UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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, 2024

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38682

KODIAK SCIENCES INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**27-0476525**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1250 Page Mill Road	
Palo Alto, CA	**94304**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 281-0850

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, par value $0.0001	KOD	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

Indicate by check mark whether the registrant 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 ☒

The aggregate market value of the common stock held by non-affiliates of the registrant, based on the closing price of a share of the registrant's common stock on June 28, 2024, the last business day of the registrant's most recently completed second fiscal quarter, as reported by the Nasdaq Global Market on such date, was approximately $76.1 million. Shares of common stock held by each executive officer and director and by each other person who may be deemed to be an affiliate of the registrant, have been excluded from this computation. The determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes.

As of February 28, 2025, the registrant had 52,748,343 shares of common stock, $0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to the 2025 Annual Meeting of Stockholders are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. The proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2024.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. Forward-looking statements should not be read as a guarantee of future performance or results and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. Forward-looking statements are based on information available at the time those statements are made and/or management's good faith beliefs as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements.

Forward-looking statements include all statements that are not historical facts. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "potential," "plan", "hope" or the negative of these terms, or similar expressions and comparable terminology intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties, including those set forth under the section of this Annual Report on Form 10-K titled "Part I, Item 1A — Risk Factors" and elsewhere in this Annual Report. Forward-looking statements include, but are not limited to, statements about:

- the success, cost and timing of our development activities, preclinical studies, clinical trials and regulatory filings;
- our ability to obtain funding for our operations, including funding necessary to develop, manufacture and commercialize our product candidates;
- the translation of our preclinical results and data and early clinical trial results in particular relating to safety, efficacy and durability into future clinical trials in humans;
- the continued durability, efficacy and safety of our product candidates;
- the portfolio of clinical trials planned for submission in our Biologics License Application, or BLA, of tarcocimab tedromer (formerly KSI-301, also known as tarcocimab);
- the scope, progress, results and costs of developing any product candidates we have or may develop, and conducting preclinical studies and clinical trials;
- the number, size and design of clinical trials that regulatory authorities may require to obtain marketing approval, including the order and number of clinical studies required to support a BLA in retinal vein occlusion, or RVO, diabetic retinopathy, or DR, and wet age-related macular degeneration, or wet AMD, or any of our current or future product candidates, including the sufficiency of a single additional pivotal study of tarcocimab tedromer and a single BLA for wet AMD, RVO and DR together;
- our and Lonza's ability to successfully execute on our manufacturing development plan;
- our expectations regarding chemistry manufacturing and controls, or CMC, requirements of the United States Food and Drug Administration, or FDA, and other regulatory bodies to support any BLA submission and potential commercial launch;
- our expectations regarding enhancements and benefits of new formulations of tarcocimab, KSI-501, KSI-101 or other ABC Platform derived molecules;
- the timing or likelihood of regulatory filings and approvals, including the potential to achieve FDA approval of any product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations and/or warnings in the label of any approved product candidate;
- the rate and degree of market acceptance of our product candidates;
- the size and growth potential of the markets for our product candidates, if approved for commercial use, and our ability to serve those markets;
- the pricing and reimbursement of our product candidates, if approved;
- the success of competing products or platform technologies that are or may become available;
- our plans and ability to establish sales, marketing and distribution infrastructure to commercialize any product candidates for which we obtain approval;

•our expectation as to the concentration of retinal specialists in the United States and its impact on our sales and marketing plans;

•our expectations regarding our ability to enter into manufacturing-related commitments, and the timing thereof;

•future agreements with third parties in connection with the commercialization of our product candidates;

•our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;

•the expected potential benefits of strategic collaboration agreements and our ability to attract collaborators with development, regulatory and commercialization expertise;

•the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;

•potential claims relating to our intellectual property and third-party intellectual property;

•existing regulations and regulatory developments in the United States and foreign countries;

•the impact of the unfavorable U.S. and global economic conditions on our business and operations, the business and operations of our collaborators, and on the global economy;

•the accuracy of our estimates regarding the sufficiency of our cash resources, expenses, future revenue, capital requirements and needs for additional financing, as well as, our ability to continue as a going concern;

•our financial performance;

•our aspirational goals and objectives related to our human capital resources and workforce objectives; and

•our ability to attract and retain key managerial, scientific and medical personnel.

All forward-looking statements are based on information available to us on the date of this Annual Report on Form 10-K and we will not update any of the forward-looking statements after the date of this Annual Report on Form 10-K, except as required by law. Our actual results could differ materially from those discussed in this Annual Report on Form 10-K. The forward-looking statements contained in this Annual Report on Form 10-K, and other written and oral forward-looking statements made by us from time to time, are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements, and you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. Factors that might cause such a difference include, but are not limited to, those discussed in the following discussion and within the section of this Annual Report on Form 10-K titled "Part I, Item 1A — Risk Factors".

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

All brand names or trademarks appearing in this Annual Report are the property of their respective holders. Unless the context requires otherwise, references in this Annual Report to "Kodiak" the "Company," "we," "us," and "our" refer to Kodiak Sciences Inc. and its subsidiaries.

Kodiak®, Kodiak Sciences®, ABC®, ABC Platform™, ABCD™ and the Kodiak logo are registered trademarks or trademarks of Kodiak Sciences Inc. in various global jurisdictions.

RISK FACTOR SUMMARY

Investing in our common stock involves numerous risks, including the risks described in "Part I, Item 1A — Risk Factors" of this Annual Report on Form 10-K, any one of which could materially adversely affect our business, financial condition, results of operations, and prospects. These risks include, among others, the following:

- We are in the clinical stage of drug development and have a very limited operating history and no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability.
- We have incurred significant net losses in each period since our inception and anticipate that we will continue to incur significant and increasing net losses for the foreseeable future.
- Our financial condition raises substantial doubt about our ability to continue as a going concern.
- If we fail to obtain additional financing, we may be unable to complete the development and, if approved, commercialization of our product candidates.
- Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have never generated any revenue from product sales, and we may never generate revenue or be profitable.
- Our prospects are heavily dependent on our tarcocimab, KSI-501 and KSI-101 product candidates, which are currently in clinical development for multiple indications.
- The failure of pivotal studies of tarcocimab to meet their primary efficacy endpoints may lead us to pause, change or discontinue development of other product candidates based on our ABC Platform.
- Our plan for the development of tarcocimab, KSI-501 or KSI-101 may be unsuccessful.
- Research and development of biopharmaceutical products is inherently risky. We cannot give any assurance that any of our product candidates will receive regulatory, including marketing, approval, which is necessary before they can be commercialized.
- Due to the significant resources required for the development of our product candidates, and depending on our ability to access capital, we must prioritize development of certain product candidates. Moreover, we may expend our limited resources on product candidates that do not yield a successful product and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- We may encounter substantial delays in our clinical trials, or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all.
- Our clinical trials may fail to demonstrate substantial evidence of the durability, efficacy and safety of our product candidates, which would prevent, delay or limit the scope of regulatory approval and commercialization.
- We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may retain their market share with existing drugs, or achieve regulatory approval before us or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize any product candidates we may develop and ultimately harm our financial condition.
- The regulatory approval processes of the FDA, EMA and comparable foreign regulatory authorities are lengthy, time consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.
- We expect to rely on third parties to conduct many aspects of our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.
- We contract with third parties for the manufacture of materials for our product candidates and preclinical studies and clinical trials and for commercialization of any product candidates that we may develop. This reliance on third parties carries and may increase the risk that we will not have sufficient quantities of such materials, product candidates or any medicines that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

•If we are unable to obtain and maintain patent protection for any product candidates we develop or for our ABC Platform, our competitors could develop and commercialize products or technology similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop, and our technology may be adversely affected.

•We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

PART I

ITEM 1. BUSINESS

Overview

Since its founding in 2009, Kodiak Sciences Inc. ("Kodiak," the "Company," "we" or "our") has developed a new technology platform, the Antibody Biopolymer Conjugate ("ABC") Platform, for retinal medicines. Our goal is to prevent and treat the major causes of blindness by developing and commercializing next-generation therapeutics to address multiple unmet needs on the spectrum of retinal diseases.

Kodiak has developed three clinical programs based on its internal discovery and development engine. The lead investigational medicine, tarcocimab tedromer ("KSI-301" or "tarcocimab"), is built from Kodiak's ABC Platform and to date, has completed three successful Phase 3 pivotal clinical studies across three high prevalence retinal vascular diseases. Tarcocimab is intended to be a mainstay intravitreal biologic that provides high immediacy, driven by the enhanced formulation, and high durability, driven by the ABC Platform and our science of durability, with the ultimate objective of providing, once approved, a flexible 1-month through 6-month label for all patients who may benefit from anti-vascular endothelial growth factor ("anti-VEGF") therapy. Tarcocimab is currently being studied in two Phase 3 clinical studies, the GLOW2 study in diabetic retinopathy ("DR") and the DAYBREAK study in wet age-related macular degeneration ("AMD"). GLOW2 has completed enrollment, and DAYBREAK is actively enrolling. Kodiak anticipates to be in a position to announce topline data for the primary endpoint for GLOW2 in 1Q 2026 and for the primary endpoint for DAYBREAK in 2Q 2026. If both are successful, we intend to file a single Biologics License Application ("BLA") in 2026 in the three large indications of wet AMD, retinal vein occlusion ("RVO") and DR.

Kodiak's second investigational medicine, KSI-501, is a first-in-class bispecific antibody biopolymer conjugate designed to inhibit interleukin-6 ("IL-6")-mediated inflammation and VEGF-mediated vascular permeability. KSI-501 is being developed for the treatment of high prevalence retinal diseases to address the leading unmet needs targeting multiple disease biologies beyond VEGF for differentiated efficacy together with extended durability. KSI-501 is designed to provide high immediacy/efficacy, driven by the enhanced formulation, and high durability, driven by the ABC Platform and our science of durability. A Phase 1 study was conducted to evaluate KSI-501's safety, tolerability and bioactivity. Based on the positive results from this study, Kodiak has advanced KSI-501 into the Phase 3 DAYBREAK study to evaluate its efficacy and safety in wet AMD. DAYBREAK is actively enrolling patients.

Additionally, Kodiak is developing a third investigational medicine, KSI-101, an unconjugated bispecific protein targeting IL-6 and VEGF. KSI-101 is being developed for patients who have retinal fluid and inflammation, a new market segment separate from the established anti-VEGF market. KSI-101 is a clinical program with opportunities and risks uncoupled from the ABC Platform, and as such we believe it is an important part of our portfolio. We initiated the Phase 1b study APEX to evaluate KSI-101's safety and tolerability and to identify two dose levels to progress into Phase 2b/3 pivotal studies (PEAK and PINNACLE). We expect to initiate our pivotal program in 2Q 2025. In January 2025, we presented early APEX data in patients with macular edema secondary to inflammation ("MESI") that demonstrated strong treatment response at all KSI-101 dose levels. We expect to present additional APEX data at an Investor R&D update in June 2025.

Beyond its clinical pipeline, Kodiak is advancing its platform technology to embed small molecules and other active pharmaceutical ingredients ("API"), into Kodiak's proprietary biopolymer backbone to enable high drug-antibody ratio ("DAR") medicines. The diverse APIs are designed to be released over time to achieve targeted, multi-specific and tailored modulation of biological pathways. We believe this unique combination of high DAR and extended therapeutic benefit offers potential for broad and important utility for multifactorial ophthalmic and systemic diseases. We call this platform extension our Antibody Biopolymer Conjugate Drug ("ABCD") Platform because we are extending our platform capabilities to include the conjugation of small molecule drugs whereas historically we primarily conjugated biologics such as antibodies. Our ABCD platform is advancing a next set of investigational therapies for high prevalence retinal diseases, including our novel "duet" technology for glaucoma and geographic atrophy.

In addition to advancing our pipeline, we have made progress in process development and commercial scale manufacturing, including the commissioning and regulatory approval of Ursus, our dedicated commercial-scale drug substance manufacturing facility that was custom-designed and built in collaboration with Lonza. We believe these manufacturing efforts could position Kodiak well for potential market share capture if tarcocimab and KSI-501 are approved.

Notably, up to this point, Kodiak has retained all global rights to make, use and sell its product candidates, which we believe preserves future value and allows for agile decision-making.

While engaged in these research and development efforts, we believe we have demonstrated a disciplined and creative approach to building and financing the Company. As of December 31, 2024, we had $168.1 million in cash and cash equivalents.

Our objective is to develop our retina-focused product candidates, seek FDA approval, and ultimately commercialize our product candidates.

Following from these efforts, we believe Kodiak has the potential to achieve our ambition of becoming an important retinal development and commercialization franchise, but we recognize there are substantial risks to realizing this potential.

Tarcocimab Clinical Program Summary and Update

Kodiak's lead clinical program tarcocimab is an investigational anti-VEGF therapy built on Kodiak's ABC Platform and is designed to maintain potent and effective drug levels in ocular tissues for longer than existing available agents. It is being developed as a mainstay intravitreal biologic monotherapy intended to provide high immediacy, driven by the enhanced formulation, and high durability, driven by the ABC Platform and our science of durability, with the ultimate objective of providing, once approved, a flexible 1-month through 6-month label. Kodiak's objective with tarcocimab is to enable earlier treatment and prevention of vision loss for patients with diabetic retinopathy and to develop a new high immediacy and high durability agent to improve outcomes for patients with retinal vascular diseases.

To date, tarcocimab has been studied in six pivotal clinical studies: Phase 3 GLOW1 study in diabetic retinopathy ("DR"), Phase 3 BEACON study in retinal vein occlusion ("RVO"), Phase 3 DAYLIGHT study in wet AMD, Phase 3 GLEAM and GLIMMER studies with identical study design in diabetic macular edema ("DME"), and Phase 2/3 DAZZLE study in wet AMD. Of the six registrational studies, GLOW1, BEACON and DAYLIGHT successfully met the primary endpoint. Tarcocimab is currently being studied in two Phase 3 clinical trials, the GLOW2 study in DR and the DAYBREAK study in wet AMD. GLOW2 has completed enrollment, and DAYBREAK is actively enrolling. Kodiak anticipates to be in a position to announce topline data for the primary endpoint for GLOW2 in 1Q 2026 and for the primary endpoint for DAYBREAK in 2Q 2026. Kodiak plans to wait for DAYBREAK topline data expected 2Q 2026 in order to file a single Biologics License Application ("BLA") for tarcocimab in wet AMD, DR and RVO.

Both GLOW2 and DAYBREAK use tarcocimab's enhanced 50 mg/mL formulation containing both conjugated and unconjugated antibody that is intended to deliver high immediacy and high durability.

More information about study design and results, if completed, from each individual pivotal study are summarized below:

Ongoing Phase 3 Studies:

GLOW2 – Phase 3 Study in Patients with Diabetic Retinopathy

The Phase 3 GLOW2 study is the second registrational trial of tarcocimab in DR. GLOW2 has a similar design as GLOW1 in which all patients randomized to investigational therapy will receive tarcocimab on extended, 6-month dosing. GLOW2 features the benefit of an additional, third monthly loading dose (baseline, Week 4, Week 8) to explore even further benefits with tarcocimab in diabetic retinopathy patients.

GLOW2 study is a prospective, randomized, double-masked, multi-center pivotal superiority study designed to evaluate the efficacy and safety of tarcocimab in treatment-naïve patients with DR. Patients are randomized 1:1 and receive either sham injections or tarcocimab via intravitreal injection at baseline, Week 4, Week 8, Week 20 and Week 44. The primary endpoint is the proportion of eyes improving ≥2 steps on Diabetic Retinopathy Severity Scale ("DRSS") from baseline at Week 48. Additional outcome measures include the proportion of eyes developing a sight threatening complication of diabetic retinopathy and the proportion of eyes improving ≥3 steps on DRSS from baseline at Week 48.

On March 10, 2025, Kodiak announced that GLOW2 completed enrollment, randomizing more than 250 patients. Kodiak expects to be in a position to announce topline data in 1Q 2026.

DAYBREAK – Phase 3 Study in Patients with Wet Age-Related Macular Degeneration

The Phase 3 DAYBREAK study is a non-inferiority study evaluating parallel investigational arms of tarcocimab and KSI-501 against active comparator aflibercept. Patients randomized to tarcocimab will receive individualized dosing every 4 to 24 weeks on an as needed basis following four monthly loading doses. Patients randomized to aflibercept will be dosed per its label. The individualized dosing of tarcocimab is determined by a treat-to-dryness proactive approach, using presence of retinal fluid as a disease activity marker, instead of a combination of central subfield thickness ("CST") and vision loss, which resembles retina specialists' practice and optimizes each patient's treatment. The objectives for tarcocimab in DAYBREAK are to assess its 6-month durability potential, strengthen its competitive position in wet AMD and bolster the regulatory application package for the program.

DAYBREAK is actively enrolling patients, and Kodiak anticipates to be in a position to announce topline data for the primary endpoint in 2Q 2026.

Completed Studies:

GLOW1 – Phase 3 Study in Patients with Non-Proliferative Diabetic Retinopathy without DME

The Phase 3 GLOW1 study was a global, multi-center, randomized pivotal superiority study designed to evaluate the efficacy and safety of tarcocimab in treatment-naïve patients with moderately severe to severe DR. Patients were randomized to receive either tarcocimab every six months after initiating doses given at baseline, 8 weeks and 20 weeks into the study, or to receive sham injections. The primary endpoint was at one year.

On November 6, 2023, Kodiak announced that GLOW1 met its primary endpoint of the proportion of patients with at least a 2-step improvement on the Diabetic Retinopathy Severity Scale (DRSS) score, a grading system measuring the degree of retinopathy. Tarcocimab achieved a 29-fold increased response rate ratio, with 41.1% of evaluable patients on tarcocimab demonstrating at least 2-step improvement versus 1.4% of evaluable patients in the sham group (p-value less than 0.0001). Visual acuity and retinal anatomy were improved and stable with tarcocimab on its extended-dosing intervals. At one year, GLOW1 also met its key secondary endpoint of greater reductions in the proportion of patients developing sight-threatening complications (such as diabetic macular edema and proliferative diabetic retinopathy), versus sham, demonstrating an 89% decreased risk, achieving 21.0% versus 2.3% (p-value less than 0.0001). Tarcocimab also showed a 95% risk reduction in the development of DME, versus sham, from 13.7% on sham versus 0.7% on tarcocimab. The rates of serious ocular adverse events and intraocular inflammation in patients treated with tarcocimab and sham were similar.

