424 shares and 41,881,319 shares issued and outstanding as of December 31, 2025 and 2024, respectively	12	11
Class B ordinary shares, par value of $0.000273235 per share; 1,795,158 shares issued and outstanding as of December 31, 2025 and 2024	1	1
Class A1 ordinary shares, $0.000273235 par value; 12,781,964 shares issued and outstanding as of December 31, 2025 and 2024	4	4
Class B1 ordinary shares, $0.000273235 par value; 16,057,618 shares issued and outstanding as of December 31, 2025 and 2024	4	4
Additional paid-in capital	1,029,748	959,722
Accumulated other comprehensive loss	(25)	(163)
Accumulated deficit	(462,138)	(521,143)
Total shareholders' equity	567,606	438,436
Total liabilities and shareholders' equity	$ 763,633	$ 580,553

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

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

	Years Ended December 31,		
	2025	2024	2023
Revenue:			
Product revenue, net	$ 677,564	$ 417,029	$ 233,176
License and collaboration revenue	—	6,210	37,083
Total revenue	677,564	423,239	270,259
Operating expenses:			
Cost of goods sold	77,673	60,910	33,407
Collaboration expenses	229,545	128,311	56,524
Research and development	96,853	111,623	76,097
Selling, general and administrative	196,272	168,011	129,427
Total operating expenses	600,343	468,855	295,455
Income (loss) from operations	77,221	(45,616)	(25,196)
Other income, net	11,647	9,464	8,544
Income (loss) before income taxes	88,868	(36,152)	(16,652)
Benefit (provision) for income taxes	(29,863)	(7,041)	30,736
Net income (loss)	$ 59,005	$ (43,193)	$ 14,084
Net income (loss) per share attributable to ordinary shareholders—basic	$ 0.80	$ (0.60)	$ 0.20
Net income (loss) per share attributable to ordinary shareholders—diluted	$ 0.75	$ (0.60)	$ 0.20
Weighted average ordinary shares outstanding—basic	74,200,924	71,424,159	70,058,952
Weighted average ordinary shares outstanding—diluted	78,979,030	71,424,159	71,922,915
Comprehensive income (loss):			
Net income (loss)	$ 59,005	$ (43,193)	$ 14,084
Other comprehensive income (loss):			
Unrealized gain (loss) on short-term investments and currency translation adjustments, net of tax	138	(169)	(38)
Total other comprehensive income (loss)	138	(169)	(38)
Total comprehensive income (loss)	$ 59,143	$ (43,362)	$ 14,046

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

KINIKSA PHARMACEUTICALS INTERNATIONAL, PLC
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(In thousands, except share amounts)

	Ordinary Shares (Class A, B, A1 and B1)		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
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 and employee share purchase plan	763,114	1	1,494	—	—	1,495
Share-based compensation expense	—	—	27,149	—	—	27,149
Unrealized loss on short-term investments and currency translation adjustments	—	—	—	(38)	—	(38)
Net income	—	—	—	—	14,084	14,084
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 and employee share purchase plan	2,055,442	—	12,266	—	—	12,266
Share-based compensation expense	—	—	30,693	—	—	30,693
Unrealized loss on short-term investments and currency translation adjustments	—	—	—	(169)	—	(169)
Net loss	—	—	—	—	(43,193)	(43,193)
Balances at December 31, 2024	72,516,059	$ 20	$ 959,722	$ (163)	$ (521,143)	$ 438,436
Issuance of Class A ordinary shares under incentive award plans and employee share purchase plan	3,778,105	1	33,023	—	—	33,024
Share-based compensation expense	—	—	37,003	—	—	37,003
Unrealized gain on short-term investments and currency translation adjustments	—	—	—	138	—	138
Net income	—	—	—	—	59,005	59,005
Balances at December 31, 2025	76,294,164	$ 21	$ 1,029,748	$ (25)	$ (462,138)	$ 567,606

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

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

	Years Ended December 31,		
	2025	**2024**	**2023**
Cash flows from operating activities:			
Net income (loss)	$ 59,005	$ (43,193)	$ 14,084
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation and amortization expense	1,554	1,695	2,341
Share-based compensation expense	37,003	30,693	27,149
Non-cash lease expense	3,666	3,136	3,054
Net amortization (accretion) of discounts on short-term investments	(916)	441	(1,068)
Net (gain) loss on disposal of property and equipment	(120)	(24)	179
Deferred income taxes	13,002	8,132	(33,788)
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(22,481)	(2,710)	(7,067)
Accounts receivable, net	26,130	(20,458)	(8,606)
Inventory	(28,531)	4,758	(9,523)
Contract asset	—	—	7,656
Other long-term assets	(1,210)	(9,735)	4,584
Accounts payable	142	(6,306)	347
Accrued expenses, accrued collaboration expenses and other current liabilities	37,497	43,729	16,940
Operating lease liabilities	(3,455)	(3,984)	(3,261)
Deferred revenue	—	19,550	261
Other long-term liabilities	16,699	(35)	19
Net cash provided by operating activities	137,985	25,689	13,301
Cash flows from investing activities:			
Proceeds from sale of property and equipment	—	25	—
Purchases of property and equipment	(1,568)	(277)	(130)
Purchases of short-term investments	(386,915)	(202,014)	(204,933)
Proceeds from the maturities of short-term investments	199,490	239,938	175,506
Net cash provided by (used in) investing activities	(188,993)	37,672	(29,557)
Cash flows from financing activities:			
Proceeds from issuance of Class A ordinary shares under incentive award plans and employee share purchase plan	40,753	17,250	3,701
Payments in connection with ordinary stock tendered for employee tax obligations	(7,730)	(4,984)	(2,206)
Net cash provided by financing activities	33,023	12,266	1,495
Net increase (decrease) in cash and cash equivalents	(17,985)	75,627	(14,761)
Cash and cash equivalents at beginning of period	183,581	107,954	122,715
Cash and cash equivalents at end of period	$ 165,596	$ 183,581	$ 107,954
Supplemental information:			
Cash paid for income taxes, net	$ 3,012	$ 2,003	$ 5,605
Supplemental disclosure of non-cash investing and financing activities:			
Change in right-of-use asset as a result of new, modified, and terminated leases	$ 3,097	$ 1,581	$ 9,600
Additions to property and equipment included in accrued expenses and other liabilities	$ 83	$ 153	$ 54

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

1. Nature of the Business and Basis of Presentation

Kiniksa Pharmaceuticals International, plc (the "Company" or "Kiniksa International") is a biopharmaceutical company developing and commercializing novel therapies for diseases with unmet need, with a focus on cardiovascular indications. 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 Bermuda and from and after the Redomiciliation, to Kiniksa International. In addition, references to "ordinary shares" prior to the Redomiciliation are to Kiniksa Bermuda's common shares and from and after the Redomiciliation are to Kiniksa International's ordinary shares. The Company subsequently liquidated Kiniksa Bermuda in November 2025, completing the Redomiciliation.

The Company is subject to risks common to companies in the biopharmaceuticals industry including, but not limited to, commercialization of existing and new products, conducting clinical research and development, its current and future products and product candidates, risks from existing or new competition, protection of proprietary intellectual and other technology and compliance with United States and foreign regulations and approval requirements.

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 purposes. 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") and Kiniksa Pharmaceuticals (UK), Ltd. ("Kiniksa UK") as well as the subsidiary of Kiniksa US, Primatope Therapeutics, Inc. ("Primatope") and subsidiaries of Kiniksa UK, Kiniksa Pharmaceuticals, GmbH ("Kiniksa Switzerland"), Kiniksa Pharmaceuticals (Germany) GmbH ("Kiniksa Germany") and Kiniksa Pharmaceuticals (France) SARL ("Kiniksa France"), after elimination of all significant intercompany accounts and transactions. Where the Kiniksa Pharmaceuticals International, plc entity is referred to in its single, unconsolidated form, it is referred to as "Kiniksa 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 loss or cash flows. A reclassification has been made to Note 9 *Accrued Expenses* for fiscal year ended December 31, 2024, to reclassify the accrued inventory and manufacturing 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, uncertain tax positions, and the valuation of the Company's 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.

Reporting and Functional Currency

The financial results of the Company's global activities are reported in United States dollars ("USD") and its foreign subsidiaries other than Kiniksa UK and Kiniksa Switzerland generally utilize their respective local currency to be their functional currency.

Transactions in other currencies are recorded in the functional currency at the rate of exchange prevailing when the transactions occur. Monetary assets and liabilities denominated in other currencies are re-measured into the functional currency at the rate of exchange in effect at the balance sheet date. Exchange rate gains and losses arising from re-measurement of foreign currency-denominated monetary assets and liabilities are included in income or losses in the period in which they occur.

For the Company's foreign subsidiaries where the local currency is the functional currency, assets and liabilities denominated in local currencies are translated into USD at end-of-period exchange rates and the resulting translation adjustments are reported as a component of accumulated other comprehensive income (loss) within shareholders' equity.

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 December 31, 2025, the Company had an accumulated deficit of $462,138. During the year ended December 31, 2025, the Company recorded a net income of $59,005 and provided $137,985 of cash from operating activities. As of December 31, 2025, the Company had cash, cash equivalents and short-term investments of $414,074.

Based on its current operating plan, the Company expects that its cash, cash equivalents and short-term investments combined with cash anticipated to be generated from sales of ARCALYST 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.

2. Summary of Significant Accounting Policies

Cash and Cash Equivalents

The Company classifies deposits in banks, money market funds and cash invested temporarily in various instruments with maturities of three months or less at the time of purchase as cash and cash equivalents. As of December

31, 2025 and 2024 cash and cash equivalents consisted principally of amounts held in money market accounts and cash on deposit at commercial banks.

Short-Term Investments

The Company generally invests its excess cash in money market funds and short-term investments in U.S. Treasury securities. The Company has classified its investments with maturities beyond one year as short-term, based on their highly liquid nature and because such marketable securities represent the investment of cash that is available for current operations. Such investments which are included in short-term investments on the Company's consolidated balance sheets are considered available-for-sale ("AFS") debt securities and are reported at fair value with unrealized gains and losses recognized in accumulated other comprehensive income (loss) in shareholders' equity, net of related tax effects. Realized gains and losses, if any, on short-term investments are included in interest income.