BEACON – Phase 3 Study in Patients with Treatment-Naïve Retinal Vein Occlusion

The Phase 3 BEACON study was a randomized, double-masked, multicenter, active comparator-controlled study in treatment naïve patients with vision loss and macular edema due to retinal vein occlusion, including both branch ("BRVO") and central ("CRVO") subtypes. In the initial six months of the study, patients received tarcocimab on a fixed every-8-week dosing regimen following 2 monthly loading doses or aflibercept 2mg on a fixed monthly dosing regimen per its label. In the second six months of the study, tarcocimab and aflibercept were tested head-to-head according to a pro re nata (“PRN") protocol in which patients in both groups were treated only when disease reactivated according to matched predefined disease activity criteria.

In August 2022, Kodiak announced that the BEACON study met the primary efficacy endpoint of non-inferior visual acuity change from baseline at week 24 for subjects given tarcocimab every two months after 2 monthly loading doses compared to subjects given monthly aflibercept.

On September 7, 2023, Kodiak announced new one-year results from the BEACON study. Tarcocimab demonstrated matched efficacy with differentiated durability versus aflibercept in the head-to-head comparison. After 4 initiating doses in the first 6 months, 47% of tarcocimab-treated patients required no additional injections in the second 6 months while matching the vision and anatomic outcomes of aflibercept-treated patients. Despite receiving 6 initiating monthly doses, only 37% of aflibercept patients were injection free in the second half of the study. 77% of tarcocimab treated patients received 5 or fewer doses in year one, while 93% of aflibercept treated patients received 6 or more doses. BRVO patients received a median of 4.0 injections on tarcocimab versus 7.0 injections of aflibercept. Despite materially fewer injections in tarcocimab treated patients, vision outcomes favored tarcocimab-treated patients achieving an observed mean of 76.6 letters versus 75.6 letters for aflibercept treated patients. All RVO patients received a median of 5.0 injections on tarcocimab versus 7.0 injections of aflibercept. Despite materially fewer injections in tarcocimab treated patients, vision outcomes favored tarcocimab-treated patients achieving an observed mean of 74.6 letters versus 74.3 letters for aflibercept treated patients.

Safety and tolerability were comparable between tarcocimab and aflibercept. Intraocular inflammation (IOI) rate was comparable between groups (tarcocimab 2.5% vs aflibercept 0.7%). No cases of inflammation associated with vascular occlusion or vasculitis were reported.

DAYLIGHT – Phase 3 Study in Patients with Treatment-Naïve Wet AMD

The DAYLIGHT study was a randomized, double-masked, active comparator-controlled study evaluating the efficacy and safety of a high intensity dosing regimen of tarcocimab in 557 treatment-naïve subjects with wet AMD. On July 24, 2023, Kodiak announced that the DAYLIGHT study met the primary endpoint of non-inferior visual acuity gains at year 1 for tarcocimab dosed monthly compared to aflibercept dosed every 8 weeks following 3 monthly loading doses. Intraocular inflammation occurred in 3.3% of patients treated with monthly tarcocimab and 0.4% of patients treated with aflibercept with no vasculitis or occlusion.

GLEAM / GLIMMER – Paired Phase 3 Studies in Patients with Treatment-Naïve Diabetic Macular Edema

The GLEAM and GLIMMER studies were identically designed, randomized, double-masked, active comparator-controlled studies evaluating the efficacy, durability and safety of tarcocimab in 460 and 457 treatment-naïve subjects with DME, respectively, run in parallel.

On July 24, 2023, Kodiak announced that although high proportions of patients on meaningfully longer treatment intervals were observed with tarcocimab, with half of patients on every 24-week dosing at the primary endpoint, the GLEAM and GLIMMER studies did not meet their primary efficacy endpoints of showing non-inferior visual acuity gains for tarcocimab dosed every 8 to 24 weeks after 3 monthly loading doses compared to aflibercept given every 8 weeks after 5 monthly loading doses. At the primary efficacy endpoint of the GLEAM study, patients treated with tarcocimab gained an observed average of 6.4 eye chart letters (to 73.1 letters), compared with 10.3 letters for patients treated with aflibercept (to 76.5 letters). In GLIMMER, patients treated with tarcocimab gained an observed average of 7.4 eye chart letters at the primary endpoint (to 72.5 letters) compared with 12.2 letters (to 76.4 letters) for patients treated with aflibercept.

An unexpected increase in cataract adverse events was reported over time in the tarcocimab arms of both GLEAM and GLIMMER, with 19% on tarcocimab versus 9% on aflibercept at the primary endpoint based on the pooled safety population. Kodiak's evaluation suggested that the decline in visual acuity associated with cataracts likely contributed meaningfully to the failure of each study.

Half of tarcocimab treated patients in the GLEAM and GLIMMER studies were on every 24-week dosing at the primary endpoint, two-thirds achieved at least one 6-month dosing interval during the studies, and three-quarters achieved at least one 5-month or longer treatment interval. Intraocular inflammation was rare, occurring in 1.3% and 0.2% of tarcocimab and aflibercept treated patients, respectively. No cases of intraocular inflammation with vasculitis or vascular occlusion were observed.

DAZZLE – Phase 2b/3 Study in Patients with Treatment-Naïve Wet AMD

The DAZZLE study was a global, multi-center, randomized pivotal study designed to evaluate the durability, efficacy and safety of tarcocimab in patients with treatment-naïve wet AMD. In February 2022 Kodiak announced that this initial pivotal study did not meet its primary efficacy endpoint of non-inferior visual acuity gains for subjects dosed on extended regimens every 12-, 16- or 20 weeks with tarcocimab compared to subjects given aflibercept every 8 weeks. Following this announcement, Kodiak discontinued the study and concluded remaining trial-associated activities.

Antibody Biopolymer Conjugate Drug Substance Manufacturing

In August 2020, we entered into a manufacturing agreement with Lonza Ltd ("Lonza") for the clinical and commercial supply of the Company's antibody biopolymer conjugate drug substance which included a custom-built manufacturing facility. The manufacturing agreement has an initial term of 8 years, and the Company has the right to extend the term up to a total of 16 years. The Company and Lonza each have the ability to terminate this agreement upon the occurrence of certain events.

In April 2021, the agreement was amended to provide for greater manufacturing flexibility, to define a comprehensive mandate as an antibody biopolymer conjugates manufacturing facility to be used for the Company's antibody biopolymer conjugates pipeline, at clinical as well as commercial scales, across a broad capacity range under the tight quality controls required for ophthalmology and retinal medicines, and to allow for future process and equipment changes as needed.

Under the agreement, Kodiak and Lonza planned a custom-built facility ("Ursus") dedicated to the commercial-scale manufacturing of Kodiak's drug substance. In January 2023, the custom-built manufacturing suite Ursus was commissioned as a cGMP facility. Kodiak worked together with Lonza and regulatory authorities to obtain approval for Ursus, and we released our first commercial scale cGMP batch of tarcocimab in July 2023. In October 2023, Kodiak made a final payment of $26.8 million to Lonza for final activation of Ursus. Separately, tarcocimab drug product based on our enhanced formulation was released in March 2024 and is being used in the GLOW2 and DAYBREAK pivotal studies.

KSI-501 Clinical Program Update

KSI-501 is an anti-IL-6, VEGF-trap bispecific antibody biopolymer conjugate built on the ABC Platform and is being developed for high prevalence retinal vascular diseases to address the unmet needs of extended durability and targeting disease biology beyond VEGF for differentiated efficacy. KSI-501 is designed to provide high immediacy/efficacy, driven by the enhanced formulation, and high durability, driven by the ABC Platform and our science of durability.

Higher intraocular levels of IL-6 are correlated with poorer BCVA outcomes over time in wet AMD patients treated with anti-VEGF monotherapy, which suggests that IL-6 inhibition in combination with anti-VEGF therapy could lead to improved outcomes. In preclinical models, KSI-501 was shown to be a potent inhibitor of VEGF and IL-6 and, further, was shown to normalize the blood retinal barrier, opening up the possibility that KSI-501 may be a disease-modifying therapy for retinal vascular diseases. A completed Phase 1 multiple ascending dose study demonstrated that repeated monthly dosing of KSI-501 was well tolerated and achieved clinically meaningful and sustained improvement in visual acuity and fluid reduction in patients with diabetic macular edema.

Kodiak has advanced KSI-501 into a Phase 3 study DAYBREAK to evaluate its efficacy and safety in wet AMD. The DAYBREAK study is a non-inferiority study evaluating parallel investigational arms of KSI-501 and tarcocimab against active comparator aflibercept. Patients randomized to KSI-501 will receive fixed every 8-week dosing with additional individualized dosing (up to monthly dosing) on an as needed basis after 4 monthly loading doses. Patients randomized to aflibercept will be dosed per its label. The primary endpoint is non-inferiority in change in visual acuity from baseline to the average of Week 40, 44 and 48. DAYBREAK uses KSI-501's enhanced 50 mg/mL formulation containing both conjugated and unconjugated antibody that is intended to deliver high immediacy and high durability. The objective for KSI-501 in DAYBREAK is to explore the efficacy potential of bispecific VEGF and IL-6 inhibition in a broad treatment-naïve wet AMD population. DAYBREAK is now actively enrolling patients.

KSI-101 Clinical Program Update

KSI-101 is a novel, potent and high strength (100 mg/mL) bispecific protein targeting IL-6 and VEGF. We are developing KSI-101 for patients who have retinal fluid and inflammation. Currently there are no available intravitreal biologic therapies addressing the spectrum of inflammatory conditions of the retina. We believe that retinal inflammatory conditions represent a new market segment separate from the established anti-VEGF market. KSI-101 is a clinical prospect with opportunities and risks uncoupled from the ABC Platform, and as such is an important part of our late-phase portfolio. We have initiated a dose-finding Phase 1b study APEX. The APEX study evaluates KSI-101 in two cohorts, Cohort 1 in patients with diabetic macular edema ("DME") and Cohort 2 in patients with macular edema secondary to inflammation ("MESI"). The goal of the APEX study is to evaluate the safety and tolerability of KSI-101 and to identify two dose levels to progress into dual Phase 2b/3 studies (PEAK and PINNACLE) in MESI. In January 2025, we presented early APEX data in patients with MESI that demonstrated strong treatment response at all KSI-101 dose levels.

APEX is continuing to actively enroll patients. Kodiak intends to present new APEX clinical trial data for KSI-101 in an Investor R&D Update to be scheduled for June 2025.

KSI-501 and KSI-101 Manufacturing

We have been progressing the manufacturing of KSI-501 and KSI-101 in preparation for the anticipated clinical studies. Clinical material for both KSI-501 (50 mg/mL strength in our enhanced formulation) and KSI-101 (100 mg/mL strength) were successfully manufactured in the first quarter of 2024.

ABC Platform Development

Kodiak is advancing its platform technology to embed small molecules and other active pharmaceutical ingredients ("API") into Kodiak's proprietary biopolymer backbone to enable high drug-antibody-ratio ("DAR") medicines. The diverse APIs are designed to be released over time to achieve targeted, multi-specific and tailored modulation of biological pathways. The unique combination of high DAR and tailored therapeutic benefit offers potential for broad application to multifactorial systemic and ocular diseases and builds directly from our Antibody Biopolymer Conjugate technology and its 15 years of design, development and manufacturing experience. We call this platform extension our Antibody Biopolymer Conjugate Drug ("ABCD") Platform because we are extending our platform capabilities to include the conjugation of small molecule drugs whereas historically we primarily conjugated biologics such as antibodies.

One program is for the treatment of glaucoma, embedding in the biopolymer backbone (i) an NLRP3 small molecule inhibitor, and (ii) a second small molecule that lowers intraocular pressure ("IOP"). The NLRP3 inflammasome is an intracellular complex that drives inflammation and cell death and is known to play a key role in glaucoma progression. The goal of this duet program is to create an intravitreally injected therapy that delivers two mechanisms of action ("MOA") in a sustained release fashion, to fulfill the unmet needs in the glaucoma field for non-topical, long-durability therapy that delivers MOAs beyond IOP lowering and has the potential of quarterly dosing.

The second program is for the treatment of geographic atrophy (“GA”). There are two approved therapies, both complement inhibitors, and they require monthly or every other month intravitreal injections and neither sufficiently halts disease progression. This program at Kodiak explores the potential to embed in the biopolymer backbone (i) a macrocyclic peptide inhibitor of the complement pathway, and (ii) an NLRP3 small molecule inhibitor. The NLRP3 inflammasome is known to play a key role in AMD disease biology. The objective of this duet program is to create an intravitreally injected ABCD platform-enabled therapy with a dual mechanism of action to achieve better efficacy and extended durability, for quarterly dosing, as compared to currently approved therapies for GA.

Digital Health Platform Development

Kodiak also continues to advance its VETi (Visual Engagement Technology and imager) program. VETi is built on Kodiak’s suite of proprietary LiDAR (Light Detection and Ranging) sensor technologies. VETi is an autonomous AI- and machine-learning-enabled headset that engages directly into the eye. Kodiak’s goal is to commercialize VETi together with Kodiak’s emerging portfolio of retinal medicines using apps that apply AI-enabled tools. Kodiak also believes VETi has future potential to be used to build correlations between VETi data and many human diseases outside of retina and then to be used to diagnose disease and monitor treatment. VETi may also have future potential as an AI-enabled device with similarities to a consumer smartwatch but with direct access into the body and the brain through the eye rather than through the skin.

Competition

The current standard of care for DR (including DME), RVO and wet AMD is intravitreal administration of anti-VEGF therapies, principally Avastin, Lucentis and Eylea, which are well-established therapies and are widely accepted by physicians, patients and third-party payors.

In addition, newer competitors have received FDA approval in recent years, such as Vabysmo (faricimab) from Roche. Vabysmo is a bispecific antibody targeting VEGF and angiopoietin-2 (Ang-2) and received FDA approval for the treatment of wet AMD and DME in January 2022 and received FDA approval for RVO in October 2023. Vabysmo demonstrated non-inferiority in visual acuity gains to Eylea in wet AMD and DME, with extended dosing of up to once every 16 weeks for slightly less than half of patients in Phase 3 trials at the Year 1 primary endpoint. Vabysmo also demonstrated non-inferiority in visual acuity gains to Eylea in Phase 3 studies in RVO with monthly dosing regimen for both therapies. We believe Vabysmo may be perceived to offer better anatomical improvement (drying the retina) and, secondarily, incremental benefit in durability over currently established therapies such as Lucentis and Eylea. Vabysmo has been gaining adoption since launch and we believe it has become an important product in the marketplace.

In August 2023, Regeneron's product, Eylea HD (high dose aflibercept) gained FDA approval for the treatment of wet AMD, DME and DR. High dose aflibercept demonstrated non-inferior visual acuity gains to Eylea in Phase 3 studies in wet AMD and DME while dosing a majority of patients on an every 3 or 4 month interval compared to Eylea dosed every 8 weeks per its label. We believe Eylea HD may become an important therapy in the marketplace given Regeneron's incumbent position in retinal diseases.

There are also other companies and research organizations developing treatments targeting other molecular targets, potential gene therapy treatments, stem cell transplant treatments, medical devices as well as biosimilars for the treatment of DR, RVO and wet AMD. We believe the therapeutic space of retinal diseases may become increasingly competitive in the future.

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries 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 and biological products. Generally, before a new drug or biologic 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.

U.S. Drug Development

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations, and biologics under the FDCA, the Public Health Service Act, or PHSA, and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Any future product candidates must be approved by the FDA through either a new drug application, or NDA, or a biologics license application, or BLA, process before they may be legally marketed in the United States. The process generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice, or GLP, requirements;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, or ethics committee at each clinical trial site before each trial may be initiated;

•performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practice, or GCP, requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;

•submission to the FDA of an NDA or BLA;

•a determination by the FDA within 60 days of its receipt of an NDA or BLA to accept the filing for review;

•satisfactory completion of FDA pre-approval inspection of the manufacturing facility or facilities where the drug or biologic will be produced to assess compliance with current good manufacturing practices, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the drug or biologic's identity, strength, quality and purity;

•potential FDA audit of the preclinical and/or clinical trial sites that generated the data in support of the NDA or BLA;

•FDA review and approval of the NDA or BLA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug or biologic in the United States; and

•compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and the potential requirement to conduct post-approval studies.

The data required to support an NDA or BLA are generated in two distinct developmental stages: preclinical and clinical. The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for any future product candidates will be granted on a timely basis, or at all.

Preclinical Studies and IND

The preclinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. 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.

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as in vitro and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time, the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and 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, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted 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 approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative, and must monitor the clinical trial until completed. There also are requirements governing the reporting of on-going clinical trials and completed clinical trial results to public registries.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA or BLA. The FDA will accept a well-designed and well-conducted foreign clinical study not conducted under an IND if the study was conducted in accordance with GCP requirements and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials in the United States generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the drug.

- Phase 2 clinical trials involve studies in disease-affected patients to determine the dose required to produce the desired benefits. 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 large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

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 patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or BLA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the drug, findings from animal or in vitro testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients 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 or biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the drug or biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that our product candidates do not undergo unacceptable deterioration over their shelf life.

NDA/BLA Review Process

Following completion of the clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of an NDA or BLA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. In short, the NDA or BLA is a request for approval to market the drug or biologic for one or more specified indications and must contain proof of safety and efficacy for a drug or safety, purity and potency for a biologic. The application may include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of FDA. FDA approval of an NDA or BLA must be obtained before a drug or biologic may be marketed in the United States.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each NDA or BLA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for approved human drugs and biologics. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews all submitted NDAs and BLAs before it accepts them for filing, and may request additional information rather than accepting the NDA or BLA for filing. The FDA must make a decision on accepting an NDA or BLA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months, from the filing date, in which to complete its initial review of a new molecular-entity NDA or original BLA and respond to the applicant, and six months from the filing date of a new molecular-entity NDA or original BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs or BLAs, and the review process is often extended by FDA requests for additional information or clarification.

Before approving an NDA or BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates an NDA or BLA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA or BLA identified by the FDA. The Complete Response Letter may require additional clinical data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

Expedited Development and Review Programs

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs and biologics that meet certain criteria. Specifically, new drugs and biologics are eligible for fast track designation if they are intended to treat a serious or life threatening condition and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. The sponsor can request the FDA to designate the product for fast track status any time before receiving NDA or BLA approval, but ideally no later than the pre-NDA or pre-BLA meeting.

Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it treats a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies.

A product may also be eligible for accelerated approval, if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate 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, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. If the FDA concludes that a drug or biologic shown to be effective can be safely used only if distribution or use is restricted, it may require such post-marketing restrictions, as it deems necessary to assure safe use of the product.

Additionally, a drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The benefits of breakthrough therapy designation include the same benefits as fast track designation, plus intensive guidance from the FDA to ensure an efficient drug development program. Fast track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process.

Abbreviated Licensure Pathway of Biological Products as Biosimilar or Interchangeable

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products shown to be highly similar to an FDA-licensed reference biological product. An application for licensure of a biosimilar product must include information demonstrating biosimilarity based upon the following, unless the FDA determines otherwise:

- analytical studies demonstrating that the proposed biosimilar product is highly similar to the approved product notwithstanding minor differences in clinically inactive components;
- animal studies (including the assessment of toxicity); and
- a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) sufficient to demonstrate safety, purity and potency in one or more conditions for which the reference product is licensed and intended to be used.

In addition, an application must include information demonstrating that:

- the proposed biosimilar product and reference product utilize the same mechanism of action for the condition(s) of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism(s) of action are known for the reference product;
- the condition or conditions of use prescribed, recommended, or suggested in the labeling for the proposed biosimilar product have been previously approved for the reference product;
- the route of administration, the dosage form, and the strength of the proposed biosimilar product are the same as those for the reference product; and
- the facility in which the biological product is manufactured, processed, packed or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

Biosimilarity means that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and that there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product. In addition, the law provides for a designation of "interchangeability" between the reference and biosimilar products, whereby the biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product. The higher standard of interchangeability must be demonstrated by information sufficient to show that:

- the proposed product is biosimilar to the reference product;
- the proposed product is expected to produce the same clinical result as the reference product in any given patient; and

•for a product that is administered more than once to an individual, the risk to the patient in terms of safety or diminished efficacy of alternating or switching between the biosimilar and the reference product is no greater than the risk of using the reference product without such alternation or switch.

FDA approval is required before a biosimilar may be marketed in the United States. In addition, as with BLAs, biosimilar product applications will not be approved unless the product is manufactured in facilities designed to assure and preserve the biological product's safety, purity and potency.

The timing of final FDA approval of a biosimilar for commercial distribution depends on a variety of factors, including whether the manufacturer of the branded product is entitled to one or more statutory exclusivity periods, during which time the FDA is prohibited from approving any products that are biosimilar to the branded product. The FDA cannot approve a biosimilar application for twelve years from the date of first licensure of the reference product. Additionally, a biosimilar product sponsor may not submit an application for four years from the date of first licensure of the reference product. A reference product may also be entitled to exclusivity under other statutory provisions. For example, a reference product designated for a rare disease or condition (an "orphan drug") may be entitled to seven years of exclusivity, in which case no product that is biosimilar to the reference product may be approved until either the end of the twelve-year period provided under the biosimilarity statute or the end of the seven-year orphan drug exclusivity period, whichever occurs later. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block biosimilarity applications from being approved on or after the patent expiration date. In addition, the FDA may under certain circumstances extend the exclusivity period for the reference product by an additional six months if the FDA requests, and the manufacturer undertakes, studies on the effect of its product in children, a so-called pediatric extension.

Post-Approval Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping requirements, requirements to report adverse experiences, and comply with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA/BLA or NDA/BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the product. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

•the restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;

•fines, warning letters or holds on post-approval clinical studies;

•refusal of the FDA to approve pending applications or supplements to approved applications;

•applications, or suspension or revocation of product license approvals;

•product seizure or detention, or refusal to permit the import or export of products; or

•injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Drugs and biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Other U.S. Regulatory Laws

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, or HHS, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments.

For example, in the United States, our business operations, including any sales, marketing and scientific and educational programs, also must comply with state and federal fraud and abuse laws, including the federal Anti-Kickback Statue and false claims laws; federal data privacy and security laws; and federal transparency laws related to payments and/or other transfers of value made to physicians and other healthcare professionals and teaching hospitals. The federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Moreover, the Patient Protection and Affordable Health Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Federal false claims laws, including the False Claims Act, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of federal funds, and knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme or artifice 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 by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. 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.

Many states have similar laws and regulations that may differ from federal law in significant ways, thus complicating compliance efforts. For example, states have anti-kickback and false claims laws that may be broader in scope than analogous federal laws and may apply regardless of payor. In addition, the federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act," created under the ACA and its implementing regulations, require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses and their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information as well as their covered subcontractors, relating to the privacy, security, and transmission of such individually identifiable health information. In addition, state data privacy laws that protect the security of health information may differ from each other and may not be preempted by federal law.

Moreover, several states and local jurisdictions have enacted legislation requiring pharmaceutical manufacturers to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales and marketing activities, report information related to drug pricing, require the registration of sales representatives, and prohibit certain other sales and marketing practices. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above.

Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of biologic and pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

Failure to maintain compliance with these healthcare laws could result in the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, 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.

Data Privacy and Security

Data privacy and security laws in the U.S. are also increasingly complex and changing rapidly. Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. These state laws allow for statutory fines for noncompliance.

In addition, the processing of personal data in connection with clinical trials in the EU must comply with the EU's General Data Protection Regulation, or EU GDPR. The EU GDPR imposes stringent data protection requirements and provides for penalties for noncompliance that can include bans on processing personal data and fines of up to the greater of 20 million euros or four percent of worldwide annual revenues. The EU GDPR requires organizations to give detailed disclosures about how they collect, use and share personal data; under certain conditions, obtain explicit consent to process sensitive personal data, such as health or genetic information; contractually require vendors to meet data protection requirements; maintain adequate data security measures; notify regulators and affected individuals of certain data breaches; meet extensive privacy governance and documentation requirements; and afford individuals' data protection rights, including their rights to access, correct and delete their personal data.

European data protection laws generally restrict the transfer of personal data from Europe, including from the European Economic Area, the United Kingdom and Switzerland, to the U.S. and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. Legal challenges have in the past and may in the future be successful in limiting the mechanisms available to transfer personal data across national borders.

The failure to comply with any of these laws, regulatory, or other legal requirements may result in legal and regulatory actions. Depending on the circumstances, failure to meet applicable obligations can result in significant penalties, including administrative, civil, and criminal penalties, fines, imprisonment, disgorgement, injunctions, exclusion from participation in federal healthcare programs, integrity oversight and reporting obligations, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts. Any action against us for violation of these obligations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

U.S. Health Care Reform

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (1) changes to our manufacturing arrangements; (2) additions or modifications to product labeling; (3) the recall or discontinuation of our products; or (4) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. Further, the United States, there have been and continue to be a number of healthcare-related legislative initiatives that have significantly affected the healthcare industry. For example, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear how any additional challenges and healthcare form measures of the second Trump administration will impact the ACA and our business.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs that have been on the market for at least 7 years and biologics that have been on the market for at least 11 years covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, or the Medicare Drug Price Negotiation Program, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions began to take effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

U.S. Patent-Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of any future product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent-term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA or BLA plus the time between the submission date of an NDA or BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA or BLA.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of a NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for a NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

A reference biological product is granted twelve 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. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity, or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

European Union Drug Development

As in the United States, medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority, or NCA, and one or more Ethics Committees, or ECs. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical-trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. Recently enacted Clinical Trials Regulation EU No 536/2014 ensures that the rules for conducting clinical trials in the EU will be identical. In the meantime, Clinical Trials Directive 2001/20/EC continues to govern all clinical trials performed in the EU.

European Union Drug Review and Approval

In the European Economic Area, or EEA, which is comprised of the 27 Member States of the European Union (including Norway and excluding Croatia), Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations.

- The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another 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 various 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, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (*i.e.,* in the RMS and the Member States Concerned).

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Coverage and Reimbursement

Sales of our products will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. In the United States no uniform policy of coverage and reimbursement for drug or biological products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Adoption of general controls and measures, coupled with the tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceutical drugs.

The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP and adding a new rebate calculation for "line extensions" (*i.e.,* new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. CMS has proposed to expand Medicaid rebate liability to the territories of the United States as well.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan likely will be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. In 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, as 340B drug prices are determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.

As noted above, the marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. An increasing emphasis on cost containment measures in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In addition, in most foreign 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. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Intellectual Property

We strive to protect and enhance the proprietary technology, inventions, and improvements that are commercially important to our business, including seeking, maintaining, and defending patent rights. We seek to protect our proprietary position by, among other methods, filing patent applications in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements, and product candidates that are important to the development and implementation of our business. We also rely on trade secrets and know-how relating to our proprietary technology and product candidates and continuing innovation to develop, strengthen, and maintain our proprietary position in the field. Although we are not party to any material in-license agreements as of the date of this Annual Report on Form 10-K, we may in the future pursue in-licensing opportunities to strengthen our proprietary position in the field. We additionally rely on data exclusivity, market exclusivity, and patent term extensions when available, and may seek and rely on regulatory protection afforded through orphan drug designations. Our commercial success may depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions, and improvements; to preserve the confidentiality of our trade secrets; to defend and enforce our proprietary rights, including our patents; and to operate without infringing the valid and enforceable patents and other proprietary rights of third parties.

We have prosecuted numerous patents and patent applications and possess know-how and trade secrets relating to the development and commercialization of our ABC Platform and product candidates, including related manufacturing processes and technology. As of December 31, 2024, we were the assignee of record for approximately 14 U.S. issued patents, and the applicant for approximately 18 U.S. pending patent applications and 9 pending PCT applications directed to certain of our proprietary technology, inventions, and improvements and our most advanced product candidates, as well as 49 patents issued in jurisdictions outside of the United States and 63 patent applications pending in jurisdictions outside of the United States that, in many cases, are counterparts to the foregoing U.S. patents and patent applications. For example, these patents and patent applications include claims directed to:

- therapeutic proteins and biologically active agents conjugated to a biopolymer;
- specific therapeutics; and
- components of our therapeutics.

The following patents and patent applications (including anticipated 20-year expiration dates, which could be altered by, for example, a disclaimer, patent term adjustment or patent term extension) relate to tarcocimab, KSI-501, KSI-101 and/or ABC Platform:

Patent and Patent Application Numbers	Anticipated U.S. Expiration Date	Description of Representative U.S. Claims
US 8,846,021	2/28/2027	Representative claims include conjugates
US Appl. No. 18/638556, AU Patent No. 2011239434, AU Patent No. 2017201930, BR Patent No. 11 2012 0261185, CA Patent No. 2795667, EP Patent No. 2558538, EP Patent No. 3549963, HK Patent No. 40015590, JP Patent No. 6568748, JP	4/15/2031	Representative claims include conjugates

Patent No. 6754749, JP Patent No. 7217245, KR Patent No. 10-2416359, KR Patent No. 10-2562175, and MX Patent No. 365521		
US 8,765,432, US 11,819,531, US Appl. No. 18/490,182, AU Patent No. 2010330727, BR Patent No. 1120120145568, CA Patent No. 2783615, CA Patent No. 3039426, EP Patent No. 2512462, EP Patent No. 3254678, EP Patent No. 3659591, CN Patent No. ZL201080062252.7, HK Patent No. 1247828, IN Patent No. 319269, JP Patent No. 5760007, JP Patent No. 5990629, JP Patent No. 6416832, JP Patent No. 6777706, MX Patent No. 346423, MX Patent No. 374020, KR Patent No. 10-1852044, and MO Patent No. J/002943	5/10/2030	Representative claims include copolymers and methods of making copolymers (ABC Platform specifically)
US 10,702,608, US 11,590,235, US 12,214,044, EP Patent No. 3041513, JP Patent No. 6463361, JP Patent No. 6732056, JP Patent No. 7232796, and foreign applications in certain jurisdictions claiming priority to PCT/US2014/054622	12/21/2034	Representative claims include polymers and method of making polymers
US 11,066,465, US Appl. No. 17/301599, AU Patent No. 2016381964, IL Patent No. 260323, JP Patent No. 7088454, JP Patent No. 7414371, MX Patent No. 407292, RU Patent No. 2744860, and foreign applications in certain jurisdictions claiming priority to PCT/US2016/069336	12/29/2036	Representative claims include antibody and antibody conjugate, and methods of making and using the conjugates
US Patent No. 11,912,784, US Appl. No. 18/504723, and foreign applications in certain jurisdictions claiming priority to PCT/US2020/055074	10/9/2040	Representative claims include method of treating an eye disorder using the antibody conjugates
US Appl. No. 18/555122, EP and HK applications claiming priority to PCT/US2022/024598	4/13/2042	Representative claims include method of treating an eye disorder using the antibody conjugates
US Appl. No. 18/166755 and foreign applications in certain jurisdictions claiming priority to PCT/US2023/062322	2/9/2043	Representative claims include method of purifying the antibody conjugates
PCT Application No. PCT/US2023/074805	9/21/2043	Representative claims include methods of preparing a protein solution or therapeutic formulation
US Patent No. 12,071,476, US Appl. No. 18/736105 and foreign applications in certain jurisdictions claiming priority to PCT/US2019/020418	3/1/2039	Representative claims include fusion proteins and conjugates thereof, and methods of making and using the fusion proteins and the conjugates
US Appl. No. 17/997866 and EP application claiming priority to PCT/US2021/031194	5/6/2041	Representative claims include method of treating a disorder related to an infection or a systemic inflammatory condition using fusion proteins and conjugates thereof

PCT Application No. PCT/US2023/082545	12/5/2043	Representative claims include formulations of a fusion protein and conjugates thereof, and methods of producing the same
PCT Application No. PCT/US2024/032770	6/6/2044	Representative claims include protein conjugate formulation and methods of preparing the formulation
PCT Application No. PCT/US2024/032771	6/6/2044	Representative claims include method and apparatus for analyzing a mixed formulation of proteins and protein conjugates thereof
PCT Application No. PCT/US2024/058543	12/4/2044	Representative claims include fusion protein / conjugate formulations

In the normal course of business, we intend to pursue, when possible, composition, method of use, dosing and formulation patent protection, as well as manufacturing and drug development processes and technology. The patents and patent applications we have filed outside of the United States are in Europe, Japan, and various other jurisdictions.

Individual patents extend for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance, and the legal term of patents in the countries in which they are obtained. Generally, patents issued for applications filed in the United States are effective for 20 years from the earliest effective filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period. The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The duration of patents outside of the United States varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date.

Our issued U.S. patents will expire on dates ranging from 2027 to 2040. If patents are issued on our pending patent applications, the resulting patents are projected to expire on dates ranging from 2030 to 2044. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country, and the validity and enforceability of the patent.

As of December 31, 2024, we have a total of 33 pending trademark applications and issued trademark registrations. These include two trademark registrations and three pending trademark applications in the United States, and 27 trademark registrations and one pending trademark application in jurisdictions outside of the United States. Of the trademark registrations in jurisdictions outside of the United States, 17 are in China, 2 are in each of the European Union, Japan and the United Kingdom, and one is in each of Canada, India, Singapore and Switzerland. The pending trademark application in a jurisdiction outside of the United States is in Canada. We also may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We seek to protect our technology and product candidates, in part, by entering into confidentiality agreements with those who have access to our confidential information, including our employees, contractors, consultants, collaborators, and advisors. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. Although we have confidence in these individuals, organizations, and systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or may be independently discovered by competitors. To the extent that our employees, contractors, consultants, collaborators, and advisors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For this and more comprehensive risks related to our proprietary technology, inventions, improvements and products, please refer to the section on "Part I, Item 1A — Risk Factors—Risks Related to Our Intellectual Property."

Human Capital Management

As of December 31, 2024, we had 109 employees worldwide, of whom 10 were based outside of the United States. Of these employees, 74 employees were engaged in or support research, development and clinical activities, 29 of whom hold a Ph.D. degree or M.D. (or equivalent) degree. None of our employees is subject to a collective bargaining agreement. We continually assess employee turnover, recruitment initiatives, compensation and benefits programs, safety in performing critical laboratory work, diversity and other matters relevant to human capital management, and we review results with our Board of Directors on a periodic basis. We aim to offer competitive compensation (including salary, incentive bonus, and equity) and benefits packages in each of our locations and in each of employee groups at each level around the globe as assessed with internal and external benchmarking data.

Additional Information

We were formed as a limited liability company on June 22, 2009 under the name Oligasis LLC, and subsequently changed our name to Kodiak Sciences Inc. and converted into a corporation which was incorporated in the state of Delaware on September 8, 2015. Our principal executive office is located at 1250 Page Mill Road, Palo Alto, California 94304. Our telephone number is (650) 281-0850.

We maintain an internet website at the following address: https://kodiak.com. The information on our website is not incorporated by reference in this Annual Report on Form 10-K or in any other filings we make with the Securities and Exchange Commission, or SEC.

We make available on or through our website certain reports and amendments to those reports that we file with or furnish to the SEC in accordance with the Securities Exchange Act of 1934, as amended, or the Exchange Act. These include our annual reports on Form 10-K, our quarterly reports on Form 10-Q, and our 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. We make this information available on or through our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC. In addition, the SEC maintains a website at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

ITEM 1A. RISK FACTORS

You should consider carefully the following risk factors, together with all the other information in this report, including the section of this report titled "Part II, Item 7 — Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and notes thereto. The occurrence of any events described in the following risk factors and the risks described elsewhere in this report could harm our business, operating results, financial condition, and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements that we have made in this report and those may make from time to time. You should consider all of the risk factors described when evaluating our business.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

We are in the clinical stage of drug development and have a very limited operating history and no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability.

We are a clinical stage biopharmaceutical company committed to researching, developing and commercializing transformative therapeutics to treat a broad spectrum of retinal diseases. We commenced operations in June 2009, have no products approved for commercial sale and have not generated any revenue. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have conducted clinical trials, including Phase 3 pivotal clinical trials, of tarcocimab in patients with wet AMD, DME, DR and RVO. We completed enrollment for the Phase 3 GLOW2 clinical trial of tarcocimab in patients with DR and continued enrollment for the on-going Phase 3 DAYBREAK clinical trial of tarcocimab and KSI-501 in patients with wet AMD and Phase 1b APEX clinical trial of KSI-101 in patients with DME and patients with MESI.

To date, we have not obtained marketing approval for any of our product candidates, manufactured a commercial scale product, or conducted sales and marketing activities necessary for successful product commercialization. Our limited operating history as a company and stage of drug development make any assessment of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by biopharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully overcome such risks and difficulties. If we do not address these risks and difficulties successfully, our business will suffer.

Our prospects are heavily dependent on our tarcocimab, KSI-501 and KSI-101 product candidates, which are currently in clinical development for multiple indications.