If the AFS debt security's fair value declines below its amortized cost the Company considers all available evidence to evaluate the extent to which the decline is due to credit-related factors or noncredit-related factors. If the decline is due to noncredit-related factors then no credit loss is recorded and the unrealized loss is recognized in accumulated other comprehensive income (loss) in shareholders' equity, net of the related tax effects. If the decline is considered to be a credit-related impairment, it is recognized as an allowance on the consolidated balance sheet with a corresponding charge to the consolidated statement of operations and comprehensive income (loss). The credit allowance is limited to the difference between the fair value and the amortized cost basis. No credit-related allowances or impairments have been recognized on the Company's investments in available-for-sale debt securities.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and short-term investments. As of December 31, 2025 and 2024, substantially all of the Company's cash, cash equivalents and short-term investments were held at two financial institutions. The Company generally maintains balances in various operating accounts at financial institutions that management believes to be of high credit quality, in amounts that may exceed federally insured limits. The Company has not experienced any losses related to its cash, cash equivalents and short-term investments and does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company is also subject to credit risk from the accounts receivable related to product revenue. The majority of trade accounts receivable are recorded net of allowances for cash discounts associated with prompt payments from customers. All trade accounts receivable arise from product revenue in the United States due from the Company's third party logistics provider. There were no material write-offs charged against the allowance for the year ended December 31, 2025.

Fair Value Measurements

Certain assets and liabilities of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. 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 Company's cash equivalents and short-term investments, consisting of money market accounts and U.S. Treasury securities, are carried at fair value, determined based on Level 1 and 2 inputs in the fair value hierarchy described above (see Note 3). The carrying values of the Company's prepaid expenses and other current assets, accounts receivable, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a "lease" as defined by ASC 842. A lease is an arrangement, or part of an arrangement, that conveys the right to control the use of identified property, plant, or equipment (an identified asset) for a period of time in exchange for consideration. The Company determines if the arrangement conveys the right to control the use of an identified asset for a period of time. It assesses throughout the period of use whether the Company has both of the following (1) the right to obtain substantially all of the economic benefits from use of the identified asset and (2) the right to direct the use of the identified asset. This determination is reassessed if the terms of the arrangement are changed. Leases are classified as operating or finance leases based on the terms of the lease agreement and certain characteristics of the identified asset. Right-of-use ("ROU") assets and lease liabilities are recognized at lease commencement date based on the present value of the minimum future lease payments.

Leases with a term greater than one year are recognized on the balance sheet as ROU assets with corresponding lease liabilities and, if applicable, long-term lease liabilities. The Company has elected not to recognize leases with a term of one year or less on its balance sheet. The Company recognizes lease expense for these leases on a straight-line basis over the lease term. Operating leases, ROU assets and their corresponding lease liabilities are recorded based on the present value of lease payments over the expected remaining lease term. However, certain adjustments to the ROU assets may be required for items such as incentives received. The interest rate implicit in lease arrangements is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

In accordance with the guidance in ASU 2016-02, components of a lease should be split into three categories: lease components (e.g., land, building, etc.), non-lease components (e.g., common area maintenance, consumables, etc.), and non-components (e.g., property taxes, insurance, etc.); then the fixed and in-substance fixed contract consideration (including any related to non-components) must be allocated based on fair values to the lease components and non-lease components.

The Company has elected to account for the lease and non-lease components of each of its operating leases as a single lease component and allocate all of the arrangement consideration to the lease component only. The lease component results in an operating ROU asset being recorded on the balance sheet and amortized on a straight-line basis as lease expense.

Property and Equipment

Property and equipment are recorded at cost and depreciated over the estimated useful lives of the related assets using the straight-line method. Maintenance and repairs are charged to expense as incurred. When assets are retired or otherwise disposed of, the cost of these assets and related accumulated depreciation or amortization are eliminated from the consolidated balance sheet and any resulting gains or losses are included in the consolidated statement of operations and comprehensive income (loss) in the period of disposal. The expected useful lives of the respective assets are as follows:

	Estimated Useful Life
Computer hardware and software	3 - 5 years
Laboratory equipment	5 years
Furniture, fixtures and vehicles	5 - 7 years
Leasehold improvements	Shorter of estimated useful life or lease term

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 the Company's 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 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 write-down 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 the Company's patient assistance program are recognized as selling expenses 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 Samsung Biologics Co., Ltd. ("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 years ended December 31, 2025, 2024 and 2023 the Company incurred $11,704, $15,849 and $3,265, respectively, of expense related to the technology transfer of ARCALYST drug substance manufacturing in cost of goods sold.

Revenue Recognition

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

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

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

Product Revenue, Net

Following the FDA approval of ARCALYST in March 2021, the Company began generating product revenue from sales of ARCALYST. ARCALYST is sold through a third party logistics provider that distributes primarily through a network of authorized specialty pharmacies and specialty distributors ("customer"), which deliver the medication to patients by mail. The Company's payment terms are between 30 to 35 days.

Net revenue from product sales is recognized at the transaction price when the specialty pharmacy or specialty distributors obtains control of the Company's products, which occurs at a point in time, typically upon shipment of the product from the third party logistics provider.

The Company's 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.

Discounts and Allowances

Revenue from product sales is recorded at the transaction price, which includes estimates for discounts and allowances and includes cash discounts, chargebacks, rebates, returns, copay assistance, and specialty pharmacy and distributor fees. These reserves are classified as reductions of accounts receivable (if the amount is payable to the Customer and right of offset exists) or a current liability (if the right of offset does not exist, the amount is payable to a third party, or is related to a future return). These allowances are established by management as its best estimate based on historical experience and data points available and are adjusted to reflect known changes in the factors that impact such reserves. Allowances for customer credits, chargebacks, rebates, data fees for services, returns, and discounts are

established based on contractual terms with customers and analyses of historical usage of these items. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known. The nature of the allowances and accruals requiring estimates, and the specific considerations the Company uses in estimating these amounts are as follows:

Government Chargebacks and Rebates

Government and other rebates and chargebacks include amounts payable to payors and healthcare professionals under various programs and by payor and individual payor plans. Rebates and chargebacks are based on contractual arrangements or statutory requirements which may vary by product, payor and individual payor plans. For qualified programs that can purchase products through wholesalers or other distributors at a lower contractual price, the wholesalers or distributors charge back to the Company the difference between their acquisition cost and the lower contractual price.

Rebates and chargebacks are estimated primarily based on product sales, and expected payor mix and discount rates, which require significant estimates and judgment. Additionally, in developing the estimates the Company considers: historical and estimated payor mix; statutory discount requirements and contractual terms; historical claims experience and processing time lags; estimated patient population; known market events or trends; market research; channel inventory data obtained from customers; and other pertinent internal or external information. The Company assesses and updates the estimates every quarter to reflect actual claims and other current information.

Government and other chargebacks are recognized as reduction of revenue upon the sale to the Customers. These items are payable to customers and other rebates that are payable to other third party payors are classified as accrued expense liabilities.

Cash Discounts

The Company estimates cash discounts based on contractual terms and expectations regarding future customer payment patterns.

Specialty Pharmacy & Distributor Fees

Under the inventory management agreements with specialty pharmacies and distributors, the Company pays a fee primarily for compliance with certain contractually determined covenants such as the maintenance of agreed upon inventory levels. These specialty pharmacy and distributor fees are based on a contractually determined fixed percentage of sales.

The Company has contracted with certain specialty pharmacies to obtain transactional data related to the products in order to develop a better understanding of the selling channel as well as patient activity and utilization by the Medicaid program and other government agencies and managed care organizations. The Company pays a variable fee to the specialty pharmacies to provide the data. The Company also pays the specialty pharmacies a fee in exchange for providing distribution and inventory management services, including the provision of inventory management data to the Company. The Company estimates the fee for service accruals and allowances based on sales to each specialty pharmacy and the applicable contracted rate.

Sales Returns

Allowances are made for estimated sales returns by the customers and are recorded in the period the related revenue is recognized. The Company typically permit returns if the product is out of date or damaged during transition to

the common carrier. The Company's estimates of sales returns are based primarily on the Company's historical return rate. The Company also takes into consideration known or expected changes in the marketplace specific to ARCALYST.

Shipping and Handling

Shipping and handling activities are considered to be fulfillment activities and not considered to be a separate performance obligation.

Other Incentives

Other incentives include a co-pay assistance program for eligible patients with commercial insurance in the United States. The co-pay assistance programs assist certain commercially insured patients by reducing each participating patient's financial responsibility for the purchase price, up to a specified dollar amount of assistance.

Collaboration Expenses

Collaboration expenses consist of Regeneron's share of the profit related to ARCALYST sales under the license agreement (the "Regeneron Agreement") with Regeneron (see Note 13) and the cost of products sold under collaboration agreements. The Company also evenly splits with Regeneron any proceeds received by the Company from any licensees, sublicensees and distributors in consideration for the sale, license or other disposition of rights with respect to ARCALYST, including upfront payments, milestone payments and royalties.

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.

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

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

Key assumptions to determine the standalone selling price may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

The Company recognize revenue associated with each performance obligation as the control over the promised goods or services transfer to the Company's collaboration partner which occurs either at a point in time or over time. If control transfers over time, revenue is recognized by using a method of measuring progress that best depicts the transfer of goods or services. The Company evaluates the measure of progress and related inputs each reporting period and any resulting adjustments to revenue are recorded on a cumulative catch-up basis.

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

Intangible Assets

Upon FDA approval and commercial launch of ARCALYST in March 2021, the Company capitalized the $20,000 milestone payment to Regeneron for a specified regulatory milestone as a finite-lived intangible asset (see Note 13). The intangible asset is amortized on a straight-line basis over the life of the underlying intellectual property of 20 years. Amortization expense is recorded as cost of goods sold in the Company's consolidated statement of operations and comprehensive income (loss).