Our prospects will be heavily dependent on our tarcocimab, KSI-501 and KSI-101 product candidates and the results of planned or pending clinical studies. We cannot be certain that our product candidates will be successful in any of the planned or pending clinical trials.

Our previous clinical trial results are not necessarily predictive of the results of our on-going or future discovery programs or any future preclinical or clinical studies. Our ability to demonstrate efficacy, safety and clinical durability in pivotal studies may be affected by the patient populations sampled and the design of our pivotal studies. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical studies after achieving positive results in previous clinical studies, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical studies were underway or safety or efficacy observations made in preclinical studies and clinical studies, including previously unreported or unobserved adverse events as more patients are treated and followed for longer periods of time.

For example, in our Phase 2b/3 DAZZLE clinical trial evaluating the efficacy, durability and safety of tarcocimab in treatment-naïve subjects with neovascular wet AMD and in our Phase 3 GLEAM and GLIMMER studies, tarcocimab did not meet the primary efficacy endpoint of showing non-inferior visual acuity gains.

There can be significant variability in safety or efficacy results between different clinical studies of the same product candidate due to numerous factors, including changes in study procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical study protocols and the rate of dropout among clinical study participants. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical studies nonetheless failed to obtain FDA approval. If approved, clinical study designs and data are not necessarily predictive of the final marketed product label. FDA may not approve a label for a particular dosing frequency, even if we believe the data demonstrate support for that dosing.

We have conducted a Phase 1 study of KSI-501 to evaluate the safety, tolerability and bioactivity of KSI-501 in DME. Although we have continued enrolling patients in the Phase 3 DAYBREAK study for patients with wet AMD, it could take years before a registrational-type trial is completed, if at all. In addition, we initiated a dose-finding Phase 1b APEX study in 2024 and may initiate dual Phase 2b/3 studies, PEAK and PINNACLE. We may in the future develop other product candidates, advance additional product candidates into clinical trials and terminate such trials prior to their completion. It will take additional investment and time for such programs to reach the same stage of development as tarcocimab, KSI-501 and KSI-101.

The failure of pivotal studies of tarcocimab to meet their primary efficacy endpoints may lead us to pause, change or discontinue development of other product candidates based on our ABC Platform.

In July 2023, we announced that the Phase 3 GLEAM and GLIMMER clinical trials of tarcocimab did not meet their primary efficacy endpoints and, as a result, we paused further development of tarcocimab pending review of Year 1 data from the Phase 3 BEACON study in patients with RVO and the Phase 3 GLOW1 study patients with DR. Although we resumed the development of tarcocimab in November 2023, we may again determine to discontinue development of tarcocimab or our ABC Platform or other product candidates based on future information or trials results, which could prevent us from, or significantly delay, achieving profitability and could result in disruptions to our business including potential impairment charges, restructuring costs, or costs that are greater than expected.

Our plan for the development of tarcocimab, KSI-501 or KSI-101 may be unsuccessful.

We resumed further development of tarcocimab in November 2023 following the outcomes of two other trials that were then underway. While we have previous trials with favorable results and we have since resumed development of tarcocimab, further development of tarcocimab may ultimately not be successful. In connection with our development program, we developed an enhanced, commercial formulation of tarcocimab. While the FDA has advised that the additional clinical studies to be conducted with the revised formulation should be sufficient to bridge the former material to the go-to-market material, we cannot be sure that the FDA, EMA or comparable foreign regulatory authorities would agree or accept our planned BLA even if our planned additional trials are successful.

Research and development of biopharmaceutical products is inherently risky. We cannot give any assurance that any of our product candidates will receive regulatory, including marketing, approval, which is necessary before they can be commercialized.

We are at an early stage of development of our product candidates. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize our product candidates, and we may fail to do so for many reasons, including the following:

- our product candidates have in the past and may in the future not successfully complete preclinical studies or clinical trials;
- if a product candidate obtains regulatory approval, approval may be for indications, dosage and administration or patient populations that are not as broad as intended or desired;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria, for example a positive benefit-risk profile;
- our competitors may develop therapeutics that render our product candidates obsolete or less attractive;
- our competitors may develop platform technologies that render our ABC Platform obsolete or less attractive;
- the product candidates and ABC Platform that we develop may not be sufficiently covered by intellectual property for which we hold exclusive rights or may be covered by third party patents or other intellectual property or exclusive rights;
- the market for a product candidate may change so that the continued development of that product candidate is no longer reasonable or commercially attractive;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- if a product candidate obtains regulatory approval, we may be unable to establish sales and marketing capabilities, or successfully market such approved product candidate, to gain market acceptance; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable.

If any of these events occurs, we may be forced to abandon our development efforts for a product candidate or candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations. Failure of a product candidate may occur at any stage of preclinical or clinical development, and, because our product candidates and our ABC Platform are in development, there is a relatively higher risk of failure and we may never succeed in developing marketable products or generating product revenue.

Further, we may not be successful in our efforts to further develop our product candidates and our ABC Platform in time to meet the current and identified market opportunity. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Each of our product candidates is in various stages of development and will require significant additional clinical development, management of preclinical, clinical, and manufacturing activities, regulatory approval, adequate manufacturing supply, a commercial organization, and significant marketing efforts before we generate any revenue from product sales, if at all. Any clinical studies that we may conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. If the results of our on-going or future clinical studies are inconclusive with respect to the efficacy of our product candidates or if we do not meet the clinical endpoints with statistical significance or if there are safety concerns or adverse events associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for our product candidates.

If any of our product candidates successfully completes clinical trials, we generally plan to seek regulatory approval to market our product candidates in the United States, the EU, and in additional foreign countries where we believe there is a viable commercial opportunity. We have never commenced, compiled or submitted an application seeking regulatory approval to market any product candidate in any jurisdiction. We may never receive regulatory approval to market any product candidates even if such product candidates successfully complete clinical trials, which would adversely affect our viability. To obtain regulatory approval in countries outside the United States, we must comply with numerous and varying regulatory requirements of such other countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical trials, commercial sales, pricing, and distribution of our product candidates. We may also rely on our collaborators or partners to conduct the required activities to support an application for regulatory approval, and to seek approval, for one or more of our product candidates. We cannot be sure that our collaborators or partners will conduct these activities successfully or do so within the timeframe we desire. Even if we (or our collaborators or partners) are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. If we are unable to obtain approval for our product candidates in multiple jurisdictions, our revenue and results of operations could be negatively affected.

Even if we receive regulatory approval to market any of our product candidates, we cannot assure you that any such product candidate will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. That approval may be for indications, dosage and administration or patient populations that are not as broad as intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We may also be required to perform additional or unanticipated clinical studies to obtain approval or be subject to additional post-marketing testing requirements to maintain regulatory approval. In addition, regulatory authorities may withdraw their approval of a product or impose restrictions on its distribution, such as in the form of a modified Risk Evaluation and Mitigation Strategy, or REMS. The failure to obtain timely regulatory approval of product candidates, any product marketing limitations or a product withdrawal would negatively impact our business, results of operations and financial condition.

Investment in biopharmaceutical product development involves significant risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We cannot provide any assurance that we will be able to successfully advance any of our product candidates through the development process or, if approved, successfully commercialize any of our product candidates.

We may encounter substantial delays in our clinical trials, or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all.

Clinical testing is expensive, time consuming, and subject to uncertainty. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. We cannot be sure that submission of an IND application or a clinical trial application, or CTA, will result in the FDA, European Medicines Agency, or EMA, or any other regulatory authority as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Events that may prevent successful or timely initiation or completion of clinical trials include:

•inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;

•delays in reaching a consensus with regulatory agencies on study design;

•the determination by the reviewing regulatory authority to require more costly or lengthy clinical trials than we currently anticipate;

•delays in reaching agreement on acceptable terms with clinical trial sites or other third-party vendors, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites or vendors;

•delays in identifying, recruiting and training suitable clinical investigators;

•delays in obtaining required Institutional Review Board, or IRB, approval at each clinical trial site;

•imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND or amendment, CTA or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical trial operations or study sites; developments on trials conducted by competitors for related technology that raises FDA, EMA or any other regulatory authority concerns about risk to patients of the technology broadly; or if the FDA, EMA or any other regulatory authority finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;

•delays in identifying, recruiting and enrolling suitable patients to participate in our clinical trials, and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;

•difficulty collaborating with patient groups and investigators;

•failure by third parties or us to adhere to clinical trial requirements;

•failure to perform in accordance with the FDA's or any other regulatory authority's good clinical practices, or GCPs, requirements, or applicable EMA or other regulatory guidelines in other countries;

•occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;

•changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;

•changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;

•the cost of clinical trials of our product candidates being greater than we anticipate;

•clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates;

•transfer of manufacturing processes to larger-scale facilities operated by CMOs or by us, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and

•delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials and for use in regulatory filings or the inability to do any of the foregoing.

Any inability to successfully initiate or complete clinical trials could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board for such trial or by the FDA, EMA or any other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Regulatory authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. We may also face delays if we are unable to reach agreement with the FDA, EMA or other regulatory authorities regarding CMC matters, including methodologies for, and assessment of, comparability of manufacturing procedures and lots.

Delays in the commencement, conduct or completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Adverse events or other undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EMA or other comparable foreign regulatory authorities.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. It is possible that as we test our product candidates in larger, longer and more extensive clinical trials, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were not observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational products are tested in large-scale Phase 3 clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that any of our product candidates has side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, or, if the product candidate has received regulatory approval, such approval may be revoked, which would severely harm our business, prospects, operating results and financial condition. For example, in the tarcocimab arms of our completed GLEAM and GLIMMER clinical trials, we observed an unexpected increase in cataracts, which we believe may have contributed meaningfully to the failure of each study to meet its primary efficacy endpoint.

Our most advanced product candidate, tarcocimab, is an anti-VEGF biologic that we have studied in wet AMD, DME, DR and RVO. Our KSI-501 product candidate is a first-in-class bispecific antibody conjugate designed to inhibit two mechanisms implicated in retinal diseases: IL-6 and VEGF. Our KSI-101 product candidate is the unconjugated protein portion of KSI-501 and is a novel bispecific protein targeting IL-6 and VEGF. There are some potential side effects associated with intravitreal anti-VEGF therapies such as intraocular hemorrhage, intraocular pressure elevation, retinal detachment, inflammation, vasculitis, artery occlusion or infection inside the eye, progression of cataract, and over-inhibition of VEGF, as well as the potential for potential systemic side effects such as heart attack, stroke, wound healing problems and high blood pressure. Recent trends in the development of anti-VEGF therapies have favored increased molar dosages, as compared to currently marketed treatments. To date these heightened dosages have not exhibited a safety profile significantly worse than that of current treatments, as attributable to molar dose. However, anti-VEGF product candidates featuring higher molar dosages, including tarcocimab, KSI-501 and KSI-101 may heighten the risk of adverse effects associated with anti-VEGF treatments generally, both in the eye and in the rest of the body. There are risks inherent in the intravitreal injection procedure of drugs like tarcocimab, KSI-501 and KSI-101 which can cause injury to the eye and other complications including conjunctival hemorrhage, punctate keratitis, eye pain, conjunctival hyperemia, intra-ocular inflammation and endophthalmitis. Any additional toxicology signal observed, be it real or perceived, may negatively impact perceptions of utilization of tarcocimab, KSI-501 and KSI-101 in broader populations and impact clinical trial enrollment, regulatory approval and commercial success.

Drug-related side effects could affect patient recruitment, the ability of enrolled patients to complete the study and/or result in potential product liability claims. We may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical trial participants, costs due to related litigation, distraction of management's attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates and decreased demand for our product candidates, if approved for commercial sale.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

We may encounter difficulties enrolling patients in our clinical trials, and our clinical development activities could thereby be delayed or otherwise adversely affected.

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. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol, including certain highly-specific criteria related to stage of disease progression, which may limit the patient populations eligible for our clinical trials to a greater extent than competing clinical trials for the same indication that do not have such patient eligibility criteria;
- the size of the study population required for analysis of the trial's primary endpoints;
- the proximity of patients to a trial site;
- the effects of health epidemics, including the resulting shelter-in-place, travel or similar restrictions;
- the design of the trial;
- new safety events may cause physicians to decrease patient enrollment in our current or planned studies;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or targeting patient populations meeting our patient eligibility criteria;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies and product candidates;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will not complete such trials, for any reason.

Our inability to enroll a sufficient number of patients for our clinical trials could result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, delay or halt the development of and approval processes for our product candidates and jeopardize our ability to commence sales of and generate revenues from our product candidates, which may harm our business and results of operation.

Our clinical trials may fail to demonstrate substantial evidence of the durability, efficacy and safety of our product candidates, which would prevent, delay or limit the scope of regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. For those product candidates that are subject to regulation as biological drug products, we will need to demonstrate that they are safe, pure, and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use, which is especially true for anti-VEGF biologic agents, where available marketed therapies are well-established products with accepted safety profiles.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. The results of preclinical studies of our product candidates may not be predictive of the results of early-stage or later-stage clinical trials, and results of early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. The results of clinical trials in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety, efficacy or durability results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. Product candidates in later stages of clinical trials may fail to show the desired safety, efficacy and durability profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. For example, in our Phase 2b/3 DAZZLE clinical trial evaluating the efficacy, durability and safety of tarcocimab in treatment-naïve subjects with neovascular wet AMD and in our Phase 3 GLEAM and GLIMMER studies, tarcocimab did not meet the primary efficacy endpoint of showing non-inferior visual acuity gains.

We may be unable to design and execute clinical trials that support marketing approval. We cannot be certain that our planned clinical trials or any other future clinical trials will be successful. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations.

In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials or trials of a different design could be required before we submit our product candidates for approval. To the extent that the results of trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidate, which may also limit its commercial potential. Even if trial results are successful at the primary endpoint, clinical trial results may be different or worse in the extended treatment periods following the primary endpoint, and such data may negatively impact perceptions by regulatory authorities, the clinical community or commercial payors of the benefits of our product candidates.

We may not be successful in our efforts to continue to create a pipeline of product candidates or to develop commercially successful products. If we fail to successfully identify and develop additional product candidates, our commercial opportunity may be limited.

Our research methodology may be unsuccessful in identifying potential product candidates, or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make them unmarketable or unlikely to receive marketing approval. Identifying, developing, obtaining regulatory approval and commercializing additional product candidates for the treatment of retinal diseases will require substantial additional funding and is prone to the risks of failure inherent in drug development. If we are unable to successfully identify, acquire, develop and commercialize additional product candidates, our commercial opportunity may be limited.

One of our strategies is to identify and pursue clinical development of product candidates based on our ABC Platform. Our ABC Platform may not produce a pipeline of viable product candidates, or our competitors may develop platform technologies that render our ABC Platform obsolete or less attractive.

We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may retain their market share with existing drugs, or achieve regulatory approval before us or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize any product candidates we may develop and ultimately harm our financial condition.

The development and commercialization of new drug products is highly competitive. We may face competition with respect to any product candidates that we seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. 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.

There are a number of large pharmaceutical and biotechnology companies that are currently pursuing the development of products for the treatment of the retinal diseases for which we have product candidates. Several of our competitors have commercially approved products for the treatment of retinal diseases that we are pursuing or may pursue in the future, including Roche, Regeneron and Novartis for the treatment of wet AMD, DME, DR and RVO. These drugs are well established therapies and are widely accepted by physicians, patients and third-party payors, which may make it difficult to educate these parties on the benefits of switching to any product candidates developed by us. Companies that we are aware are developing and/or commercializing therapeutics in the retinal disease area include large companies with significant financial resources, such as Roche, Novartis, Bayer, Regeneron, AbbVie, Boehringer Ingelheim, Amgen, and Samsung Bioepis. In addition to competition from other companies targeting retinal indications, any products we may develop may also face competition from other types of therapies, such as gene-editing therapies and drug delivery devices.

Roche's product, Vabysmo (faricimab) received FDA approval for the treatment of wet AMD and DME in January 2022 and received FDA approval for RVO in October 2023. Vabysmo has gained rapid adoption since launch and garnered significant market share. Regeneron's product, Eylea HD (high dose aflibercept) gained FDA approval for the treatment of wet AMD, DME and DR in August 2023. It has also become an important therapy in the marketplace due to Regeneron's incumbent position in retinal diseases. Even if our product candidates present a compelling clinical profile, we may not be able to market our product candidates as effectively as our competitors. For example, entrenched franchises may seek to impede adoption of our product candidates through significant discounts or rebates.

Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our product candidates. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Furthermore, currently approved products could be discovered to have application for treatment of retinal disease indications, which could give such products significant regulatory and market timing advantages over any of our product candidates. Our competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly than we may obtain approval for ours. Additionally, products or technologies developed by our competitors may render our product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors.

In addition, we could face litigation or other proceedings with respect to the scope, ownership, validity and/or enforceability of our patents relating to our competitors' products and our competitors may allege that our products infringe, misappropriate or otherwise violate their intellectual property. For more information regarding potential disputes concerning intellectual property, refer to section "Part I, Item 1A — Risk Factors—Risks Related to Our Intellectual Property" of this Annual Report on Form 10-K.

The manufacture of our product candidates is highly complex and requires substantial lead time to produce.

Manufacturing our product candidates involves complex processes, including developing cells or cell systems to produce the biologic, growing large quantities of such cells, and harvesting and purifying the biologic produced by them. These processes require specialized facilities, highly specific raw materials and other production constraints. As a result, the cost to manufacture a biologic is generally far higher than traditional small molecule chemical compounds, and the biologics manufacturing process is less reliable and is difficult to reproduce. Because of the complex nature of our products, we need to oversee the manufacture of multiple components that require a diverse knowledge base and specialized personnel. Commercial manufacturing scale-up timelines may be negatively affected by material shortages, construction delays and supply chain challenges due to, among other factors, global supply chain shortages due to health epidemics, on-going geopolitical conflicts, global macroeconomic conditions, bank failures or other reasons.

Moreover, unlike chemical pharmaceuticals, the physical and chemical properties of a biologic such as our product candidates generally cannot be adequately characterized prior to manufacturing the final product. As a result, an assay of the finished product is not sufficient to ensure that the product will perform in the intended manner. Accordingly, we expect to employ multiple steps to attempt to control our manufacturing process to assure that the process works, and the product or product candidate is made strictly and consistently in compliance with the process.

Manufacturing biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, improper storage or transfer, inconsistency in yields and variability in product characteristics. Even minor deviations from normal manufacturing, distribution or storage processes could result in reduced production yields, product defects and other supply disruptions. Some of the raw materials required in our manufacturing process are derived from biological sources. Such raw materials are difficult to procure and may also be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt commercialization. Production of additional drug substance and drug product for any of our product candidates may require substantial lead time. In the event of significant product loss and materials shortages, we may be unable to produce adequate amounts of our product candidates or products for our operational needs.

Further, as product candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials.

We rely on third parties for raw materials needed for manufacturing our product candidates. We may not be able to obtain adequate amounts in the future. These challenges are magnified by the international nature of our supply chain, which, for tarcocimab, KSI-501 and KSI-101, requires drug substance and drug product sourced from single source suppliers from China, Japan, the United Kingdom, the United States and Switzerland.

We have limited experience manufacturing any of our product candidates at a commercial scale. If we or any of our third-party manufacturers encounter difficulties in production, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our product candidates for clinical trials, or our ability to supply our products for patients, if approved, could be delayed or stopped, or we may be unable to establish a commercially viable cost structure.

In order to conduct clinical trials of our product candidates, or supply commercial products, if approved, we will need to manufacture them in small and large quantities. Our third-party manufacturer has made only a limited number of commercial scale lots of tarcocimab based on our ABC Platform. Our manufacturing partners may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If our manufacturing partners are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of our product candidates may be delayed or become infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. The same risks would apply to any internal manufacturing facilities, should we in the future decide to build internal manufacturing capacity.

In addition, the manufacturing process for any products that we may develop is subject to FDA, EMA and foreign regulatory authority approval processes and continuous oversight. We will need to contract with manufacturers who can meet all applicable FDA, EMA and foreign regulatory authority requirements, including complying with current good manufacturing practices, or cGMPs, on an on-going basis. If we or our third-party manufacturers are unable to reliably produce products to specifications acceptable to the FDA, EMA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA, EMA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. For example, our manufacturers are also engaged in the manufacturing of vaccines and other therapeutic treatments, and the success of and demand for these vaccines and other therapeutic treatments means we and our programs are competing for scarce manufacturing resources. We hope to distribute tarcocimab in a prefilled syringe early in our commercial rollout. We may not be able to complete our prefilled syringe activities in a timely manner, or we may fail technically to design and develop a prefilled syringe for tarcocimab. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects.

Changes in methods of manufacturing or formulation of product candidates may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, our manufacturing methods and formulation of product candidates may be altered in an effort to optimize manufacturing processes and results. For example, we have created an enhanced, commercial formulation of tarcocimab; however, these changes could cause tarcocimab to perform differently and affect the results of on-going clinical trials or other future clinical trials, and we may need to revert to a prior formulation and may be unable to recover the manufacturing costs of the drug product. In addition, changes to commercial formulations from those studied clinically could also lead regulatory authorities to delay the approval of our marketing applications until we can demonstrate through additional clinical data that there is comparability in the bioavailability of the two different formulations, or they may require us to revert to the prior formulation evaluated clinically. This could delay completion of clinical trials, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of tarcocimab or any future product candidates and jeopardize our ability to commence sales and generate revenue.

The development program and timeline of tarcocimab may impact our ability to use the Ursus Facility as intended, which could result in an excess of capital expenditures.

In August 2020, we, together with our wholly owned subsidiary Kodiak Sciences GmbH, entered into a manufacturing agreement with Lonza Ltd for the clinical and commercial supply of the Company's antibody biopolymer conjugate drug substance, which included a custom-built manufacturing facility for the potential clinical and commercial supply of tarcocimab, or the Ursus Facility. The development plan for tarcocimab, and any further changes thereto, as well as the timeline and success of tarcocimab, may impact our ability to fully utilize the Ursus Facility. We may not realize any benefit from the capital expenditures to date, and we may incur substantial additional expenses and capital expenditures to repurpose the Ursus Facility for our other product candidates or for use by third parties, any of which may negatively impact our operating results and financial condition.

Even if we are successful in utilizing the Ursus Facility, our manufacturing capabilities could be affected by cost-overruns, additional changes in our development plans, unexpected delays, equipment failures, labor shortages, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business. Any problems in our manufacturing process or facilities could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs.

If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing and commercial support infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved.

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

Factors that may inhibit our efforts to commercialize any approved product on our own include:

•our inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs and other support personnel;

•the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing any future approved products;

•the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors;

•the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability;

•restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;

•the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

•unforeseen costs and expenses associated with creating an independent commercialization organization.

If we enter into arrangements with third parties to perform sales, marketing, commercial support and distribution services, our product revenue or the profitability of product revenue may be lower than if we were to market and sell any products we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates if approved.

Even if any product candidates we develop receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

The commercial success of any of our product candidates will depend upon its degree of market acceptance by physicians, patients, third-party payors and others in the medical community. Even if any product candidates we may develop receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors, and others in the medical community. The degree of market acceptance of any product candidates we may develop, if approved for commercial sale, will depend on a number of factors, including:

•the efficacy and safety of such product candidates as demonstrated in pivotal clinical trials and published in peer-reviewed journals;

•the potential and perceived advantages of our product label as compared to alternative treatments;

•the ability to offer our products for sale at competitive prices;

•the ability to offer appropriate patient access programs, such as co-pay assistance;

•the extent to which physicians recommend our products to their patients;

•convenience and ease of dosing and administration compared to alternative treatments;

•the clinical indications for which the product candidate is approved by FDA, EMA or other regulatory agencies;

•product labeling or product insert requirements of the FDA, EMA or other comparable foreign regulatory authorities, including any limitations, contraindications or warnings contained in a product's approved labeling;

•restrictions on how the product is distributed;

•the timing of market introduction of competitive products;

•publicity concerning our products or competing products and treatments;

•the strength of marketing and distribution support;

•sufficient third-party coverage or reimbursement; and

•the prevalence and severity of any side effects.

If any product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenue, and we may not become profitable.

Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

Drug pricing and access policies in the United States and internationally may change and negatively impact the commercial viability of our product candidates. Proposed policy changes, including the potential for Medicare to negotiate with drug manufacturers, or the Medicare Drug Price Negotiation Program, under the Inflation Reduction Act of 2022, or the IRA, may limit our ability to competitively price our product candidates, if approved. Further, commercial insurers may limit patient access to our product candidates, if approved and other branded therapies. The regulations that govern marketing approvals, pricing and reimbursement for new drugs vary widely from country to country. In the United States, recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. 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 or product licensing approval is granted. In some foreign 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 in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

Our ability to successfully commercialize any products that we may develop also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Government authorities currently impose mandatory discounts for certain patient groups, such as Medicare, Medicaid and Veterans Affairs, or VA, hospitals, and may seek to increase such discounts at any time. Future regulation may negatively impact the price of our products, if approved. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, that the level of reimbursement will be sufficient.

Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to get reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the medicine is approved by the FDA, EMA or other comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Further, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. Our inability to promptly obtain and maintain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates, and our overall financial condition.

Our product candidates may face competition from biological products that are biosimilar to or interchangeable with our product candidates sooner than anticipated.

The Biologics Price Competition and Innovation Act of 2009, or 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 licensed 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 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.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk when and if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit testing and commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased or interrupted demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;

•product recalls, withdrawals or labeling, marketing or promotional restrictions;

•loss of revenue;

•exhaustion of any available insurance and our capital resources;

•the inability to commercialize any product candidate; and

•a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaborators. Our insurance policies may have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

The regulatory approval processes of the FDA, EMA and comparable foreign regulatory authorities are lengthy, time consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.

The time required to obtain approval by the FDA, EMA and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. We have not submitted for or obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

•the FDA, EMA or comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials or the portfolio of clinical trials planned for submission in our BLA;

•the FDA, EMA or comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use of our products;

•the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;

•we may be unable to demonstrate to the FDA, EMA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication(s), when compared to the standard of care, is acceptable;

•the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

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

•study data may not be positive in all clinical trials demonstrating a mix of positive and negative clinical trial results;

•the FDA, EMA or comparable foreign regulatory authorities may fail to approve the chemistry, manufacturing and controls processes, test procedures and specifications, or facilities or third-party manufacturers with which we contract for clinical and commercial supplies; and

•the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects.

We have conducted clinical trials for our product candidates outside the United States (or the respective jurisdictions of other regulatory authorities), and the FDA (or EMA and applicable foreign regulatory authorities) may not accept data from such trials.

We have conducted one or more of our clinical trials outside the United States, including Europe and other foreign countries. The acceptance of study data from global clinical trials by the FDA, EMA or applicable foreign regulatory authority may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (1) the data are applicable to the U.S. population and U.S. medical practice and (2) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies 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. There can be no assurance that the FDA, EMA or any applicable foreign regulatory authority will accept data from trials conducted outside of their respective jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming, would delay aspects of our business plan and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA, EMA or grants marketing approval of a product candidate, we would not be permitted to manufacture, market or promote the product candidate in other countries unless and until comparable regulatory authorities in foreign jurisdictions had approved the candidate for use in their countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials. There can be no assurance that any clinical trials conducted in one jurisdiction will be accepted by regulatory authorities in other jurisdictions.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any collaborator we work with fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to extensive obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements.

If any of our product candidates are approved, they will be subject to on-going regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive requirements imposed by the FDA, EMA and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA or marketing authorization application, or MAA. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates will be subject to limitations on the approved indicated uses for which the product may be marketed and promoted or to the conditions of approval (including the requirement to implement a REMS), or contain requirements for potentially costly post-marketing testing. We will be required to report certain adverse reactions and production problems, if any, to the FDA, EMA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have approval. The holder of an approved BLA or MAA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval was obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue fines, warning letters or other enforcement-related letters that would result in adverse publicity;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approvals;
- suspend any of our on-going clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities;
- seize or detain products; or
- require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with on-going 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.

In addition, the policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, the U.S. Supreme Court's June 2024 decision in *Loper Bright Enterprises v. Raimondo* overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper* decision could result in additional legal challenges to regulations and decisions issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain international jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since the ACA's enactment, there have been numerous challenges and amendments to the ACA. For example, on August 16, 2022, the IRA was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is unclear how any such challenges and any additional healthcare reform measures of the second Trump administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments to the statute, including the Infrastructure Investment and Jobs Act, will remain in effect until 2032 unless additional Congressional action is taken. Further, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap for single source and innovator multiple source drugs, effective January 1, 2024.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to receive or set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Moreover, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies. At the federal level, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs that have been on the market for at least 7 years and biologics that have been on the market for at least 11 years covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. These provisions began to take effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that the ACA, the IRA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement and new payment methodologies. This could lower the price that we receive for any approved product. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidates, if approved.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements or insider trading violations, which could significantly harm our business.

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the laws of the FDA, EMA and other comparable foreign regulatory authorities; provide true, complete and accurate information to the FDA, EMA and other comparable foreign regulatory authorities; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. In particular, research, sales, marketing, education and other business arrangements in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. Employee misconduct could also involve the improper use of, including improper trading based upon, information obtained in the course of clinical studies, which could result in regulatory sanctions and serious harm to our reputation.

We have adopted a code of business conduct and ethics that applies to all our employees, including management, and our directors. However, it is not always possible to identify and deter misconduct by employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. 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 significant fines or other sanctions.

If we fail to comply with healthcare laws, we could face substantial penalties and our business, operations and financial conditions could be adversely affected.

Our current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, as well as, sell, market and distribute any products for which we obtain marketing approval. The laws that may impact our operations include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. 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. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- federal civil and criminal false claims laws, including the False Claims Act, which can be enforced by private citizens on behalf of the government through civil whistleblower or qui tam actions, and civil monetary penalty laws, which impose criminal and civil penalties against individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, 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 by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses and their respective business associates and their subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information as well as their covered subcontractors, relating to the privacy, security and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the Centers for Medicare & Medicaid Services, or CMS, under the Open Payments Program, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistant and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

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

•analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could, despite our efforts to comply, be subject to challenge under one or more of such laws. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. 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 significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, 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. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

We and the third parties with whom we work are subject to stringent and evolving obligations related to data privacy and security. These obligations include U.S. and foreign laws, regulations and rules; contractual obligations; industry standards; and policies. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations and actions; litigation (including class claims) and arbitration; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue and profits; loss of sales; and other adverse business consequences.

In the ordinary course of business, we and the third parties with whom we work collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data (collectively, sensitive information). Our data processing activities subject us to numerous data privacy and security obligations such as various provincial, state, national, and foreign laws and regulations, as well as guidance, industry standards, internal privacy and security policies, contractual requirements, and other obligations related to data privacy and security. Data privacy and security laws and regulations are evolving and resulting in increased regulatory and public scrutiny and escalating levels of enforcement and sanctions.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws and other similar laws (e.g., wiretapping laws). Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights include, in relation to their personal data, the right to access, correct, delete and opt-out of certain data processing activities (such as targeted advertising, profiling and automated decision-making). The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. Certain of these state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act, or the CCPA, provides for civil penalties and a private right of action for certain data breaches (which could lead to the recovery of significant statutory damages). Although these laws may exempt some data processed in the context of clinical trials, these laws increase compliance costs and potential liability for us and the third parties with whom we work. Similar laws are being considered in other states as well as at the federal and local levels. We expect more states to pass similar laws in the future.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR, and the United Kingdom's GDPR, or UK GDPR (collectively, GDPR), impose strict requirements for processing personal data. Violators of these laws face significant penalties. For example, government regulators may impose temporary or definitive bans on data processing and other corrective actions, as well as fines of up to 20 million Euros (under the EU GDPR) or 17.5 million pounds sterling (under the UK GDPR), or 4% of annual global revenue, whichever is greater, under either law. Further, the EU and UK GDPR also provide for private litigation related to the processing of personal data that can be brought by classes of data subjects or consumer protection organizations authorized at law to represent the data subjects' interests.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data transfers. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms (such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement/Addendum, and the EU-U.S. Data Privacy Framework and the UK extension), that may be used to lawfully transfer personal data to the United States or other countries, these mechanisms are subject to legal challenges and there is no assurance that we can satisfy or rely on these measures. An inability or material limitation on our ability to transfer personal data to the United States or other countries could materially impact our business operations. If we cannot implement a valid compliance mechanism for cross-border data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe and other foreign jurisdictions. The inability to import personal data to the United States could significantly and negatively impact our business operations by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties that are subject to such cross-border data transfer or localization laws; or requiring us to increase our personal data processing capabilities and infrastructure in foreign jurisdictions at significant expense. Additionally, entities that transfer personal data across borders are subject to increased regulator, individual and activist group scrutiny. Some European regulators have ordered certain companies to suspend or permanently cease certain data transfers out of Europe for allegedly violating the GDPR's cross-border data transfer requirements.

In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and, we are, and may become in the future, subject to such obligations. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We also publish statements regarding data privacy and security. Regulators in the U.S. are increasingly scrutinizing these statements, and if these statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading or misrepresentative of our practices, we may be subject to investigation, enforcement actions and other adverse consequences.

Obligations related to data privacy and security (and individuals' data privacy and security expectations) are quickly changing, becoming increasingly stringent and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems and practices and to those of any third parties that process personal data on our behalf. In addition, these obligations may require us to change our business model.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations which could negatively impact our business. If we or any third party with whom we work fail or are perceived to have failed to address or comply with applicable obligations relating to data privacy and security, we could face significant consequences, including but not limited to: regulatory fines and bans on processing personal data; investigations and enforcement actions, penalties and other liabilities, litigation (including class action claims and mass arbitration demands); additional reporting requirements and/or oversight; orders to destroy or not use personal data; interruptions to our development process; and damage to our reputation, any of which could materially affect our business, financial condition, results of operations and growth prospects.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our business activities may be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery and anti-corruption laws.

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate or may operate in the future, including the UK Bribery Act. The FCPA generally prohibits offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There can be no assurance that all of our employees, agents, contractors or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

Risks Related to Our Reliance on Third Parties

We expect to rely on third parties to conduct many aspects of our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.

We currently rely and expect to continue to rely on third parties, such as clinical investigators, medical institutions, clinical data management organizations, and other third-party vendors, to conduct some aspects of our research, preclinical testing and clinical trials. Any of these third parties may terminate their engagements with us or be unable to fulfill their contractual obligations. If we need to enter into alternative arrangements, it would delay our product development activities.

Our reliance on these third parties for research and development activities reduces our control over these activities, but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible, reproducible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We are also required to register on-going clinical trials and to post the results of completed clinical trials on a government-sponsored database within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for any product candidates we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of any product candidates we may develop or commercialization of our medicines, producing additional losses and depriving us of potential product revenue.

We contract with third parties for the manufacture of materials for our product candidates and preclinical studies and clinical trials and for commercialization of any product candidates that we may develop. This reliance on third parties carries and may increase the risk that we will not have sufficient quantities of such materials, product candidates or any medicines that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We currently rely on a third-party manufacturer, Lonza AG, for the manufacture of our materials for preclinical studies and clinical trials and expect to continue to do so for preclinical studies, clinical trials and for commercial supply of any product candidates that we may develop.

We may be unable to establish any further agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

•the possible breach of the manufacturing agreement by the third party or us;

•the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;

•the possible early termination of the agreement by us at a time that requires us to pay a cancellation fee;

•reliance on the third party for regulatory compliance, quality assurance, safety and pharmacovigilance and related reporting; and

•the inability to produce required volume in a timely manner and to quality standards.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in clinical holds on our trials, sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or medicines, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our medicines and harm our business, financial condition, results of operations, and prospects.

Any medicines that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply for any of our product candidates. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer and may incur added costs and delays in identifying and qualifying any such replacement. Furthermore, securing and reserving production capacity with contract manufacturers may result in significant costs.

Our current and anticipated future reliance upon others for the manufacture of any product candidates we may develop or medicines may adversely affect our future profit margins and our ability to commercialize any medicines that receive marketing approval on a timely and competitive basis.

We rely on third-party suppliers for key raw materials used in our manufacturing processes, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials could harm our business.

We rely on third-party suppliers for the raw materials required for the production of our product candidates. Our reliance on these third-party suppliers and the challenges we may face in obtaining adequate supplies of raw materials involve several risks, including limited control over pricing, availability, quality and delivery schedules. As a small company, our negotiation leverage is limited and we are likely to get lower priority than our competitors who are larger than we are. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our product candidates, including limiting supplies necessary for clinical trials and regulatory approvals, which would have a material adverse effect on our business.

We may depend on collaborations with third parties for the research, development and commercialization of certain of the product candidates we may develop. If any such collaborations are not successful, we may not be able to realize the market potential of those product candidates.