Impairment of Long-Lived Assets

The Company assesses the impairment of long-lived assets, including intangible assets and property and equipment, whenever events or changes in business circumstances indicate that the carrying amounts of the assets may not be fully recoverable. When such events occur, the Company determines whether there has been an impairment in value by comparing the asset's carrying value with the anticipated undiscounted net cash flows of the asset. If an impairment in value exists, the asset is written down to its estimated fair value. The Company has not recognized any impairment losses through December 31, 2025 and there have been no events that triggered an impairment analysis.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred to discover, research and develop drug candidates, including personnel expenses, share-based compensation expense, allocated facility-related and depreciation expenses, third party license fees and external costs of outside vendors engaged to conduct preclinical and clinical development activities and clinical trials as well as to manufacture clinical trial materials. Non-refundable prepayments determined to be used within one year for goods or services that will be used or rendered for future research and development activities are recorded as prepaid expenses. Non-refundable prepayments or minimum balance requirements associated with clinical trials determined to not be used within one year are classified as other long-term assets. 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. Milestone and other payments made to third parties with respect to in-process research and development, in accordance with the Company's license, acquisition and other similar agreements are expensed when determined to be probable and estimable.

Research Contract Costs

The Company has entered into various research and development-related contracts with companies both inside and outside of the United States. The related costs are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research and development costs. When billing terms under these contracts do not coincide with the timing of when the work is performed, the Company is required to make estimates of outstanding obligations to those third parties as of the end of the reporting period. Any accrual estimates are based on a

number of factors, including the Company's assessment of the progress towards completion of the research and development activities, invoicing to date under the contracts, communication from the research institution or other companies of any actual costs incurred during the period that have not yet been invoiced, and the costs included in the contracts. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ materially from the Company's estimates.

Patent Costs

The Company charges patent-related costs in connection with filing and prosecuting patent applications to operations as incurred as their realization is uncertain. These costs are classified as selling, general and administrative expenses.

Selling, General and Administrative Expense

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.

Advertising costs are expensed as incurred. For the years ended December 31, 2025, 2024 and 2023, advertising costs totaled $12,061, $11,433 and $9,066, respectively.

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, the Company determines 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, the Company records a cumulative expense catch-up, with remaining expense amortized over the remaining service period. Throughout the performance period, the Company re-assesses the estimated performance and updates the number of performance-based awards that the Company believes 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 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 (see Note 11). Prior to May 2018, the Company was a private company and, accordingly, lacked company-specific historical and implied volatility information for its shares. Therefore, it estimated its expected share price volatility based on the historical volatility of the Company and historical volatility of publicly traded peer companies until such time as it had 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 expected term of options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the United States 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. Expected dividend yield is based on the fact that the Company has never paid cash dividends on ordinary shares and does not expect to pay any cash dividends in the foreseeable future.

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 valuation model. 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.

Comprehensive Income (Loss)

Comprehensive income (loss) includes net income (loss) as well as other changes in shareholders' equity that result from transactions and economic events other than those with shareholders. For the years ended December 31, 2025, 2024 and 2023 the Company's other comprehensive income (loss) was comprised of unrealized gain (loss) on short-term investments and currency translation adjustments, net of tax.

Net Income (Loss) per Share

Basic net income (loss) per share attributable to ordinary shareholders is computed by dividing the net income (loss) attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding for the period. Diluted net income (loss) attributable to ordinary shareholders is computed by adjusting net income (loss) attributable to ordinary shareholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net income (loss) per share attributable to ordinary shareholders is computed based on the treasury method by dividing the diluted net income (loss) attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding for the period, including potential dilutive ordinary shares. For purpose of this calculation, outstanding share options, unvested restricted share units and unvested performance-based share units for which the market or performance condition has been met as of the date of determination, are considered potential dilutive ordinary shares.

In periods in which the Company reports a net loss attributable to ordinary shareholders, diluted net loss per share attributable to ordinary shareholders is the same as basic net loss per share attributable to ordinary shareholders, since dilutive ordinary shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to ordinary shareholders for the year ended December 31, 2024.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the (provision) benefit for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weighting of the positive and negative available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected, cumulative recent earnings and considering prudent and feasible tax planning strategies.

Prior to the Redomiciliation, the Company 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 previous 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 the reporting 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 United States 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 for the period of time prior to its liquidation in November 2025. The Company's wholly owned subsidiary Kiniksa UK, and Kiniksa UK's wholly owned subsidiaries, Kiniksa Switzerland, Kiniksa Germany, and Kiniksa France are subject to taxation in their respective countries. Certain of the Company's subsidiaries operate under cost plus intercompany arrangements.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued Accounting Standards Update ("ASU") 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, requiring public entities to disclose additional information about specific expense categories in the notes to the financial statements on an interim and annual basis. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and for interim periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2024-03 on its consolidated financial statements.

In September 2025, the FASB issued ASU 2025-06, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software*. ASU 2025-06 modernizes and simplifies the accounting for software development costs by establishing a single capitalization framework for all internally developed or acquired software, regardless of whether the software is intended for internal use, to be sold, or to be used in delivering products and services. The new guidance retains the concept of project stages but eliminates the historical distinction between internal-use software and software to be sold or marketed. ASU 2025-06 is effective for fiscal years beginning after December 15, 2027, including interim periods within those fiscal years, with early adoption permitted. The guidance is required to be applied prospectively, with optional retrospective or modified retrospective transition methods. The Company is currently evaluating the impact of ASU 2025-06 on its consolidated financial statements.

Recently adopted accounting pronouncements

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): 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 Company prospectively adopted ASU 2023-09 during the year ended December 31, 2025. See Note 14 *Income Taxes* in the accompanying notes to the consolidated financial statements for further detail.

(Amounts in thousands, except share and per share amounts)

3. Fair Value of Financial Assets and Liabilities

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 December 31, 2025 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents — money market funds	$ 77,291	$ —	$ —	$ 77,291
Short-term investments — U.S. Treasury Securities	—	248,478	—	248,478
Total	$ 77,291	$ 248,478	$ —	$ 325,769

	Fair Value Measurements as of December 31, 2024 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents — money market funds	$ 135,275	$ —	$ —	$ 135,275
Short-term investments — U.S. Treasury Securities	—	60,046	—	60,046
Total	$ 135,275	$ 60,046	$ —	$ 195,321

During the years ended December 31, 2025 and 2024 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 December 31, 2025 and 2024 included United States Treasury securities, which are not traded on a daily basis and, therefore, represent a Level 2 measurement in the fair value hierarchy at each period end.

The contractual maturities of short-term investments were as follows:

	December 31, 2025	December 31, 2024
Maturities within one year	$ 179,577	$ 60,046
Maturities after one year through five years	68,901	—
Total	$ 248,478	$ 60,046

(Amounts in thousands, except share and per share amounts)

The following tables summarize short-term investments:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Credit Losses	Fair Value
December 31, 2025					
Short-term investments — U.S. Treasury Securities	$ 248,354	$ 125	$ (1)	$ —	$ 248,478
Total	$ 248,354	$ 125	$ (1)	$ —	$ 248,478

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Credit Losses	Fair Value
December 31, 2024					
Short-term investments — U.S. Treasury Securities	$ 60,022	$ 24	$ —	$ —	$ 60,046
Total	$ 60,022	$ 24	$ —	$ —	$ 60,046

As of December 31, 2025 and 2024 the Company considers the unrealized losses in their investment portfolio to be temporary in nature and not due to credit losses. The Company has the ability to hold such investments until recovery of the fair value. The Company utilizes the specific identification method in computing realized gains and losses. The Company had no realized gains and losses on their available-for-sale securities for the years ended December 31, 2025 or 2024.

4. Product Revenue, Net

ARCALYST

The Company derives substantially all of its product revenue, net from sales of ARCALYST in the United States, which was as follows:

	Years Ended December 31,		
	2025	2024	2023
Product Revenue, net	$ 677,564	$ 417,029	$ 233,176

(Amounts in thousands, except share and per share amounts)

The following tables summarizes balances and activity in each of the product revenue allowance and reserve categories for the years ended December 31, 2025 and 2024:

	Contractual Adjustments	Government Rebates	Returns	Total
Balance at December 31, 2024	$ 3,495	$ 8,640	$ 2,294	$ 14,429
Current provisions relating to sales in the current year	36,209	26,882	1,704	64,795
Adjustments relating to prior years	—	(2,306)	(718)	(3,024)
Payments/returns relating to sales in the current year	(31,650)	(15,995)	—	(47,645)
Payments/returns relating to sales in the prior years	(3,495)	(5,338)	(156)	(8,989)
Balance at December 31, 2025	$ 4,559	$ 11,883	$ 3,124	$ 19,566

	Contractual Adjustments	Government Rebates	Returns	Total
Balance at December 31, 2023	$ 2,022	$ 3,775	$ 341	$ 6,138
Current provisions relating to sales in the current year	24,738	18,436	1,296	44,470
Adjustments relating to prior years	(31)	(155)	836	650
Payments/returns relating to sales in the current year	(21,277)	(9,796)	—	(31,073)
Payments/returns relating to sales in the prior years	(1,957)	(3,620)	(179)	(5,756)
Balance at December 31, 2024	$ 3,495	$ 8,640	$ 2,294	$ 14,429

Total revenue-related reserves as of December 31, 2025 and 2024, included in the Company's consolidated balance sheets, are summarized as follows:

	December 31, 2025	December 31, 2024
Reduction of accounts receivable	$ (831)	$ (444)
Components of other current liabilities	20,397	14,873
Total revenue-related reserves	$ 19,566	$ 14,429

(Amounts in thousands, except share and per share amounts)

5. Inventory

Inventory consisted of the following:

	December 31, 2025	December 31, 2024
Raw materials	$ 9,968	$ 9,972
Semi-finished goods	29,399	—
Finished goods	20,555	21,246
Total inventory	$ 59,922	$ 31,218
Balance Sheet Classification:		
Inventory	$ 54,895	$ 26,364
Other long-term assets	5,027	4,854
Total inventory	$ 59,922	$ 31,218

As of December 31, 2025, $20,883 of semi-finished goods were associated with the Company's technology transfer of ARCALYST drug substance manufacturing to a new facility, which is pending regulatory approval. The Company believes it is probable that regulatory approval will be obtained, and all such inventory will be available for commercial distribution in the future.

6. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31, 2025	December 31, 2024
Furniture, fixtures and vehicles	$ 177	$ 183
Computer hardware and software	96	379
Leasehold improvements	4,639	3,931
Lab equipment	4,006	4,207
Construction in progress	255	155
Total property and equipment	9,173	8,855
Less: Accumulated depreciation	(7,230)	(8,193)
Total property and equipment, net	$ 1,943	$ 662

Depreciation expense for the years ended December 31, 2025, 2024 and 2023 was $196, $448 and $1,109, respectively.

(Amounts in thousands, except share and per share amounts)

7. Leases

The Company leases office, laboratory space and vehicles under operating leases. In May 2023, the Company entered into a lease amendment to extend the term of the Lexington, Massachusetts headquarters lease by forty-eight months to August 31, 2028. The Company accounted for the lease amendment as a modification and recorded increases in the right-of-use-assets and lease liability of $8,515.

The components of lease cost for the year ended December 31, 2025, 2024 and 2023 are as follows:

	Years Ended December 31,		
	2025	2024	2023
Operating lease cost	$ 4,377	$ 3,875	$ 3,749
Variable lease cost	894	708	1,023
Short-term lease cost	15	153	-
Total lease cost	$ 5,286	$ 4,736	$ 4,772

Variable lease costs primarily related to operating expense, taxes and insurance associated with the Company's operating leases. As these costs are generally variable in nature, they are not included in the measurement of the operating lease asset and related lease liability.

	December 31, 2025
Weighted-average remaining lease term (years)	2.66
Weighted-average discount rate	6.98%

Maturities of operating leases liabilities were as follows:

As of December 31,	
2026	$ 3,480
2027	4,164
2028	2,563
2029	193
2030	80
Thereafter	—
Total future minimum lease payments	$ 10,480
Less imputed interest	(983)
Present value of lease liabilities	$ 9,497

(Amounts in thousands, except share and per share amounts)

8. Intangible Assets

Intangible assets, net of accumulated amortization, impairment charges and adjustments are summarized in the following table.

		As of December 31, 2025			As of December 31, 2024		
	Estimated life	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Regulatory milestone	20 years	$ 20,000	$ 4,750	$ 15,250	$ 20,000	$ 3,750	$ 16,250
Total		$ 20,000	$ 4,750	$ 15,250	$ 20,000	$ 3,750	$ 16,250

As of December 31, 2025 future amortization of intangible assets are as follows:

For the years ended December 31,	
2026	$ 1,000
2027	1,000
2028	1,000
2029	1,000
2030	1,000
Thereafter	10,250
Total	$ 15,250

9. Accrued Expenses

Accrued expenses consisted of the following:

	December 31, 2025	December 31, 2024
Accrued employee compensation and benefits	$ 21,437	$ 17,046
Accrued inventory and manufacturing	8,008	4,123
Accrued research and development expenses	6,629	6,881
Accrued legal, commercial and professional fees	5,348	3,617
Other	598	688
Total accrued expenses	$ 42,020	$ 32,355

10. Ordinary Shares

The rights of the holders of the Company's Class A ordinary shares, Class B ordinary shares, Class A1 ordinary shares and Class B1 ordinary shares are identical, except with respect to voting, transferability and conversion, as described below. The Company has authorized 200,000,000 shares, at a nominal value of $0.000273235 as of December 31, 2025 and 2024.

Voting

Each Class A ordinary share entitles the holder to one vote on all matters submitted to the shareholders for a vote. Each Class B ordinary share entitles the holder to ten votes on all matters submitted to the shareholders for a vote. The holders of Class A and Class B ordinary shares, voting together as a single class, are entitled to elect the directors of the Company. Holders of Class A1 ordinary shares and Class B1 ordinary shares have no voting rights.

Dividends

The Company's ordinary shareholders are entitled to receive dividends, as may be declared by the Company's board of directors. Through December 31, 2025, no cash dividends have been declared or paid.

Conversion

Each Class B ordinary share automatically converts into one Class A ordinary share upon certain transfers of such shares by the holder thereof (subject to certain exceptions). Each Class B ordinary share is convertible, at the holder's election into one Class A ordinary share or one Class B1 ordinary share. Each Class A1 ordinary share is convertible into one Class A ordinary share at the holder's election (subject to certain exceptions). Each Class B1 ordinary share automatically converts into one Class A ordinary share upon certain transfers of such shares by the holder thereof (subject to certain exceptions). Each Class B1 ordinary share is convertible into one Class A ordinary share or one Class B ordinary share at the holder's election (subject to certain exceptions). There are no conversion rights associated with the Class A ordinary shares.

Kiniksa Bermuda Shares

In connection with the Redomiciliation, Kiniksa Bermuda was issued with one ordinary share with a nominal value of £0.01 per share (the "KNSA Bermuda Ordinary Share") and 50,000 redeemable preference shares with a nominal value of £1.00 per share (the "KNSA Bermuda Preference Shares") in the capital of Kiniksa International in order to satisfy the initial authorized minimum capital requirements for an English public company which is currently prescribed as GBP£50,000. In the year ended December 31, 2025, (i) the KNSA Bermuda Ordinary Share was gifted to Kiniksa International for nil consideration; and (ii) the KNSA Bermuda Preference Shares were redeemed in order to remove Kiniksa Bermuda as a shareholder of Kiniksa International. The KNSA Bermuda Preference Shares have no rights to vote at any general meeting of Kiniksa International and have no right to receive any dividend. The rights and restrictions attaching to the Existing Preference Shares and KNSA Bermuda Ordinary Share are set out in the articles of association of Kiniksa International. As of December 31, 2025 there are no KNSA Bermuda Ordinary Shares or KNSA Bermuda Preference Shares in issue. In November 2025, Kiniksa Bermuda was liquidated as part of the completion of the Redomiciliation.

11. Share-Based Compensation

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, which include the 2018 Plan, the 2015 Plan, and the 2018 ESPP.

2018 Incentive Award Plan

In May 2018, the Company's board of directors and shareholders approved the 2018 Incentive Award Plan (the "2018 Plan"), which became effective on May 23, 2018. The 2018 Plan provides for the grant of incentive share options, nonqualified share options, share appreciation rights, restricted shares, dividend equivalents, restricted share units and other share- or cash- based awards. Upon the effectiveness of the 2018 Plan, the Company ceased granting awards under its 2015 Equity Incentive Plan (as amended, the "2015 Plan" together with the 2018 Plan, the "Plans").

A total of 4,466,500 Class A ordinary shares were initially reserved for issuance under the 2018 Plan. The number of Class A ordinary shares that may be issued under the 2018 Plan will automatically increase on each January 1, beginning in 2019 and continuing for each fiscal year until, and including, the fiscal year ending December 31, 2028, equal to the lesser of (1) 4% of the Class A ordinary shares outstanding (on an as-converted basis) on the final day of the immediately preceding calendar year and (2) a smaller number of Class A ordinary shares

determined by the Company's board of directors. As of December 31, 2025, 5,621,352 shares remained available for future grant. On January 1, 2026, the Class A ordinary shares issuable pursuant to the 2018 Plan increased by 3,051,742 shares, equal to 4% of the as-converted Class A ordinary shares outstanding on December 31, 2025. The Class A ordinary shares underlying any awards issued under the 2018 Plan or the 2015 Plan that on or after the effective date of the 2018 Plan expire, lapse unexercised or are terminated, exchanged for cash, surrendered, repurchased, canceled without having been fully exercised, or forfeited under the 2018 Plan or the 2015 Plan will be added back to the Class A ordinary shares available for issuance under the 2018 Plan.

2015 Equity Incentive Plan

Until May 23, 2018 (the effective date of the 2018 Plan), the 2015 Plan provided for the Company to grant incentive share options, nonqualified share options, share grants and other share-based awards to employees and non-employees to purchase the Company's Class A ordinary shares. On the effective date of the 2018 Plan, the Company ceased granting awards under the 2015 Plan. At that time, the 4,691,213 Class A ordinary shares subject to outstanding awards under the 2015 Plan remained reserved for issuance under the plan pursuant to such awards and the 92,170 Class A ordinary shares that had been available for future grant under the 2015 Plan were no longer authorized and reserved for issuance or available for future grant under the 2015 Plan.

As of December 31, 2025, there were 618,561 Class A ordinary shares subject to outstanding awards under the 2015 Plan and reserved for issuance thereunder pursuant to such awards. The 2015 Plan continues to govern the terms and conditions of the outstanding awards granted under it. Class A ordinary shares subject to awards granted under the 2015 Plan that expire, lapse unexercised or are terminated, exchanged for cash, surrendered, repurchased, canceled without having been fully exercised, or forfeited become available for issuance under the 2018 Plan.

The exercise price for share options granted under the 2015 Plan was determined by the Company's board of directors. All incentive share options granted to any person possessing 10% or less of the total combined voting power of all classes of shares could not have an exercise price of less than 100% of the fair market value of the Class A ordinary shares on the grant date. All incentive share options granted to any person possessing more than 10% of the total combined voting power of all classes of shares could not have an exercise price of less than 110% of the fair market value of the Class A ordinary shares on the grant date. The option term for incentive share options could not be greater than 10 years. Incentive share options granted to persons possessing more than 10% of the total combined voting power of all classes of shares could not have an option term of greater than five years. The vesting period for equity-based awards was determined by the board of directors, which was generally four to six years. For awards granted to employees and non-employees with four year vesting terms, 25% of the option vests on the first anniversary of the grant date and the remaining shares vest equally each month for three years thereafter. For awards granted to employees with six year vesting terms, 16% of the option vests on the first anniversary of the grant date and the remaining shares vest based on a predetermined vesting schedule for five years thereafter.

2018 Employee Share Purchase Plan

In May 2018, the Company's board of directors and shareholders approved the 2018 Employee Share Purchase Plan (the "2018 ESPP"), which became effective on May 23, 2018. A total of 670,000 Class A ordinary shares were initially reserved for issuance under the 2018 ESPP. The number of Class A ordinary shares that may be issued under the 2018 ESPP automatically increases on each January 1, beginning in 2019 and continuing for each fiscal year until, and including, the fiscal year ending December 31, 2028, equal to the lesser of (1) 1% of the Class A ordinary shares outstanding (on an as-converted basis) on the final day of the immediately preceding calendar year and (2) a smaller number of Class A ordinary shares determined by the Company's board of directors, provided that no more than 6,420,000 Class A ordinary shares may be issued under the 2018 ESPP. In December 2025, the Company's board of directors approved an increase as of January 1, 2026 of 110,000 Class A ordinary shares. As of December 31, 2025, 690,063 Class A ordinary shares were available for future issuance under the 2018 ESPP.