We may seek third-party collaborators for the research, development and commercialization of certain of the product candidates we may develop. Our likely collaborators for any other collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies, biotechnology companies and academic institutions. If we enter into any such arrangements with any third parties, we will likely have shared or limited control over the amount and timing of resources that our collaborators dedicate to the development or potential commercialization of any product candidates we may seek to develop with them. Our ability to generate revenue from these arrangements with commercial entities will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into.

Collaborations involving our product candidates we may develop, pose the following risks to us:

•collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations;

•collaborators may not properly obtain, maintain, enforce or defend intellectual property or proprietary rights relating to our product candidates or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual property related proceedings, including proceedings challenging the scope, ownership, validity and enforceability of our intellectual property;

•collaborators may own or co-own intellectual property covering our product candidates that result from our collaboration with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property or such product candidates;

•disputes may arise with respect to the ownership of intellectual property developed pursuant to collaborations;

•we may need the cooperation of our collaborators to enforce or defend any intellectual property we contribute to or that arises out of our collaborations, which may not be provided to us;

•collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;

•disputes may arise between the collaborators and us that result in the delay or termination of the research, development, or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;

•collaborators may decide not to pursue development and commercialization of any product candidates we develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;

•collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;

•collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

•collaborators with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of such product candidates;

•we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control;

•collaborators may undergo a change of control and the new owners may decide to take the collaboration in a direction which is not in our best interest;

•collaborators may become party to a business combination transaction and the continued pursuit and emphasis on our development or commercialization program by the resulting entity under our existing collaboration could be delayed, diminished or terminated;

•collaborators may become bankrupt, which may significantly delay our research or development programs, or may cause us to lose access to valuable technology, know-how or intellectual property of the collaborator relating to our products, product candidates;

•key personnel at our collaborators may leave, which could negatively impact our ability to productively work with our collaborators;

•collaborations may require us to incur short and long-term expenditures, issue securities that dilute our stockholders, or disrupt our management and business;

•collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates or our ABC Platform; and

•collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all.

We may face significant competition in seeking appropriate collaborations. Recent business combinations among biotechnology and pharmaceutical companies have resulted in a reduced number of potential collaborators. In addition, the negotiation process is time-consuming and complex, and we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate or delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop product candidates or bring them to market and generate product revenue.

If we enter into collaborations to develop and potentially commercialize any product candidates, we may not be able to realize the benefit of such transactions if we or our collaborator elect not to exercise the rights granted under the agreement or if we or our collaborator are unable to successfully integrate a product candidate into existing operations and company culture. In addition, if our agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely. We may also find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. Any collaborator may also be subject to many of the risks relating to product development, regulatory approval, and commercialization described in this "Risk Factors" section, and any negative impact on our collaborators may adversely affect us.

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

Reliance on third parties to conduct clinical trials, assist in research and development and to manufacture our product candidates, will at times require us to share trade secrets with them. We seek to protect our proprietary technology by in part entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's independent discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for any product candidates we develop or for our ABC Platform, our competitors could develop and commercialize products or technology similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop, and our technology may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our ABC Platform and any proprietary product candidates and other technologies we may develop. We seek to protect our proprietary position by in-licensing intellectual property and filing patent applications in the United States and abroad relating to our ABC Platform, product candidates and other technologies that are important to our business. Given that the development of our technology and product candidates is at an early stage, our intellectual property portfolio directed to certain aspects of our technology and product candidates is also at an early stage. We have filed or intend to file patent applications on core aspects of our technology and product candidates; however, there can be no assurance that any such patent applications will issue as granted patents. Furthermore, in some cases, we only have filed provisional patent applications on certain aspects of our technology and product candidates, and none of these provisional patent applications is eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of the filing date of the applicable provisional patent application. Any failure to file a non-provisional patent application within this timeline could cause us to lose the ability to obtain patent protection for the inventions disclosed in the associated provisional patent applications. Furthermore, in some cases, we may not be able to obtain issued claims covering compositions relating to our ABC Platform and product candidates, as well as other technologies that are important to our business, and instead may need to rely on filing patent applications with claims covering a method of use and/or method of manufacture for protection of such ABC Platform, product candidates and other technologies. There can be no assurance that any such patent applications will issue as granted patents, and even if they do issue, such patent claims may be insufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent protection with respect to our ABC Platform and product candidates could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If any of our patent applications does not issue as a patent in any jurisdiction, we may not be able to compete effectively.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, and obtain, maintain and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. In addition, our own fixed applications may become prior art against our current or future patent applications. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, and in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical technology and product candidates would be adversely affected.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our ABC Platform, product candidates or other technologies or that effectively prevent others from commercializing competitive technologies and product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents may be challenged, narrowed, circumvented, rendered unenforceable or invalidated by third parties. Consequently, we do not know whether our ABC Platform, product candidates or other technologies will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third party preissuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant and inter partes review, or interference proceedings or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our ABC Platform, product candidates or other technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions and other challenges in a foreign patent office or administrative tribunal, that challenge our or our licensor's priority of invention or other features of patentability with respect to our owned or in-licensed patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our ABC Platform, product candidates and other technologies. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting and defending patents relating to our ABC Platform, product candidates and other technologies in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as U.S. laws. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult, costly or impossible for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. Payment within these late fee windows may be employed in order to simplify the payment of these fees generally. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, while not relevant for tarcocimab, KSI-501, and/or KSI-101, if we rely on a different product, its development could involve the use of government funds, which can require additional compliance aspects to make certain all rights are transferred to or remain with us.

Issued patents may be challenged or invalidated, and relatively recent changes in U.S. patent law have diminished and may further diminish the value of patents in general. We rely on patents to protect our products, and any diminishment in the scope or value of our patents would adversely affect our business.

If we initiated legal proceedings against a third party to enforce a patent directed to our ABC Platform, product candidates or other technologies, the defendant could allege that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including obviousness, lack of novelty, lack of written description, or non-enablement. Grounds for an unenforceability challenge include an allegation that someone connected with prosecution of the patent withheld material information from the USPTO with an intent to deceive the USPTO, or made a misleading statement, during prosecution. The filing of a legal proceeding could also result in the third party challenging the patent at the USPTO, such as in post-grant and inter partes review.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. For patent filings beginning in March 2013, the United States employs a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. Under the current patent laws, a third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (1) file any patent application related to our ABC Platform, product candidates or other technologies or (2) invent any of the inventions claimed in our or our licensor's patents or patent applications.

Changes to U.S. patent laws since 2011 also include allowing third party submissions of prior art to the USPTO during patent prosecution and additional procedures for attacking the validity of a patent through USPTO administered post-grant proceedings, including re-examination, post-grant review, inter partes review, interference proceedings and derivation proceedings. Some of these changes apply to patents issued prior to 2011. These and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings) could result in the revocation of, cancellation of or amendment to our patents in such a way that they no longer cover our ABC Platform, product candidates or other technologies. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standards applied in United States federal courts that apply to actions seeking to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if challenged in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not otherwise have been invalidated if first challenged by the third party as a defendant in a district court action.

As compared to intellectual property-reliant companies generally, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. These rulings have created uncertainty with respect to the validity and enforceability of patents, even once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

Any future changes to patent laws could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our ABC Platform, product candidates or other technologies. Increased uncertainty with respect to, or loss of, patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our owned or in-licensed U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar extensions as compensation for patent term lost during regulatory review processes are also available in certain foreign countries and territories, such as in Europe under a Supplementary Patent Certificate. Patent term extension in the United States and/or foreign countries and territories may not be available if, among other things, we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to the expiration of relevant patents, or otherwise fail to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension received is shorter than what we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor or owner or co-owner. For example, we may have inventorship disputes arise from conflicting obligations of employees, collaborators, consultants or others who are involved in developing our ABC Platform, product candidates or other technologies. Litigation may be necessary to defend against these and other claims challenging inventorship or our ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our ABC Platform, product candidates and other technologies. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

In addition to seeking patents for our ABC Platform, product candidates and other technologies, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information and to maintain our competitive position. Trade secrets and know-how can be difficult to protect. Over time, we expect our trade secrets and know-how to be disseminated within the industry through independent development, the publication of journal articles describing the methodology and the movement of personnel from academic to industry scientific positions.

We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants, train our employees not to bring or use proprietary information or technology from former employers to us or in their work and remind former employees when they leave their employment of their confidentiality obligations to us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite our efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to contain such breaches or disclosures or obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed without the protection of a confidentiality agreement found unenforceable by relevant courts or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors and potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have improperly used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects. Where post-filing date patent assignments are not executed by an inventor, it is our practice to employ and record the assignment provision that can be found in the employee's employment agreement. This is done when possible, and when the intellectual property is of interest to us.

Third-party claims of intellectual property infringement, misappropriation or other violation against us or our collaborators may prevent or delay the development and commercialization of our product candidates, the ABC Platform and other technologies.

The field of discovering treatments for retinal diseases is highly competitive and dynamic. Due to the focused research and development that is taking place in this field by several companies, including us and our competitors, the intellectual property landscape is in flux, and it may remain uncertain in the future. As such, there may be significant intellectual property related litigation and proceedings relating to our owned, and other third party, intellectual property and proprietary rights in the future.

Our commercial success depends in part on our and our collaborators' ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. As discussed above, due to changes in U.S. law referred to as patent reform, new procedures including *inter partes* review and post-grant review have been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist relating to ABC technology and in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our ABC Platform, product candidates and other technologies may give rise to claims of infringement of the patent rights of others. We cannot assure you that our ABC Platform, product candidates and other technologies that we have developed, are developing or may develop in the future will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued or that a third party, including a competitor in the fields in which we are developing our ABC Platform, product candidates and other technologies, might assert are infringed by our current or future ABC Platform, product candidates or other technologies. Such a dispute may concern claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our ABC Platform, product candidates or other technologies. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our ABC Platform, product candidates or other technologies, could be found to be infringed by our ABC Platform, product candidates or other technologies. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that later result in issued patents that our ABC Platform, product candidates or other technologies may infringe.

Third parties may have patents or obtain patents in the future and claim that the manufacture, use or sale of our ABC Platform, product candidates or other technologies infringes these patents. If a third party alleges that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by our ABC Platform, product candidates or other technologies, even if we believe such claims are without merit. In that event, the successful plaintiff may be able to impede our ability to commercialize the applicable product candidate or technology unless we obtain a license under the applicable patents, or such patents expire or are finally determined to be invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees, royalties or both. Any license granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our ABC Platform, product candidates or other technologies, or our commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

We are aware of a number of patents and patent applications that are directed to one or more aspects of tarcocimab, KSI-501, and/or KSI-101. Our intent is to maintain our development efforts under 35 U.S.C. Section 271(e)(1) (which provides a safe harbor from patent infringement claims related to certain drug development activities) through to at least the launch of any tarcocimab, KSI-501, or KSI-101 product. We are aware of at least one pending patent application with claims that are directed to some aspect of tarcocimab, KSI-501, and/or KSI-101 that could, if issued, have a patent term beyond a potential launch date for tarcocimab or KSI-501. If this were to occur, we may be required to challenge the validity of the claims, obtain a license, modify tarcocimab or KSI-501, or delay launch. We are also aware of at least one patent family with issued claims that may be relevant to some potential future aspect(s) of KSI-501 and/or KSI-101 and that have a patent term beyond a potential launch date for KSI-501 or KSI-101. If this or any other patent family were perceived as relevant, we may be required to challenge the validity of the claims, obtain a license, modify KSI-501 and/or KSI-101, or delay launch.

If we choose to further the pipeline and develop a different product, such a product would be delayed until the expiration of any valid patent that is still in force on such product. Alternatively, our options for addressing any such patents relating to these non-tarcocimab, non-KSI-501, and/or non-KSI-101 products would include the following: challenge the validity of the claims, obtain a license, or modify the non-tarcocimab, non-KSI-501, and/or non-KSI-101 products.

Defending against infringement claims, regardless of their merit, would involve substantial litigation expense, would be a substantial diversion of management and other employee resources from our business and may adversely impact our reputation. We may be subject to an injunction that prevents or delays us from commercializing our ABC Platform, product candidates or other technologies during on-going litigation even if we ultimately prevail in the litigation proceedings or the litigation is settled in our favor. We may be subject to an injunction that prevents or delays us from commercializing our ABC Platform, product candidates or other technologies during on-going litigation even if we ultimately prevail in the litigation proceedings or the litigation is settled in our favor. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing our infringing ABC Platform, product candidates or other technologies. In addition, we may have to pay substantial damages (including treble damages and attorneys' fees for willful infringement) obtain one or more licenses from third parties, pay royalties and/or redesign our infringing product candidates or technologies, which may be impossible or require substantial time and monetary expenditure. If we were unable to further develop and commercialize our ABC Platform, product candidates or other technologies, it would harm our business significantly.

Engaging in litigation to defend against third parties alleging that we have infringed, misappropriated or otherwise violated their patents or other intellectual property rights is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensing partners, or we may be required to defend against claims of infringement. If we assert our intellectual property against others, it could increase the likelihood that our patents or the patents of our licensing partners become involved in inventorship, priority or validity disputes. As discussed above, countering or defending against such claims can be expensive and time consuming. In an infringement proceeding, a court may decide that a patent owned or in-licensed by us is invalid or unenforceable, the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1), or may refuse to stop the other party from using the technology at issue on the grounds that our owned and in-licensed patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated, rendered unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Even if we prevail in asserting our intellectual property, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. 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 common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately or to assert all claims we believe to be viable. 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. 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.

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

We rely on trademarks, service marks, tradenames and brand names. We cannot assure you that our trademark applications will be approved. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, any registered or unregistered trademarks or trade names that we currently have or may in the future acquire may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, 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. We own a registered trademark for the mark "KODIAK" and "KODIAK SCIENCES" in the United States. 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.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of the patents that we may license or own;
- we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or own now or in the future;
- we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our current or future pending owned or licensed patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Operations

We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Developing and commercializing new medicines is a challenging exercise and requires diverse expertise in a variety of scientific, clinical, manufacturing, commercial, financial, people and legal functions. Failure to adequately develop these functions will hurt our ability to compete effectively.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, particularly our Chief Executive Officer, Dr. Victor Perlroth, and our scientific and medical personnel. The loss of the services provided by any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements, could result in delays in the development of our product candidates and harm our business.

We conduct our U.S. operations at our facilities in Palo Alto, California, in a region that is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We expect that we may need to recruit talent from outside of our region and doing so may be costly and difficult.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided restricted stock and stock option grants, including early exercise stock options exercisable for restricted stock that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key man" insurance policies on the lives of all of these individuals or the lives of any of our other employees. If we are unable to attract, incentivize and retain quality personnel on acceptable terms, or at all, it may cause our business and operating results to suffer.

We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2024, we had 109 employees. As our development plans and strategies develop, and as we continue operating as a public company, we must add a significant number of additional managerial, operational, financial and other personnel. Future growth will impose significant added responsibilities on members of management, including:

•identifying, recruiting, integrating, retaining and motivating additional employees;

•managing our internal development efforts effectively, including the clinical and FDA review process for our current and future product candidates, while complying with our contractual obligations to contractors and other third parties;

•expanding our operational, financial and management controls, reporting systems and procedures; and

•managing increasing operational and managerial complexity.

Our future financial performance and our ability to continue to develop and, if approved, commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to manage these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. There can be no assurance that the services of these independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop our product candidates and, accordingly, may not achieve our research, development, and commercialization goals.

If our information technology systems, or those of third parties with whom we work, or our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, significant fines or other liability, interruptions of our development programs, harm to our reputation, and other adverse consequences.

In the ordinary course of our business, we and the third parties with whom we work process personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data collected about trial participants in connection with clinical trials, and sensitive third-party data.

Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. The information and data processed and stored in our technology systems, and those of our research collaborators, contractors, consultants, and other third parties with whom we work, are vulnerable to these threats. These threats come from a variety of sources, including traditional computer "hackers," threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors. During times of war and other major conflicts, we and the third parties with whom we work are vulnerable to a heightened risk of attacks, including retaliatory cyber-attacks that could materially disrupt our systems and operations and supply chain. We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by artificial intelligence, or AI, and other similar threats. Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Additionally, certain personnel remain in a remote work environment and outside of our corporate network security protection boundaries, which imposes additional risks to our business, including increased risk of industrial espionage, phishing and other cybersecurity attacks, and unauthorized dissemination of proprietary or confidential information, any of which could have a material adverse effect on our business. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third parties to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. While we may be entitled to damages if the third parties with whom we work fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or that of the third parties with whom we work have not been compromised. Likewise, we rely on third-party research institution collaborators, other contractors and consultants for many aspects of our business, including research and development activities and manufacturing of our product candidates, and similar events relating to their information systems could also have a material adverse effect on our business.

While we have implemented security measures designed to protect the integrity, confidentiality and security of the sensitive information under our control, we cannot assure you that our security measures, or those of the third parties with whom we work will be effective in preventing security incidents. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). We have not, and may not in the future, however, detect and remediate all such vulnerabilities including on a timely basis. There are many different and rapidly evolving cybercrime and hacking techniques, and we may be unable to anticipate attempted security incidents, identify them before our information is exploited, or react in a timely manner. We have in the past and may in the future be unable to detect vulnerabilities in our information technology systems and software. Further, we have in the past (and may in the future) experienced delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. We expend resources and may modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations have required us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

Certain of the previously identified or similar threats have in the past and may in the future cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, access to our sensitive information, or interruptions or stoppages in our business operations (including our clinical trials). For example, we have been the target of unsuccessful phishing attempts in the past, and expect such attempts will continue in the future. Although to our knowledge, we have not experienced a material system failure or security incident to date, if such an event were to occur, it could result in a material disruption of our development programs and our business operations, whether due to a loss of trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed, on-going or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for many aspects of our business, including research and development activities and manufacturing of our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business.

Additionally, applicable data protection requirements may require us, or we may voluntarily choose, to notify relevant stakeholders of security incidents, including affected individuals, partners, collaborators, regulators, law enforcement agencies, and others, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to litigation or other liability, fines, harm to our reputation, significant costs, or other materially adverse effects. Some of our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations or exclusions of liability in our contracts may not be enforceable or adequate or protect us from liability or damages.

Our insurance coverage may not be adequate for cybersecurity liabilities, may not continue to be available to us on economically reasonable terms, or at all, and insurers could deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could materially and adversely affect our reputation, business, financial condition and results of operations.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our third party vendors, suppliers, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are partly uninsured. In addition, we rely on our third-party research institution collaborators for conducting research and development of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. For example, in connection to health epidemics, the various quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to infectious diseases, could adversely affect our business, financial condition or results of operations by limiting our ability to manufacture product, forcing temporary closure of facilities that we rely upon or increasing the costs associated with obtaining clinical supplies of our product candidates. The extent to which health epidemics could impact our results will depend on future developments, which are highly uncertain and cannot be accurately predicted, including the severity and the actions to contain or treat such outbreaks, epidemics, or pandemics, among others.

Our operations are located at facilities in Palo Alto, California and Switzerland. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

We implemented a new enterprise resource planning, or ERP, system as well as other systems as part of our on-going technology and process improvements. Our ERP system is critical to our ability to accurately maintain books and records and prepare our financial statements. If we encounter unforeseen problems with our ERP system or other systems and infrastructure, our business, operations, and financial results could be adversely affected.

Our business is subject to economic, political, regulatory and other risks associated with international operations.

Our business is subject to risks associated with conducting business internationally. Some of our suppliers and collaborative relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

•economic weakness, including inflation or political instability in particular non-U.S. economies and markets;

•differing and changing regulatory requirements, pricing and reimbursement regimes in non-U.S. countries;

•challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;

•difficulties in compliance with non-U.S. laws and regulations;

•changes in non-U.S. regulations and customs, tariffs and trade barriers;

•changes in non-U.S. currency exchange rates and currency controls;

•changes in a specific country's or region's political or economic environment;

•trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;

•negative consequences from changes in tax laws;

•compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

•workforce uncertainty in countries where labor unrest is more common than in the United States;

•difficulties associated with staffing and managing international operations, including differing labor relations;

•potential liability under the FCPA or comparable foreign laws; and

•business interruptions resulting from geo-political actions, including war and terrorism or natural disasters.

Other international, geo-political, and macroeconomic events could also have an adverse impact on our business. The United States and certain other countries may impose significant sanctions, trade restrictions, and other retaliatory actions in response to these events. While we cannot predict the broader consequences of these types of events, the conflict and retaliatory and counter-retaliatory actions could materially adversely affect global trade, currency exchange rates, inflation, regional economies, and the global economy, which in turn may increase our costs, disrupt our supply chain, or otherwise adversely affect our business, financial condition, and results of operations. These and other risks associated with our planned international operations may materially adversely affect our business, financial condition, and ability to attain profitable operations.

Our business could be materially and adversely affected in the future by the effects of disease outbreaks, epidemics and pandemics, as well as the business or operations of our third parties with whom we conduct business.

Our business could be materially and adversely affected by health epidemics in regions where we have concentrations of clinical trial sites or other business operations and could cause significant disruption in the operations of third parties upon whom we rely.

In addition, our current and future clinical trials may be materially and adversely affected by health epidemics in the future. Site initiation and patient enrollment may be further delayed due to prioritization of hospital resources toward health epidemics. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure during health epidemics, and may adversely impact our clinical trial operations. Our employees and our third parties may not be able to travel to study sites, impacting further site initiations and in-person monitoring of study data quality. Our other vendors on whom we depend, such as supply chain and logistics partners and our image reading centers may be disrupted, and our operations could be affected. Our clinical studies enroll patients who have underlying risk factors such as advanced age, hypertension and/or diabetes which could lead to higher than expected study discontinuation rates and/or missed visit rates if these patients are adversely affected by health epidemics.

The extent to which the risks and evolving effects of health epidemics impact our business and our clinical development and regulatory efforts will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the ultimate duration and severity of the pandemic, government actions, such as travel restrictions, quarantines and social distancing requirements, business closures or business disruptions and the effectiveness of actions taken in the United States and in other countries to contain and treat the disease, including the effectiveness and timing of vaccine programs in the United States and worldwide. Health epidemics may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

Risks Related to Our Business, Financial Condition and Capital Requirements

We have incurred significant net losses in each period since our inception and anticipate that we will continue to incur significant and increasing net losses for the foreseeable future.

We have incurred net losses in each reporting period since our inception, including net losses of $176.2 million, $260.5 million and $333.8 million for the years ended December 31, 2024, 2023 and 2022, respectively. As of December 31, 2024, we had an accumulated deficit of $1,328.7 million.

We have invested significant financial resources in research and development activities, including for our product candidates and our ABC Platform. We do not expect to generate revenue from product sales for several years, if at all. The amount of our future net losses will depend, in part, on the level of our future expenditures and our ability to generate revenue. Moreover, our net losses 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.

We expect to continue to incur significant and increasingly higher expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- progress our current and any future product candidates through preclinical and clinical development;
- work with our contract manufacturers to scale up the manufacturing processes for our product candidates or, in the future, establish and operate a manufacturing facility;
- continue our research and discovery activities;
- initiate and conduct additional preclinical, clinical or other studies for our current and any future product candidates;
- change or add additional contract manufacturers or suppliers;
- seek regulatory approvals and marketing authorizations for our product candidates;
- establish sales, marketing and distribution infrastructure to commercialize any products for which we obtain approval;
- continue the development of our ABC Platform;
- acquire or in-license product candidates, intellectual property and technologies;
- make milestone, royalty or other payments due under any current or future collaboration or license agreements;
- obtain, maintain, expand, protect and enforce our intellectual property portfolio;
- attract, hire and retain qualified personnel;
- experience any delays or encounter other issues related to our operations;
- meet the requirements and demands of being a public company; and
- defend against any product liability claims or other lawsuits related to our products.

Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have never generated any revenue from product sales, and we may never generate revenue or be profitable.

We have no products approved for commercial sale and have not generated any revenue from product sales. We do not anticipate generating any revenue from product sales until after we have successfully completed clinical development and received regulatory approval for the commercial sale of a product candidate, if ever.

Our ability to generate revenue and achieve profitability depends significantly on many factors, including:

- successfully completing research and preclinical and clinical development of our product candidates;
- obtaining regulatory approvals and marketing authorizations for product candidates for which we successfully complete clinical development and clinical trials;

•developing a sustainable and scalable manufacturing process for our product candidates, as well as establishing and maintaining commercially viable supply relationships with third parties that can provide adequate products and services to support clinical activities and any commercial demand for our product candidates;

•identifying, assessing, acquiring and/or developing new product candidates;

•negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;

•launching and successfully commercializing product candidates for which we obtain regulatory and marketing approval, either by collaborating with a partner or, if launched independently, by establishing a sales, marketing and distribution infrastructure;

•obtaining and maintaining an adequate price for our product candidates, both in the United States and in foreign countries where our products are commercialized;

•obtaining adequate reimbursement for our product candidates from payors;

•obtaining market acceptance of our product candidates as viable treatment options;

•addressing any competing technological and market developments;

•maintaining, protecting, expanding and enforcing our portfolio of intellectual property rights, including patents, trade secrets and know-how; and

•attracting, hiring and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of our expenses, or when we will be able to generate any meaningful revenue or achieve or maintain profitability, if ever. In addition, our expenses could increase beyond our current expectations if we are required by the FDA or foreign regulatory agencies, to perform studies in addition to those that we currently anticipate, or if there are any delays in any of our or our future collaborators' clinical trials or the development of any of our product candidates. Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate and on-going compliance efforts.

Even if we are able to generate revenue from the sale of any approved products, we may not become profitable, and we will need to obtain additional funding through one or more debt or equity financings in order to continue operations. Revenue from the sale of any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price and whether we own the commercial rights for that territory. If the number of addressable patients is not as significant as we anticipate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our failure to become and remain profitable could decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or continue our operations and cause a decline in the value of our common stock, all or any of which may adversely affect our viability.

Our financial condition raises substantial doubt about our ability to continue as a going concern.

As of December 31, 2024, we had cash and cash equivalents of $168.1 million. We have incurred net losses and negative cash flows from operations since inception. We expect to continue to incur operating losses and negative operating cash flows for the foreseeable future and as a result, there is substantial doubt regarding our ability to continue as a going concern.

We have historically funded our operations primarily through the issuance of common stock and the sale of future royalties. Our ability to achieve and sustain profitability will depend on the successful development, approval and commercialization of our product candidates and on the achievement of sufficient revenue to support our cost structure and, unless and until we do, we will need to raise additional capital to maintain current operations and to continue research and development activities. We continue to monitor and reduce certain expenditures and plan to raise additional capital through approaches that include equity or debt financings, collaborations or a combination of similar transactions. While we have been able to raise multiple rounds of financing, there can be no assurance that such financing will be available on terms which are favorable or at all. We could be required to pause, scale back or discontinue one or more of our development programs, which could adversely affect our business, financial condition and results of operations.

Due to the significant resources required for the development of our product candidates, and depending on our ability to access capital, we must prioritize development of certain product candidates. Moreover, we may expend our limited resources on product candidates that do not yield a successful product and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Due to the significant resources required for the development of our product candidates, we must decide which product candidates and indications to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. If any of our future investments or allocations of research and development financial resources result in failed product candidates, our financial condition and business prospects may be significantly adversely impacted and we may never become profitable. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain product candidates may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misread trends in the biopharmaceutical industry, in particular for retinal diseases, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

If we fail to obtain additional financing, we may be unable to complete the development and, if approved, commercialization of our product candidates.

Our operations have required substantial amounts of cash since inception. To date, we have funded our operations primarily through the issuance of common stock and the sale of future royalties. Developing our product candidates is expensive, and we expect to continue our spending as we advance our product candidate development efforts. Even if we are successful in developing our product candidates, obtaining regulatory approvals and launching and commercializing any product candidate will require substantial additional funding.

Our estimate as to how long we expect our existing cash to be available to fund our operations is based on assumptions that may prove inaccurate, and we could deplete our available capital resources sooner than we currently expect. In addition, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may need to raise additional funds sooner than we anticipate if we choose to expand more rapidly than we presently anticipate.

We will require additional capital for the further development and, if approved, commercialization of our product candidates. Additional capital may not be available when we need it, on terms acceptable to us or at all. For example, geopolitical conflicts in Europe and the Middle East are expected to have further global economic consequences, including disruptions of the global supply chain. Further, inflation rates, particularly in the United States, have increased relatively recently, and the Federal Reserve has raised, and may again raise, interest rates. These conditions of economic uncertainty and market volatility could limit additional capital available to us, if and when needed, and increase its cost if available. In addition, it is possible that we may not be able to access a portion of our existing cash, cash equivalents and investments due to unforeseen market conditions. For example, on March 10, 2023, the Federal Deposit Insurance Corporation (FDIC), took control and was appointed receiver of Silicon Valley Bank. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened and could have a material adverse effect on our business and financial condition. We currently have no committed source of additional capital. If adequate capital is not available to us on a timely basis, we may be required to significantly delay, scale back or discontinue our research and development programs or the commercialization of any product candidates, if approved, or be unable to continue or expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations and cause the price of our common stock to decline.

If we engage in acquisitions, in-licensing or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We may engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;
- the issuance of our equity securities which would result in dilution to our stockholders;
- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product candidates and initiatives in pursuing such an acquisition or strategic partnership;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired intellectual property, technology and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

In addition, if we undertake such a transaction, we may incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

Unfavorable U.S. and global economic 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 U.S. and global economies, the U.S. and global financial markets and adverse geopolitical and macroeconomic developments. U.S. and global market and economic conditions have been, and continue to be, disrupted and volatile due to many factors, including heightened inflation rates, tariffs, geopolitical conflicts, and bank failures, among others. General business and economic conditions that could affect our business, financial condition or results of operations include fluctuations in economic growth, debt and equity capital markets, liquidity of the global financial markets, access to our liquidity within the U.S. banking system, the availability and cost of credit, investor and consumer confidence, and the strength of the economies in which we, our manufacturers and our suppliers operate.

A severe or prolonged global economic downturn could result in a variety of risks to our business. For example, inflation rates, particularly in the United States, have increased relatively recently, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. In addition, the U.S. Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which, coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks. Risks of a prolonged global economic downturn are particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy could also strain our suppliers and manufacturers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

The Federal Deposit Insurance Corporation only insures amounts up to $250,000 per depositor. Recently, we have seen the abrupt failure of more than one regional bank. We may from time to time have balances in bank accounts that are in excess of insured deposit limits, and could be subject to risks of bank failures. Similar bank failures could significantly impair our access to funding sources in amounts adequate to finance or capitalize our current and projected future business operations and could negatively impact the financial institutions with which we have direct arrangements, or the financial services industry or economy in general.

Additionally, financial markets around the world experienced volatility following the invasion of Ukraine by Russia. Further, a weak or declining economy could strain our suppliers and manufacturers. As a result, our business and results of operations may be adversely affected by the on-going conflict between Ukraine and Russia and related sanctions, particularly to the extent it escalates to involve additional countries, further economic sanctions or wider military conflict.

We have operations, as well as current and potential new suppliers and manufacturers, throughout Europe. If economic conditions in Europe and other key markets for our business remain uncertain or deteriorate further, we could experience adverse effects on our business, financial condition or results of operations.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2024, the Company had $111.5 million of federal and $616.3 million of state net operating loss, or NOLs, that may be available to offset future taxable income. A portion of the federal NOL carryforwards begin to expire in 2035 and the state NOL carryforwards begin to expire in 2035, if not utilized. Under Sections 382 and 383 of the United States Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50-percentage-point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period), the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change taxable income or taxes may be limited. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. As a result, our ability to use our pre-change net operating loss carryforwards and other pre-change tax attributes to offset post-change taxable income or taxes may be subject to limitation.

U.S. federal tax legislation enacted in 2017, informally titled The Tax Cuts and Jobs Act, or the Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, enacted in March 2020, among other things, includes changes to U.S. federal tax rates and the rules governing NOL carryforwards. Federal NOLs arising in tax years beginning after December 31, 2017 are permitted to be carried forward indefinitely, but carryback of such NOLs is generally permitted to the prior five taxable years only for NOLs arising in taxable years beginning before 2021. In addition, under the Tax Act, as modified by the CARES Act, the deductibility of federal NOLs incurred in taxable years beginning after December 31, 2017 is limited in taxable years beginning after December 31, 2020. For state income tax purposes, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. The new limitations on use of NOLs may significantly impact our ability to utilize our NOLs to offset taxable income in the future.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the CARES Act, modified certain provisions of the Tax Act. More recently, the IRA was enacted which includes provisions that will impact the U.S. federal income taxation of corporations, including imposing a minimum tax on the book income of certain large corporations and an excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act, the IRA, or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future reform legislation could have a material impact on the value of our net deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Foreign currency exchange rate risk may impact our financial position and results.

We use foreign currency forward contracts to protect against changes in anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates, primarily associated with non-functional currency denominated expenses. We regularly monitor our foreign currency exchange rate exposures to ensure the overall effectiveness of its foreign currency exposures. While we engage in foreign currency hedging activity to reduce our risk, for accounting purposes, none of its foreign currency forward contracts are designated as hedges.

A failure to maintain an effective system of internal control over financial reporting could result in material misstatements of our financial statements in future periods and may impair our ability to comply with the accounting and reporting requirements applicable to public companies. Furthermore, our business, financial position, and results of operations could be adversely affected.

As a public company, we are subject to reporting and other obligations under the Exchange Act, including the requirements of the Sarbanes-Oxley Act of 2002, or SOX, Section 404, which require annual management assessments of the effectiveness of our internal control over financial reporting.

The rules governing the standards that must be met for management to determine that our internal control over financial reporting is effective are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by SOX. These reporting and other obligations place significant demands on our management and administrative and operational resources, including accounting resources.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our 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 accounting principles generally accepted in the United States. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim consolidated financial statements will not be prevented or detected on a timely basis. Any failure to maintain effective internal controls could also have an adverse effect on our business, financial position and results of operations.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be volatile, which could result in substantial losses for investors purchasing shares.

The market price of our common stock may be volatile. For example, the closing price of our common stock from December 31, 2023 to December 31, 2024 ranged from a low of $2.20 to a high of $10.90 and from January 1, 2025 to February 28, 2025, ranged from a low of $3.84 to a high of $9.57. As a result, shareholders may not be able to sell their common stock at or above the price that they paid for such shares. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the success of existing or new competitive products or technologies;
- the timing and results of clinical trials for our current product candidates and any future product candidates that we may develop;
- commencement or termination of collaborations for our product candidates;
- failure or discontinuation of any of our product candidates;
- failure to develop our ABC Platform;
- results of preclinical studies, clinical trials or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the commencement of litigation;
- the level of expenses related to any of our research programs, product candidates that we may develop;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders, or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry, and market conditions, including the current inflationary environment, lowered consumer confidence, bank failures, major geopolitical conflicts; and
- the other factors described in this “Risk Factors” section.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations, including recently in connection with health epidemics, bank failures, broader macroeconomic conditional and/or geopolitical instability, which has resulted in decreased market prices, notwithstanding the lack of a fundamental change in the underlying business models or prospects of those companies. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. In this regard, worsening economic conditions, relatively heightened interest rates and/or other tapering policies from the government, and other adverse effects or developments relating to health epidemics or general economic environment may negatively affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

Future sales of our common stock in the public market could cause our share price to decline, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales, particularly sales by our directors, executive officers and significant stockholders, may have on the prevailing market price of our common stock. All of our outstanding shares of common stock are available for sale in the public market, subject only to the restrictions of Rule 144 under the Securities Act in the case of our affiliates. In addition, the shares of common stock subject to outstanding options under our equity incentive plans and the shares reserved for future issuance under our equity incentive plans, as well as shares issuable upon vesting of restricted stock unit awards, will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. In addition, certain holders of our common stock have the right, subject to various conditions and limitations, to request we include their shares of our common stock in registration statements we may file relating to our securities. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

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

We will seek additional capital through one or a combination of public and private equity offerings, debt financings, strategic partnerships and alliances or licensing arrangements. We, and indirectly, our stockholders, will bear the cost of issuing and servicing such securities. Because our decision to issue debt or equity securities in any future offering will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any future offerings. To the extent that we raise additional capital through the sale of equity securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve 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. Additionally, any future collaborations we enter into with third parties may provide capital in the near term but limit our potential cash flow and revenue in the future. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

Our principal stockholders own a significant percentage of our common stock, which could limit your ability to affect the outcome of key transactions, including a change of control.