(Amounts in thousands, except share and per share amounts)

Restricted Share Units

RSUs represent the right to receive shares of the Company's Class A ordinary shares upon vesting of the RSUs. The fair value of each RSU award is based on the closing price of the Company's Class A ordinary shares on the date of grant.

Starting March 2021, the Company granted RSUs with service conditions ("Time-Based RSUs") to eligible employees. 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.

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 performance of the members of the Nasdaq Biotechnology Index ("TSR PSUs"). The TSR PSUs and Revenue PSUs are subject to a three-year service period.

In addition, the Company from time-to-time grants performance-based restricted share units to certain eligible employees pursuant to the 2018 Plan that are earned based upon certain development and regulatory milestones ("Development PSUs" and, together with the Revenue PSUs and TSR PSUs, "PSUs"). The Company's currently outstanding Development PSUs are subject to earnout percentages based upon the date of applicable milestone achievement.

The following table summarizes RSU and PSU activity for the year ended December 31, 2025:

	RSUs		PSUs	
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2024	2,250,602	$ 17.36	59,137	$ 22.06
Granted	1,185,900	$ 28.42	437,925	$ 28.06
Vested	(771,693)	$ 16.30	—	$ —
Forfeited	(590,714)	$ 20.84	(81,755)	$ 27.51
Unvested RSUs as of December 31, 2025	2,074,095	$ 23.09	415,307	$ 27.25

RSUs granted in 2024 and 2023 had weighted average grant date fair values of $22.19 and $15.13, respectively. PSUs granted in 2024 had a weighted average grant date fair value of $22.06. No PSUs were granted in 2023.

The total grant date fair values of RSUs that vested during the years ended December 31, 2025, 2024, and 2023 totaled $12,576, $9,495 and $5,635, respectively. No PSUs vested during the years ended December 31, 2025, 2024 and 2023.

(Amounts in thousands, except share and per share amounts)

Share Options

The following table summarizes option activity for the year ended December 31, 2025:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2024	11,286,994	$ 15.25	6.49	$ 62,334
Granted	2,063,891	$ 28.58		
Exercised	(3,202,808)	$ 12.37		
Forfeited	(727,869)	$ 22.31		
Outstanding as of December 31, 2025	9,420,208	$ 18.61	6.48	$ 213,292
Share options exercisable as of December 31, 2025	6,164,885	$ 15.86	5.33	$ 156,516
Share options vested and expected to vest as of December 31, 2025	9,420,208	$ 18.61	6.48	$ 213,292

The aggregate intrinsic value of share options is calculated as the difference between the exercise price of the share options and the fair value of the Company's ordinary shares for those share options that had exercise prices lower than the fair value of the Company's ordinary shares.

The total intrinsic value of options exercised during the years ended December 31, 2025, 2024 and 2023, were $63,241, $19,235 and $2,595, respectively. The tax benefit arising on the exercise of stock options was $16,481 for the year ended December 31, 2025. The weighted-average grant-date fair value per share of share options granted during the years ended December 31, 2025, 2024 and 2023 was $17.61, $14.41 and $9.82, respectively.

Performance Share Options

Beginning in the second quarter of 2025, the Company began granting performance share options ("PSOs") to certain eligible employees pursuant to the 2018 Plan representing the right to purchase shares of the Company's Class A ordinary shares. Such PSOs vest, if at all, upon the achievement of certain specified development and regulatory milestones and are subject to earnout percentages based upon the date of applicable milestone achievement.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2024	—	$ —	—	$ —
Granted	394,815	$ 28.48		
Forfeited	(95,109)	$ 28.41		
Outstanding as of December 31, 2025	299,706	$ 28.50	9.37	$ 3,820

(Amounts in thousands, except share and per share amounts)

No PSOs were exercised during the years ended December 31, 2025, 2024 and 2023. The weighted-average grant-date fair value per share of PSOs granted during the years ended December 31, 2025 was $14.17. No PSOs were granted during the years ended December 31, 2024 and 2023.

Option Valuation

The assumptions that the Company used to determine the grant-date fair value of share options granted to employees and directors from the 2018 Plan during the years ended December 31, 2025, 2024 and 2023 were as follows, presented on a weighted-average basis:

	Years Ended December 31,		
	2025	2024	2023
Risk-free interest rate	3.07 %	4.07 %	3.96 %
Expected term (in years)	4.92	6.16	6.15
Expected volatility	50.09 %	68.29 %	71.33 %
Expected dividend yield	— %	— %	— %

During the years ended December 31, 2025, 2024 and 2023, the Company did not grant share options to non-employees.

As of December 31, 2025, total unrecognized compensation cost related to RSUs, Revenue PSUs, TSR PSUs, and share options was $90,372 which is expected to be recognized over a weighted average remaining period of 2.52 years. As of December 31, 2025, total unrecognized compensation cost related to outstanding Development PSUs and PSOs was $9,576 which will be recognized when the applicable milestones are deemed probable of achievement through the date the awards vests with a cumulative catch-up.

Share-Based Compensation

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

	Years Ended December 31,		
	2025	2024	2023
Cost of goods sold	$ 2,125	$ 1,623	$ 1,812
Research and development expenses	6,646	6,133	5,496
Selling, general and administrative expenses	28,232	22,937	19,841
Share-based compensation expense included in total operating expenses	$ 37,003	$ 30,693	$ 27,149

The tax benefit from share-based compensation recognized during the years ended December 31, 2025, 2024 and 2023, were $9,643, $7,976 and $7,433, respectively.

12. Out-Licensing Agreements

Genentech License Agreement

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

(each, a "Genentech Licensed Product"). The Genentech License Agreement became effective in September 2022 (the "Genentech Effective Date") following termination of the statutory waiting period under the Hart-Scott Rodino Act.

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 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 2024. In 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 $570,000 remain as of December 31, 2025. 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 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. In 2024, the Company fulfilled its responsibility under the Genentech License Agreement with respect to completing its Phase 2b clinical trial assessing the efficacy, safety and tolerability of vixarelimab in reducing pruritis in prurigo nodularis.

Under the Genentech License Agreement, Genentech has the right to assume manufacturing responsibilities for Genentech Licensed Products.

Absent early termination, the Genentech License Agreement will continue until there are no more royalty or other payment obligations owed to the Company. Genentech has the right to terminate the Genentech License Agreement at its discretion with prior written notice and either party may terminate the Genentech License Agreement in the event of an uncured material breach of the other party or in the case of insolvency of the other party. In addition, the Genentech License Agreement will terminate upon termination of the Biogen Agreement (as defined below).

The Company concluded that Genentech is a customer in this license agreement, and as such, the Genentech License Agreement falls within the scope of the revenue recognition guidance in ASC 606.

Accounting for Genentech License Agreement

As of the Genentech Effective Date, the Company identified the following material promises 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 also evaluated whether certain options outlined within the Genentech License Agreement represented material rights that would give rise to a performance obligation, including the option to purchase additional drug substance, and concluded that none of the options convey a material right to Genentech and therefore are not considered separate performance obligations within the Genentech License Agreement.

(Amounts in thousands, except share and per share amounts)

The Company assessed the above promises and determined that the exclusive license for vixarelimab is reflective of a vendor-customer relationship and therefore represents a performance obligation. The exclusive license for vixarelimab is considered functional intellectual property and distinct from other promises under the Genentech License Agreement as Genentech can benefit from the license on its own or together with other readily available resources and the license is separately identifiable from the other promises. The initial drug supply and drug product resupply are considered distinct from the exclusive license for vixarelimab as Genentech can benefit from such supply together with the license transferred by the Company at the inception of the Genentech License Agreement. The completion of the Phase 2b clinical trial is considered distinct from the exclusive license for vixarelimab as Genentech can benefit from the data generated by such trial together with such license. Therefore, each represents a separate performance obligation within a contract with a customer at contract inception.

The Company determined the transaction price at the inception of the Genentech License Agreement which consists of the $80,000 upfront payment. The Company determined that the $20,000 variable consideration related to the delivery of the initial drug supply and drug product resupply was no longer constrained during the fourth quarter of 2022, as the Company determined that it could assert it was not probable that a significant reversal in the amount of cumulative revenue recognized would occur. The Company met the milestone in 2023 and invoiced Genentech for the related $20,000 payment for the delivery of certain drug material. In 2023 and 2024, the Company added $25,000 and $5,000, respectively, to the transaction price following Genentech's achievement of development milestones under the Genentech License Agreement. The Company determined that all other variable considerations related to the future development and regulatory milestones, 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 also determined that it could not assert that it was not probable that a significant reversal in the amount of cumulative revenue recognized would occur. The Company also determined that royalties and sales milestones relate solely to the license of intellectual property. Revenue related to these royalties and sales milestones will only be recognized when the associated sales occur, and relevant thresholds are met, under the sales or usage-based royalty exception of Topic 606.

As noted above, the Company identified 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 ("SSP") with the objective of determining the price at which it would sell such an item if it were to be sold regularly on a standalone basis. The Company allocated the transaction price to each of the four performance obligations noted above.

Performance Obligation	Method of Recognition
Exclusive license for vixarelimab	Point in time; that is 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 no collaboration revenue during the year ended December 31, 2025. The Company recognized $5,261 and $37,083 of collaboration revenue during the years ended December 31, 2024 and 2023, respectively, under the Genentech License Agreement related to the license, completed portion of the Phase 2b clinical trial for vixarelimab, and materials delivered. As a result of the $5,000 in development milestones achieved by

Genentech, the Company recognized revenue of $4,989, during the year ended December 31, 2024, related to performance obligations satisfied in prior periods. The remaining revenue was recognized as a result of the completed portion of the Phase 2b clinical trial for vixarelimab. The Company completed its obligation for the Phase 2b clinical trial for vixarelimab during the year ended December 31, 2024. As such, the Company has recognized all revenue allocated to the completion of the Phase 2b clinical trial for vixarelimab performance obligation as of the end of the year ended December 31, 2024.

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 ARCALYST 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.

In April 2025, the Company and Huadong entered into a mutual termination agreement pursuant to which the parties agreed to terminate the mavrilimumab Huadong Collaboration Agreement and release all claims related thereto. The ARCALYST Huadong Collaboration Agreement remains in effect.

Under the Huadong Collaboration Agreements, the Company received a total upfront cash payment of $22,000, which included $12,000 for the Huadong Territory license of ARCALYST and $10,000 for the Huadong Territory license of mavrilimumab. In 2024, following the achievement of a regulatory milestone under the ARCALYST Huadong Collaboration Agreement, Huadong became obligated to make an additional cash payment of $20,000 to the Company. The Company will be eligible to receive up to approximately $50,000 in contingent sales-based milestone payments for ARCALYST, all of which remain as of December 31, 2025. Due to its termination, the Company does not expect to receive any future payments under the mavrilimumab Huadong Collaboration Agreement. Huadong will also be obligated to pay the Company tiered percentage royalties ranging from the low-to-mid teens on annual net sales of ARCALYST in the Huadong Territory, subject to certain reductions tied to ARCALYST manufacturing costs and certain other customary reductions, with an aggregate minimum floor. Royalties will be payable on ARCALYST on a country-by-country or region-by-region basis until the later of (i) 12 years after the first commercial sale of ARCALYST 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 ARCALYST in such country or region in the Huadong Territory, and (iii) the expiration of the last regulatory exclusivity for ARCALYST in such country or region in the Huadong Territory.

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

The Company will supply certain materials to support development and commercialization activities for ARCALYST.

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

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

Accounting for Mavrilimumab Huadong Collaboration Agreement

As of the Effective Date, the Company identified the following material promises 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 included an estimate of variable consideration associated with the clinical manufacturing supply of certain materials when those materials were shipped.

The Company recognized 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. Due to the termination of the mavrilimumab Huadong Collaboration Agreement in April 2025, the Company will not recognize any additional revenue from that agreement.

Accounting for ARCALYST Huadong Collaboration Agreement

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

The Company also evaluated whether certain options outlined within the ARCALYST Huadong Collaboration Agreement represented material rights that would give rise to a performance obligation and concluded that none of the

(Amounts in thousands, except share and per share amounts)

options convey a material right to Huadong and therefore are not considered separate performance obligations within the ARCALYST Huadong Collaboration Agreement.

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

The Company determined the transaction price at the inception of the ARCALYST Huadong Collaboration Agreement which includes $12,000, consisting of the upfront payment. In 2024 the Company added $20,000 to the transaction price following the achievement of a regulatory milestone. 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.

As noted above, the Company identified a single combined performance obligation in the ARCALYST Huadong Collaboration Agreement consisting of the exclusive license for ARCALYST and clinical and commercial manufacturing obligations for ARCALYST products in the Huadong Territory. The Company recognizes revenue for the combined performance obligation consisting of the exclusive license for ARCALYST and clinical and commercial manufacturing obligations for ARCALYST 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 ARCALYST Huadong Collaboration Agreement and may be reduced or increased based on changes in the various activities.

The Company has not recognized any revenue under the ARCALYST Huadong Collaboration Agreement for the years ended December 31, 2025 and 2023 as there were no deliveries of materials under the ARCALYST Huadong Collaboration Agreement. The Company recognized $189 of the transaction price in collaboration revenue during the year ended December 31, 2024, under the ARCALYST Huadong Collaboration Agreement related to materials delivered. As of December 31, 2025, $31,811 is recorded in non-current deferred revenue, based upon timing of anticipated future shipments.

The following tables summarizes the Company's contract assets and contract liabilities in connection with license and collaboration agreements for the years ended December 31, 2025 and 2024:

	Balance at Beginning of Period	Additions	Revenue Recognized	Reclassification	Balance at End of Period
Year ended December 31, 2025					
Contract Liabilities:					
Huadong ARCALYST	$ 31,811	$ —	$ —	$ —	$ 31,811

(Amounts in thousands, except share and per share amounts)

	Balance at Beginning of Period	Additions	Revenue Recognized	Reclassification	Balance at End of Period
Year ended December 31, 2024					
Contract Liabilities:					
Genentech vixarelimab	$ 261	$ 5,000	$ (5,261)	$ —	$ —
Huadong ARCALYST	12,000	20,000	(189)	—	31,811
Total Contract Liabilities	$ 12,261	$ 25,000	$ (5,450)	$ —	$ 31,811

13. 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 to the Company a non-exclusive, sublicensable, worldwide license to certain background patent rights related to the vixarelimab program. The Company is obligated to use commercially reasonable efforts to develop and commercialize such acquired products.

In exchange for these rights, the Company made an upfront payment to Biogen of $11,500 and a technology transfer payment of $500. The Company accounted for the acquisition of technology as an asset acquisition because it did not meet the definition of a business. The Company recorded the upfront payment and technology transfer payment as research and development expense in the consolidated statement of operations and comprehensive income (loss) because the acquired technology represented in-process research and development and had no alternative future use.

Under the Biogen Agreement, the Company is obligated to make milestone payments to Biogen of up to $179,000 upon the achievement of specified clinical and regulatory milestones in multiple indications in various territories, of which $165,000 remains as of December 31, 2025. Additionally, the Company could be obligated to make up to an aggregate of up to $150,000 of payments upon the achievement of specified annual net sales milestones and to pay tiered royalties on escalating tiers of annual net sales of licensed products starting in the high single-digit percentages and ending below the teens.

The Company also agreed to pay certain obligations under third party contracts retained by Biogen that relate to the vixarelimab program. Under these retained contracts, the Company paid a one-time upfront sublicense fee of $150 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 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 years ended December 31, 2025, 2024 and 2023, the Company recorded expenses of $44, $144 and $94 respectively, related to a milestone and the annual maintenance fee in connection with the retained contracts.

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 (also known as KPL-404). 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 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 years ended December 31, 2025, 2024 and 2023, the Company recorded expenses of $14, $10 and $40, respectively in connection with the BIDMC Agreement.

Regeneron License Agreement

In September 2017, the Company entered into the Regeneron Agreement with 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 CAPS and DIRA in the United States.

The Company has made $32,500 in payments under the Regeneron Agreement in connection with upfront fees and achievement of regulatory milestones, including a $20,000 payment in the first quarter of 2021 in connection with the achievement of a regulatory milestone. The Company accounted for the acquisition of technology as an asset acquisition because it did not meet the definition of a business.

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

or other disposition of rights with respect to ARCALYST, including upfront payments, milestone payments and royalties. For the years ended December 31, 2025, 2024 and 2023, the Company recognized $229,545, $127,375 and $56,524 respectively, of expenses related to the profit sharing agreement presented within collaboration expenses.

Pursuant to the Regeneron Agreement, in September 2017, the parties entered into a clinical supply agreement under which Regeneron agreed to manufacture product solely for the Company's use in development activities. Pursuant to the Regeneron Agreement, during the year ended December 31, 2021, the Company entered into a commercial supply agreement under which Regeneron agreed to manufacture product for the Company's use, including for commercial sales. The commercial supply agreement terminates upon the sooner of the termination of the Regeneron Agreement and the date of completion of the transfer of technology related to the manufacture of ARCALYST. During the year ended December 31, 2023, the Company incurred $1,356 of research and development expense related to the purchase of drug materials under the clinical supply agreement. During the years ended December 31, 2025 and 2024, the Company did not incur any research and development expense related to the purchase of drug materials under the clinical supply agreement. As of December 31, 2025 and 2024, the Company recorded inventory of $29,071 and $21,246 related to the purchase of commercial product under the commercial supply agreement (see Note 5). As of December 31, 2024, the Company had non-cancelable purchase commitments under the commercial supply agreement (see Note 16).

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

MedImmune License Agreement

In December 2017, the Company entered into a license agreement (as amended from time to time, the "MedImmune Agreement") with MedImmune, Limited (subsequently acquired by AstraZeneca PLC) ("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 was obligated to use commercially reasonable efforts to develop and commercialize the licensed products.

In February 2025, the Company delivered a notice of termination to MedImmune, notifying them of its intent to terminate the MedImmune Agreement, for convenience, effective May 22, 2025. Following such date, the exclusive worldwide sublicense rights to certain intellectual property rights to make, use, develop and commercialize mavrilimumab were returned to MedImmune. The Company did not record any significant charges related to the termination of the MedImmune Agreement.

During the years ended December 31, 2025, 2024 and 2023, the Company did not record expenses in connection with milestone payments due under the MedImmune Agreement.

14. Income Taxes

Prior to the Redomiciliation, the Company 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 previous 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 the reporting 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 United States 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 remained subject to taxation, if any, in Bermuda for the period of time prior to its liquidation in November 2025. The Company's wholly owned subsidiary Kiniksa UK, and Kiniksa UK's wholly owned subsidiaries, Kiniksa Switzerland, Kiniksa Germany, and Kiniksa France are subject to taxation in their respective countries. Certain of the Company's subsidiaries operate under cost plus intercompany arrangements.

The Company has engaged in a series of intra-entity asset transfers and allocations to contribute assets to its wholly owned Switzerland subsidiary and Kiniksa UK's Swiss branch office. 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. 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, KPL-387 and certain preclinical assets. In October 2024, Kiniksa UK 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 UK insofar as they related exclusively or primarily to vixarelimab to Kiniksa Switzerland.

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. 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 consolidated Company did not incur tax liabilities on any of the October 2024 intra-entity transfers since the transferor, Kiniksa UK, is the sole direct shareholder of Kiniksa Switzerland. 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 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. The Company maintains a valuation allowance on the full amount of the Kiniksa Switzerland deferred tax assets. There are no material deferred tax assets in the jurisdictions outside the United States, UK and Switzerland.

(Amounts in thousands, except share and per share amounts)

On July 4, 2025, new United States tax legislation was signed into law (known as the "One Big Beautiful Bill Act" or "OBBBA") which makes permanent many of the tax provisions enacted in 2017 as part of the Tax Cuts and Jobs Act that were set to expire at the end of 2025. In addition, the OBBBA makes changes to certain United States corporate tax provisions, but many are generally not effective until 2026. The Company continues to assess the impact of the tax provisions of the OBBBA on its consolidated financial statements, the Company currently believes that the tax provisions of the legislation are not expected to have a material impact on its operations.

Income (loss) before benefit (provision) for income taxes consisted of the following:

	Years Ended December 31,		
	2025	2024	2023
Domestic (1)	$ 2,775	$ (7,674)	$ (91,133)
Foreign (2)	86,093	(28,478)	74,481
Total	$ 88,868	$ (36,152)	$ (16,652)

(1) As a result of the redomiciliation the Company's years ended December 31, 2025 and 2024 domestic operations refer to the UK and the year ended December 31, 2023 domestic operations refer to Bermuda
(2) As a result of the redomiciliation the Company's years ended December 31, 2025 and 2024 foreign operations include the United States, Switzerland, Germany, France and Bermuda, and the year ended December 31, 2023 foreign operations include the United States, UK, Switzerland, Germany and France.

The components of the Company's income tax benefit (provision) were as follows:

	Years Ended December 31,		
	2025	2024	2023
Current income tax benefit (provision):			
Domestic (1)	$ (16,667)	$ 1,862	$ (122)
United States federal	(102)	(402)	(566)
United States state	(85)	(252)	(567)
Foreign (2)	(7)	(117)	(1,797)
Total current income tax benefit (provision)	(16,861)	1,091	(3,052)
Deferred income tax benefit (provision):			
Domestic (1)	(2,908)	1,913	—
United States federal	4,150	2,075	12,958
United States state	1,678	(178)	5,122
Foreign (2)	(15,922)	(11,942)	15,708
Total deferred income tax benefit (provision)	(13,002)	(8,132)	33,788
Total benefit (provision) for income taxes	$ (29,863)	$ (7,041)	$ 30,736

(1) As a result of the redomiciliation the Company's years ended December 31, 2025 and 2024 domestic operations refer to the UK and the year ended December 31, 2023 domestic operations refer to Bermuda
(2) As a result of the redomiciliation the Company's years ended December 31, 2025 and 2024 foreign operations include the United States, Switzerland, Germany, France and Bermuda, and the year ended December 31, 2023 foreign operations include the United States, UK, Switzerland, Germany and France.

(Amounts in thousands, except share and per share amounts)

A reconciliation of the statutory income tax rate of the Company's effective income tax rate for the year ended December 31, 2025, after the adoption of ASU 2023-09 for 2025 is as follows:

	Year Ended December 31, 2025	
	Dollars	Percent
United Kingdom Statutory Tax Rate	$ (22,316)	25.0 %
Foreign Tax Effects		
United States		
Statutory tax rate difference between United States and United Kingdom	714	(0.8)
State and local income taxes (1)	342	(0.4)
Research and development tax credits	3,509	(3.9)
Share-based compensation	6,569	(7.4)
Other	(1,035)	1.2
Switzerland		
Statutory tax rate difference between Switzerland and United Kingdom	5,576	(6.2)
Cantonal income taxes	3,439	(3.9)
Change in valuation allowance	(10,464)	11.7
Enacted changes in tax laws or rates	(7,296)	8.2
Other	899	(1.0)
Other foreign jurisdictions	(3)	-
Changes in Unrecognized Tax Benefits	(10,949)	12.3
Other Adjustments	1,152	(1.3)
Effective income tax rate	$ (29,863)	33.5 %

(1) State taxes in Massachusetts made up the majority of the tax effect in this category.

A reconciliation of the statutory income tax rate of the Company's effective income tax rate for the years ended December 31, 2024 and 2023, prior to the adoption of ASU 2023-09 were as follows:

	Years Ended December 31,	
	2024	2023
Statutory income tax rate (1)	25.0 %	— %
United States and Europe tax rate differential	(21.6)	(103.1)
Research and development tax credits	8.9	13.7
Share-based compensation	4.8	(7.4)
United States state taxes, net of federal	(2.0)	(7.9)
Foreign-Derived Intangible Income ("FDII")	2.2	13.8
Uncertain tax positions	(31.9)	—
IP transfers and allocation	1,655.4	258.6
Inventory allocation	—	181.4
Other	(2.6)	(4.7)
Change in valuation allowance	(1,657.7)	(159.8)
Effective income tax rate	(19.5)%	184.6 %

(Amounts in thousands, except share and per share amounts)

(1) Prior to the Redomiciliation in 2024, the Company 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.

Net deferred tax assets consisted of the following:

	December 31, 2025	December 31, 2024
Deferred tax assets:		
Research and development tax credit carryforwards	$ 4,093	$ 967
Share-based compensation	13,328	16,296
Operating lease liability	2,187	2,559
Intangible assets	733,224	773,687
Inventory	—	188
Depreciation and amortization	111	48
Net operating losses	109,363	85,372
Accrued expenses and other liabilities	4,602	—
Total deferred tax assets	866,908	879,117
Valuation allowance	(666,461)	(656,712)
Deferred tax liabilities:		
Right of use asset	(2,298)	(2,695)
Accrued expenses and other liabilities	—	(8,559)
Net deferred tax assets	$ 198,149	$ 211,151

As of December 31, 2025 and 2024, the Company had United States federal research and development tax credit carryforwards of approximately $3,224 and $808 available to reduce future tax liabilities, respectively, which begin to expire in 2045. As of December 31, 2025 and 2024, the Company had state research and development tax credit carryforwards of approximately $869 and $184 respectively, available to reduce future tax liabilities, which can be carried forward indefinitely. As of December 31, 2025 and 2024 the Company had foreign net operating loss (NOL) carryforwards of $106,244 and $66,990 respectively, available to reduce future tax liabilities. As of December 31, 2025 and 2024 the Company had UK domestic NOLs of $3,119 and $18,382, respectively. The NOLs may be carried forward and utilized, subject to local limitations.

As required by ASC 740 management regularly reassesses the 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 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.

The valuation allowance increased by $9,749 in 2025 primarily as a result of additional net operating losses of Kiniksa Switzerland. The valuation allowance increased by $610,452 in 2024 primarily as a result of the establishment of the valuation allowance for the Kiniksa Switzerland deferred tax assets which primarily consisted of the tax basis in intellectual property transferred from Bermuda and net operating losses.

In the second quarter of 2023, the Company assessed the valuation allowance on its United States deferred tax assets and considered positive evidence, including cumulative United States income in recent years, primarily related to cost plus intercompany arrangements and expectations regarding future profitability. The Company determined it was more likely than not that its United States deferred tax assets are realizable in the future and released the associated valuation allowance as of June 30, 2023.

(Amounts in thousands, except share and per share amounts)

In the fourth quarter of 2023, the Company assessed the valuation allowance on its Kiniksa UK deferred tax assets and considered positive and negative evidence, including among other things, the impact of future profitability decreasing in the UK as a result of the allocation of ARCALYST to the Swiss branch office. After assessing both the positive and negative evidence, the Company determined it was more likely than not that a portion of the UK deferred tax assets would not be realized in the future and established a partial valuation allowance on those assets during the year ended December 31, 2023. In 2025, the Company reassessed the valuation allowance on its Kiniksa UK deferred tax assets. After assessing both the positive and negative evidence, including but not limited to future profitability in the UK, the Company determined it was more likely than not that all the UK deferred tax assets would be realized in the future, and released the remaining partial valuation allowance on those assets.

The Company recognized a non-cash deferred tax benefit of $33,788 during the year ended December 31, 2023. This benefit primarily resulted from the step up in basis of intangible assets and inventory received in Switzerland associated with the allocation of ARCALYST to the Swiss branch office and the release of the United States valuation allowance. This was partially offset by the establishment of a partial UK valuation allowance. There are no material deferred tax assets in the jurisdictions outside the United States, UK and Switzerland.

Utilization of the United States federal and state NOLs and research and development tax credits may be subject to substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership changes that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the shares of a corporation by more than 50% over a three-year period.

The Company recognizes the tax benefit from an uncertain tax position only if it is more-likely-than-not that the tax position will be sustained on examination by taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. The amount of unrecognized tax benefits is $32,675, $13,390 and $1,794 as of December 31, 2025, 2024 and 2023, respectively. The net change in 2025, 2024 and 2023 relate to tax positions on the Company's intellectual property transfers.

As of December 31, 2025, the Company had a liability of $32,675 for unrecognized tax benefits of which, $19,214, if recognized, would reduce the effective tax rate. A roll forward of the Company's uncertainties in its income tax provision liability is presented below:

	Years Ended December 31,		
	2025	2024	2023
Gross balance at the beginning of year	$ 13,390	$ 1,794	$ 1,794
Gross increases based on current period tax positions	19,387	11,767	—
Gross increases based on tax positions of the prior periods	—	—	122
Gross decreases based on tax positions of the prior periods	(102)	(171)	(122)
Unrecognized tax benefits at the end of the year	$ 32,675	$ 13,390	$ 1,794

The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision. The Company has accrued $1,117 at year end December 31, 2025 and immaterial interest and penalties on the tax positions during the year ended December 31, 2024 and 2023.

The Company files United States federal income tax returns and income tax returns in various state, local and foreign jurisdictions. The Company's income tax returns are subject to tax examinations for the tax years ended December 31, 2022 and subsequent years. His Majesty's Revenue and Customs ("HMRC") commenced an examination

(Amounts in thousands, except share and per share amounts)

of the Company's 2023 and 2024 UK corporate income tax returns. At December 31, 2025, the examination is in the preliminary stages. Based upon available information, the Company does not believe that the audit will result in any adjustment that would result in a material change in the Company's financial position. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by tax authorities to the extent utilized in a future period.

The following table summarizes income taxes paid net of tax refunds:

	Year Ended December 31, 2025
Foreign:	
United States federal	$ 1,500
United States state and local	1,512
Total income taxes paid net of tax refunds	3,012

15. Net 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 ordinary shares are identical, except with respect to voting, transferability and conversion (see Note 10). 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 ordinary shareholders will, therefore, be the same for both Class A and Class B ordinary shares on an individual or combined basis.

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

	Years Ended December 31,		
	2025	2024	2023
Numerator:			
Net income (loss) attributable to ordinary shareholders	$ 59,005	$ (43,193)	$ 14,084
Denominator:			
Weighted-average basic shares outstanding	74,200,924	71,424,159	70,058,952
Effect of dilutive securities			
Options to purchase ordinary shares	3,787,871	—	1,362,250
Performance options to purchase ordinary shares	—	—	—
Unvested RSUs	900,424	—	501,712
Unvested PSUs	89,811	—	—
Weighted-average diluted shares	78,979,030	71,424,159	71,922,915
Basic net income (loss) per share	$ 0.80	$ (0.60)	$ 0.20
Diluted net income (loss) per share	$ 0.75	$ (0.60)	$ 0.20

The Company's unvested RSUs and PSUs have been excluded from the computation of basic net income (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 PSUs for which the market or 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,

(Amounts in thousands, except share and per share amounts)

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 ordinary stock at the average market price during the period.

For year ended December 31, 2024 the Company's potentially dilutive securities, which include options, unvested RSUs and unvested PSUs, have been excluded from the computation of diluted net loss per share attributable to ordinary shareholders for the periods indicated as the effect would be to reduce the net loss per share attributable to ordinary shareholders. Therefore, the weighted average number of ordinary shares outstanding used to calculate both basic and diluted net loss per share attributable to ordinary shareholders is the same. The Company excluded the following potential ordinary shares, presented based on amounts outstanding at each period end, from the computation of diluted net income (loss) per share attributable to ordinary shareholders for the periods indicated because including them would have had an anti-dilutive effect:

	Years ended December 31,		
	2025	2024	2023
Share options to purchase ordinary shares	2,725,729	11,286,994	8,498,144
Performance share options to purchase ordinary shares	—	—	—
Unvested RSUs	580,558	2,250,602	975,608
Unvested PSUs	—	31,433	—
Total anti-dilutive shares	3,306,287	13,569,029	9,473,752

PSUs and PSOs that are outstanding and contain performance-based or market-based vesting criteria for which the performance or market conditions have not been met are excluded from the presentation of common stock equivalents outstanding in the table above.

16. Commitments and Contingencies

License Agreements

The Company has entered into license agreements with various parties under which it is obligated to make contingent and non-contingent payments (see Note 13).

Manufacturing Commitments

The Company entered into supply agreements with Regeneron to provide both clinical supply and commercial product (see Note 13). In May 2023, the Company signed a letter of intent with Samsung related to its technology transfer of the manufacturing process for ARCALYST drug substance. The Company has additionally entered into agreements with several CDMOs to provide the Company with preclinical and clinical trial materials for its non-ARCALYST assets. As of December 31, 2025, the Company had committed to minimum payments under these agreements totaling $175,704, of which $46,924 are due within one year.

The Company issued termination notices to CDMOs in February 2025 to terminate the clinical supply agreements for the production of abiprubart. During the year ended December 31, 2025, the Company recorded and paid $2,500 in research and development expenses because of these terminations. The Company does not expect to incur any additional expenses because of these terminations.

Performance Cash Awards

Beginning in the second quarter of 2025, the Company began granting cash awards ("Performance Cash Awards") to certain eligible employees pursuant to the 2018 Plan, which were eligible to be received upon the achievement of certain specified development and regulatory milestones and that are subject to earnout percentages

based upon the date of applicable milestone achievement. As of December 31, 2025, the Company estimates the future cash payments under such Performance Cash Awards to be $23,118 if the milestones are achieved. The Performance Cash Awards will be recognized when the applicable milestones are deemed probable of achievement with a cumulative catch-up and recognized over the remaining term. The Company has not deemed any of the Performance Cash Award development or regulatory milestones as probable as of December 31, 2025, and no expense has been recognized related to such awards.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors, officers and other key personnel that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors, officers or other key personnel. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company does not believe that the outcome of any claims under indemnification arrangements will 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 December 31, 2025, 2024 or 2023.

Legal Proceedings

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

17. Segment Information and Geographic Data

The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is on developing and commercializing novel therapies that target cardiovascular diseases with significant unmet medical need. The Company's Chief Operating Decision Maker ("CODM") is the Chief Executive Officer. The Company's CODM reviews consolidated operating results and decides how to allocate resources based on net income that also is reported on the income statement as consolidated net income. The measure of segment assets is reported on the balance sheet as total consolidated assets. The CODM utilizes net income to make key decisions about how to allocate resources across the Company's commercial product and development programs.

(Amounts in thousands, except share and per share amounts)

The following table presents selected financial information with respect to the Company's single operating segment for the years ended December 31, 2025, 2024 and 2023:

	Years Ended December 31,		
	2025	2024	2023
Revenue:			
Product revenue, net	$ 677,564	$ 417,029	$ 233,176
License and collaboration revenue	—	6,210	37,083
Total revenue	677,564	423,239	270,259
Operating expenses:			
Cost of goods sold	77,673	60,910	33,407
Collaboration expenses	229,545	128,311	56,524
Direct research and development expenses by program:			
ARCALYST	1,040	1,080	2,628
KPL-387	47,265	11,221	2,537
KPL-1161	4,198	581	—
Abiprubart	6,122	59,459	28,388
Vixarelimab	44	1,530	7,717
Unallocated research and development expenses	38,184	37,752	34,827
Selling, general and administrative	196,272	168,011	129,427
Total operating expenses	600,343	468,855	295,455
Other income, net (1)	11,647	9,464	8,544
Income (loss) before income taxes	88,868	(36,152)	(16,652)
Benefit (provision) for income taxes	(29,863)	(7,041)	30,736
Net income (loss)	$ 59,005	$ (43,193)	$ 14,084
Other significant non-cash items:			
Share-based compensation expense	$ 37,003	$ 30,693	$ 27,149
Non-cash lease expense	3,666	3,136	3,054
Deferred income taxes	13,002	8,132	(33,788)

(1) Includes interest income of $11,636, $9,036 and $8,227 for the years ended December 31, 2025, 2024 and 2023 respectively.

(Amounts in thousands, except share and per share amounts)

The following table presents total revenue by geographic region of the customer for years ended December 31, 2025, 2024 and 2023:

	Years Ended December 31,		
	2025	2024	2023
Revenue:			
United States	$ 676,750	$ 421,434	$ 269,772
United Kingdom	814	930	487
Rest of world	—	875	—
Total revenue	$ 677,564	$ 423,239	$ 270,259

The following table presents property and equipment, net by geographic region:

	Years Ended December 31,	
	2025	2024
Property and Equipment, net		
United States	$ 1,608	$ 313
United Kingdom	76	99
Rest of world	259	250
Total property and equipment, net	$ 1,943	$ 662

18. Benefit Plans

The Company has established a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all Kiniksa US employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. The Company provides matching contributions of 100% of the first 3% of each participant's salary contributed, plus 50% for each of the next 2% contributed. Employees are immediately and fully vested in their own contributions and the Company's match. During the years ended December 31, 2025, 2024 and 2023, the Company contributed $3,544, $2,923 and $2,305 respectively, to the plan.

(This page has been left blank intentionally.)

(This page has been left blank intentionally.)

(This page has been left blank intentionally.)

Corporate Directory

Management Team

Sanj K. Patel*
Chief Executive Officer &
Chairman of the Board

John F. Paolini, MD, PhD*
Chief Medical Officer

Mark Ragosa*
Chief Financial Officer

Eben Tessari*
Chief Strategy Officer

Ross Moat*
Chief Operating Officer

Martina Struck, PhD
Chief Regulatory Officer

Mei Jang, PhD
Chief Technical Officer

Doug Barry
Chief Legal Officer

Mike Megna*
Chief Accounting Officer

* Executive officers as defined under Rule 3b-7 under the Securities Exchange Act of 1934, as amended.

Board Of Directors

Chairman

Sanj K. Patel
Chief Executive Officer

Lead Independent Director

Felix J. Baker, PhD
Co-Managing Member,
Baker Bros. Advisors LP

Directors

Stephen R. Biggar, MD, PhD
Partner, Baker Bros. Advisors LP

M. Cantey Boyd
Managing Director,
Baker Bros. Advisors LP

G. Bradley Cole
Chief Financial Officer,
Genomic Life, Inc.

Richard S. Levy, MD
Biopharmaceutical Consultant

Thomas R. Malley
President, Mossrock Capital, LLC

Tracey L. McCain
Former Executive Vice President,
Chief Legal and Compliance Officer,
Blueprint Medicine Corporation

Kimberly J. Popovits
Former Chief Executive Officer &
Chairman of the Board,
Genomic Health, Inc.

Barry D. Quart, PharmD
Chief Executive Officer,
Connect Biopharma

Address

Kiniksa Pharmaceuticals International, plc
105 Piccadilly, Second Floor
London, W1J 7NJ
England, United Kingdom

Kiniksa Pharmaceuticals Corp.
100 Hayden Avenue
Lexington, MA 02421
United States of America

Website

Kiniksa.com

Legal Counsel

Ropes & Gray LLP
Boston, Massachusetts

Independent Registered Accounting Firm

PricewaterhouseCoopers LLP
Boston, Massachusetts

Transfer Agent and Registrar

Computershare Trust Company, N.A.
Canton, Massachusetts

Stock Information

Nasdaq Global Select Market: KNSA

Investor Relations

Jonathan Kirshenbaum
Director, Investor Relations
ir@kiniksa.com

This Annual Report contains forward-looking statements that involve risks, uncertainties and other important factors that could cause results to differ materially from those projected. In some cases, you can identify these 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 their negative or other similar expressions. These important factors include those discussed in our Annual Report on Form 10-K for the year ended December 31, 2025 (which forms a part of this Annual Report) under the captions "Special Note Regarding Forward-Looking Statements," "Summary Risk Factors" and "Risk Factors." Accordingly, you are cautioned not to place undue reliance on such statements. We undertake no obligation to update any forward-looking statements.

Unless otherwise expressly stated, we obtained the industry, business, market, and other data contained in this Annual Report from reports, research surveys, clinical trials, studies, and similar data prepared by market research firms and other third parties, from industry, medical and general publications, and from government data and similar sources.

KINIKSA

WWW.KINIKSA.COM