Our directors, executive officers, significant holders of outstanding common stock and their respective affiliates beneficially own a significant amount of our common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

Delaware law and provisions in our certificate of incorporation and bylaws might discourage, delay, or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions in our certificate of incorporation and bylaws may discourage, delay, or prevent a merger, acquisition, or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our charter documents:

•provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;

•eliminate cumulative voting in the election of directors;

•authorize our board of directors to issue shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;

•provide our board of directors with the exclusive right to elect a director to fill a vacancy or newly created directorship;

•permit stockholders to only take actions at a duly called annual or special meeting and not by written consent;

•prohibit stockholders from calling a special meeting of stockholders;

•require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;

•authorize our board of directors, by a majority vote, to amend the bylaws; and

•require the affirmative vote of at least 66 2/3% or more of the outstanding shares of common stock to amend many of the provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware, or DGCL, prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our certificate of incorporation, bylaws, or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

Our bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for:

•any derivative action or proceeding brought on our behalf;

•any action asserting a claim of breach of fiduciary duty;

•any action asserting a claim against us arising under the DGCL, our certificate of incorporation, or our bylaws; and

•any action asserting a claim against us that is governed by the internal-affairs doctrine.

Our bylaws further provide that the U.S. federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If a court were to find either exclusive-forum provision in our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business. Our bylaws further provide that unless we otherwise consent in writing, the U.S. federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Risk Management and Strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, hardware, software, and our high value data, including intellectual property, trade secrets, confidential and sensitive information (collectively, "Information Systems and Data").

Our management team works with our digital transformation team in an effort to identify, assess and manage the Company's cybersecurity threats and risks. Depending on the environment, we implement and maintain various technical, physical and organizational measures, processes, standards and policies designed to manage, mitigate and remediate material risk from cybersecurity threats to our Information Systems and Data. These measures include but are not limited to firewalls, endpoint detection and response, antivirus programs, email security measures, backups and recovery procedures, privileged access management, multi-factor authentication schemes, data encryption, automatic patching, and security system information event monitoring to detect and respond to any emerging threats. Our information security and privacy policy framework includes standards for incident response, vulnerability management, data protection and logical access controls.

Our assessment and management of material risks from cybersecurity threats are integrated into our Company's overall risk management process, which, in part, establishes intended uses of our computerized systems and identifies critical and/or material risks. After a system reaches operation, the risk management approach continues following processes for change control, system maintenance, logical access control, discrepancy management and periodic review.

We use independent service providers to assist us from time to time in an effort to identify, assess, and manage material risks from cybersecurity threats. We periodically conduct vulnerability assessments and perform intrusion and penetration testing to evaluate our cybersecurity response capabilities.

We maintain cybersecurity awareness training for our employees and periodically perform phishing simulations. We routinely communicate with employees about the potential for cybersecurity threats, including the latest adversary trends and social engineering techniques and how to avoid them, and the best use of our established communications channels.

We have a vendor management process designed to manage cybersecurity risks associated with our use of third parties. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve varying methods of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under "Part I, Item 1A. — Risk Factors" in this Annual Report on Form 10-K, including the risk factor titled ***"If our information technology systems, or those of third parties with whom we work, or our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, significant fines or other liability, interruptions of our development programs, harm to our reputation, and other adverse consequences."***

Governance

The Nominating and Corporate Governance Committee of our Board of Directors is responsible for overseeing cybersecurity risk management processes, including oversight and mitigation of risk from cybersecurity threats. The Nominating and Corporate Governance Committee receives reports, as necessary, from the Chief Financial Officer of the Company regarding cybersecurity threats or incidents.

Our cybersecurity risk assessment and management processes are implemented and maintained by our digital transformation team under the supervision of the Chief Financial Officer and Chief Executive Officer of the Company, both of whom have experience in business operations including risk management and oversight of information technology functions within the biopharmaceutical industry. Our digital transformation team includes members with relevant expertise in cybersecurity, incident response, and the safeguarding of company assets. The digital transformation team undertakes efforts to learn about the Company's cybersecurity threats by reviewing security assessments and other security-related reports.

Our cybersecurity incident response and vulnerability management follow our information security and privacy policy framework. This framework is designed to escalate certain cybersecurity incidents to the Chief Financial Officer and, depending upon an incident's particular facts, the Chief Financial Officer will report certain cybersecurity incidents to the Nominating and Corporate Governance Committee of the Board of Directors.

ITEM 2. PROPERTIES

Our corporate offices are located in Palo Alto, California, where we lease approximately 155,000 square feet of office, research and development, engineering and laboratory space pursuant to lease agreements that commenced in June 2020. Our corporate offices in Palo Alto, California house substantially all of our personnel. The initial lease term for 1200 Page Mill Road is 6.5 years, with an option to extend the lease term for a period of 6.5 years. The initial lease term for 1250 Page Mill Road is 13 years, with two options to extend the lease term for a period of 5 years each.

In March 2025, we entered into a sublease agreement for the corporate office space located at 1200 Page Mill Road for the remainder of the initial lease term until February 2027. We retain the option to reoccupy the space and to extend the lease term of the building located at 1200 Page Mill Road for a period of 6.5 years.

In April 2020, we entered into a lease agreement for office and laboratory space at Rottenstrasse 5 in Visp, Switzerland. The space is approximately 1,000 square meters. The initial lease term is 5 years, with automatic renewals every 5 years for a maximum lease term of 15 years.

ITEM 3. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings at this time. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

ITEM 4. MINE SAFETY DISCLOSURES

None.

PART II

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

Our common stock trades on the Nasdaq Global Market under the trading symbol "KOD".

Holders of Common Stock

As of February 28, 2025, there were approximately 21 holders of record of our common stock. The approximate number of holders is based upon the actual number of holders registered in our records at such date and excludes holders in "street name" or persons, partnerships, associations, corporations or other entities identified in security positions listings maintained by depository trust companies.

Dividend Policy

We have never declared or paid any cash dividends on our common stock and do not anticipate paying cash dividends in the foreseeable future.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchases

None.

ITEM 6. RESERVED

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K. This discussion and analysis and other parts of this Annual Report on Form 10-K contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives, expectations, forecasts and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under the section titled "Part I, Item 1A — Risk Factors" and elsewhere in this Annual Report on Form 10-K.

Overview

Kodiak Sciences ("we", the "Company" or "Kodiak") is a biopharmaceutical company committed to researching, developing, and commercializing transformative therapeutics to treat a broad spectrum of retinal diseases. We are focused on bringing new science to the design and manufacture of next generation retinal medicines to prevent and treat the leading causes of blindness globally. Our ABC Platform uses molecular engineering to merge the fields of protein-based and chemistry-based therapies and has been at the core of Kodiak's discovery engine. We are developing a portfolio of three clinical programs, two of which are late-stage today and derived from our ABC Platform and one which is platform-independent and which we believe can progress rapidly into pivotal studies.

Kodiak's lead investigational medicine, tarcocimab, is a novel anti-VEGF antibody biopolymer conjugate under development for the treatment of high prevalence retinal vascular diseases. Tarcocimab is currently being studied in two Phase 3 clinical trials, GLOW2 in patients with diabetic retinopathy and DAYBREAK in patients with wet AMD. GLOW2 enrollment is complete, and DAYBREAK is actively enrolling patients.

KSI-501 is our second investigational medicine, a first-in-class anti-IL-6, VEGF-trap bispecific antibody biopolymer conjugate designed to inhibit both IL-6 mediated inflammation and VEGF-mediated angiogenesis and vascular permeability. KSI-501 is being developed for the treatment of high prevalence retinal vascular diseases to address the unmet needs of extended durability and targeting disease biology beyond VEGF for differentiated efficacy. The Phase 3 DAYBREAK study of KSI-501 in wet AMD is actively enrolling patients.

KSI-101, our third product candidate, is a novel anti-IL-6, VEGF-trap bispecific protein. Kodiak is developing KSI-101 for the treatment of retinal inflammatory diseases, as currently there are no available intravitreal biologic therapies addressing the spectrum of inflammatory conditions of the retina. The Phase 1b APEX study of KSI-101 is actively enrolling patients, as a precursor to activating the Phase 2b/3 studies in patients with macular edema secondary to inflammation ("MESI").

Kodiak is advancing its platform technology to embed small molecules and other active pharmaceutical ingredients ("APIs") into Kodiak's proprietary biopolymer backbone to enable high drug-antibody-ratio ("DAR") medicines. The diverse APIs are designed to be released over time to achieve targeted, multi-specific and tailored modulation of biological pathways. The unique combination of high DAR and tailored therapeutic benefit offers potential for broad application to multifactorial diseases and builds directly from our Antibody Biopolymer Conjugate technology and its 15 years of design, development and manufacturing experience. We call this platform extension our Antibody Biopolymer Conjugate Drug ("ABCD") Platform because we are extending our platform capabilities to include the conjugation of small molecule drugs whereas historically we conjugated biologics such as antibodies.

Recent Updates

Tarcocimab Clinical Program Summary and Update

Kodiak's lead clinical program tarcocimab is an investigational anti-VEGF therapy built on Kodiak's ABC Platform and is designed to maintain potent and effective drug levels in ocular tissues for longer than existing available agents. It is being developed as a mainstay intravitreal biologic monotherapy intended to provide high immediacy, driven by the enhanced formulation, and high durability, driven by the ABC Platform and our science of durability, with the ultimate objective of providing, once approved, a flexible 1-month through 6-month label. Kodiak's objective with tarcocimab is to enable earlier treatment and prevention of vision loss for patients with diabetic retinopathy and to develop a new high immediacy and high durability agent to improve outcomes for patients with retinal vascular diseases.

To date, tarcocimab has been studied in six pivotal clinical studies: Phase 3 GLOW1 study in diabetic retinopathy (“DR”), Phase 3 BEACON study in retinal vein occlusion (“RVO”), Phase 3 DAYLIGHT study in wet AMD, Phase 3 GLEAM and GLIMMER studies with identical study design in diabetic macular edema (“DME”), and Phase 2/3 DAZZLE study in wet AMD. Of the six registrational studies, GLOW1, BEACON and DAYLIGHT successfully met the primary endpoint. Tarcocimab is currently being studied in two Phase 3 clinical trials, the GLOW2 study in DR and the DAYBREAK study in wet AMD. GLOW2 has completed enrollment and DAYBREAK is actively enrolling. Kodiak anticipates to be in a position to announce topline data for the primary endpoint for GLOW2 in 1Q 2026 and for the primary endpoint for DAYBREAK in 2Q 2026. Kodiak plans to wait for DAYBREAK topline data expected 2Q 2026 in order to file a single Biologics License Application (“BLA”) for tarcocimab in wet AMD, DR and RVO.

Both GLOW2 and DAYBREAK use tarcocimab’s enhanced 50 mg/mL formulation containing both conjugated and unconjugated antibody that is intended to deliver high immediacy and high durability.

More information about study design and results, if completed, from each individual pivotal study are summarized below:

Ongoing Phase 3 Studies:

GLOW2 – Phase 3 Study in Patients with Diabetic Retinopathy

The Phase 3 GLOW2 study is the second registrational trial of tarcocimab in DR. GLOW2 has a similar design as GLOW1 in which all patients randomized to investigational therapy will receive tarcocimab on extended, 6-month dosing. GLOW2 features the benefit of an additional, third monthly loading dose (baseline, Week 4, Week 8) to explore even further benefits with tarcocimab in diabetic retinopathy patients.

GLOW2 study is a prospective, randomized, double-masked, multi-center pivotal superiority study designed to evaluate the efficacy and safety of tarcocimab in treatment-naïve patients with DR. Patients are randomized 1:1 and receive either sham injections or tarcocimab via intravitreal injection at baseline, Week 4, Week 8, Week 20 and Week 44. The primary endpoint is the proportion of eyes improving ≥2 steps on Diabetic Retinopathy Severity Scale ("DRSS") from baseline at Week 48. Additional outcome measures include the proportion of eyes developing a sight threatening complication of diabetic retinopathy and the proportion of eyes improving ≥3 steps on DRSS from baseline at Week 48.

On March 10, 2025, Kodiak announced that GLOW2 completed enrollment, randomizing more than 250 patients. Kodiak expects to be in a position to announce topline data in 1Q 2026.

DAYBREAK – Phase 3 Study in Patients with Wet Age-Related Macular Degeneration

The Phase 3 DAYBREAK study is a non-inferiority study evaluating parallel investigational arms of tarcocimab and KSI-501 against active comparator aflibercept. Patients randomized to tarcocimab will receive individualized dosing every 4 to 24 weeks on an as needed basis following four monthly loading doses. Patients randomized to aflibercept will be dosed per its label. The individualized dosing of tarcocimab is determined by a treat-to-dryness proactive approach, using presence of retinal fluid as a disease activity marker, instead of a combination of central subfield thickness ("CST") and vision loss, which resembles retina specialists' practice and optimizes each patient's treatment. The objectives for tarcocimab in DAYBREAK are to assess its 6-month durability potential, strengthen its competitive position in wet AMD and bolster the regulatory application package for the program.

DAYBREAK is actively enrolling patients, and Kodiak anticipates to be in a position to announce topline data for the primary endpoint in 2Q 2026.

Completed Studies:

GLOW1 – Phase 3 Study in Patients with Non-Proliferative Diabetic Retinopathy without DME

The Phase 3 GLOW1 study was a global, multi-center, randomized pivotal superiority study designed to evaluate the efficacy and safety of tarcocimab in treatment-naïve patients with moderately severe to severe DR. Patients were randomized to receive either tarcocimab every six months after initiating doses given at baseline, 8 weeks and 20 weeks into the study, or to receive sham injections. The primary endpoint was at one year.

On November 6, 2023, Kodiak announced that GLOW1 met its primary endpoint of the proportion of patients with at least a 2-step improvement on the Diabetic Retinopathy Severity Scale (DRSS) score, a grading system measuring the degree of retinopathy. Tarcocimab achieved a 29-fold increased response rate ratio, with 41.1% of evaluable patients on tarcocimab demonstrating at least 2-step improvement versus 1.4% of evaluable patients in the sham group (p-value less than 0.0001). Visual acuity and retinal anatomy were improved and stable with tarcocimab on its extended-dosing intervals. At one year, GLOW1 also met its key secondary endpoint of greater reductions in the proportion of patients developing sight-threatening complications (such as diabetic macular edema and proliferative diabetic retinopathy), versus sham, demonstrating an 89% decreased risk, achieving 21.0% versus 2.3% (p-value less than 0.0001). Tarcocimab also showed a 95% risk reduction in the development of DME, versus sham, from 13.7% on sham versus 0.7% on tarcocimab. The rates of serious ocular adverse events and intraocular inflammation in patients treated with tarcocimab and sham were similar.

BEACON – Phase 3 Study in Patients with Treatment-Naïve Retinal Vein Occlusion

The Phase 3 BEACON study was a randomized, double-masked, multicenter, active comparator-controlled study in treatment naïve patients with vision loss and macular edema due to retinal vein occlusion, including both branch ("BRVO") and central ("CRVO") subtypes. In the initial six months of the study, patients received tarcocimab on a fixed every-8-week dosing regimen following 2 monthly loading doses or aflibercept 2mg on a fixed monthly dosing regimen per its label. In the second six months of the study, tarcocimab and aflibercept were tested head-to-head according to a pro re nata (“PRN") protocol in which patients in both groups were treated only when disease reactivated according to matched predefined disease activity criteria.

In August 2022, Kodiak announced that the BEACON study met the primary efficacy endpoint of non-inferior visual acuity change from baseline at week 24 for subjects given tarcocimab every two months after 2 monthly loading doses compared to subjects given monthly aflibercept.

On September 7, 2023, Kodiak announced new one-year results from the BEACON study. Tarcocimab demonstrated matched efficacy with differentiated durability versus aflibercept in the head-to-head comparison. After 4 initiating doses in the first 6 months, 47% of tarcocimab-treated patients required no additional injections in the second 6 months while matching the vision and anatomic outcomes of aflibercept-treated patients. Despite receiving 6 initiating monthly doses, only 37% of aflibercept patients were injection free in the second half of the study. 77% of tarcocimab treated patients received 5 or fewer doses in year one, while 93% of aflibercept treated patients received 6 or more doses. BRVO patients received a median of 4.0 injections on tarcocimab versus 7.0 injections of aflibercept. Despite materially fewer injections in tarcocimab treated patients, vision outcomes favored tarcocimab-treated patients achieving an observed mean of 76.6 letters versus 75.6 letters for aflibercept treated patients. All RVO patients received a median of 5.0 injections on tarcocimab versus 7.0 injections of aflibercept. Despite materially fewer injections in tarcocimab treated patients, vision outcomes favored tarcocimab-treated patients achieving an observed mean of 74.6 letters versus 74.3 letters for aflibercept treated patients.

Safety and tolerability were comparable between tarcocimab and aflibercept. Intraocular inflammation (IOI) rate was comparable between groups (tarcocimab 2.5% vs aflibercept 0.7%). No cases of inflammation associated with vascular occlusion or vasculitis were reported.

DAYLIGHT – Phase 3 Study in Patients with Treatment-Naïve Wet AMD

The DAYLIGHT study was a randomized, double-masked, active comparator-controlled study evaluating the efficacy and safety of a high intensity dosing regimen of tarcocimab in 557 treatment-naïve subjects with wet AMD. On July 24, 2023, Kodiak announced that the DAYLIGHT study met the primary endpoint of non-inferior visual acuity gains at year 1 for tarcocimab dosed monthly compared to aflibercept dosed every 8 weeks following 3 monthly loading doses. Intraocular inflammation occurred in 3.3% of patients treated with monthly tarcocimab and 0.4% of patients treated with aflibercept with no vasculitis or occlusion.

GLEAM / GLIMMER – Paired Phase 3 Studies in Patients with Treatment-Naïve Diabetic Macular Edema

The GLEAM and GLIMMER studies were identically designed, randomized, double-masked, active comparator-controlled studies evaluating the efficacy, durability and safety of tarcocimab in 460 and 457 treatment-naïve subjects with DME, respectively, run in parallel.

On July 24, 2023, Kodiak announced that although high proportions of patients on meaningfully longer treatment intervals were observed with tarcocimab, with half of patients on every 24-week dosing at the primary endpoint, the GLEAM and GLIMMER studies did not meet their primary efficacy endpoints of showing non-inferior visual acuity gains for tarcocimab dosed every 8 to 24 weeks after 3 monthly loading doses compared to aflibercept given every 8 weeks after 5 monthly loading doses. At the primary efficacy endpoint of the GLEAM study, patients treated with tarcocimab gained an observed average of 6.4 eye chart letters (to 73.1 letters), compared with 10.3 letters for patients treated with aflibercept (to 76.5 letters). In GLIMMER, patients treated with tarcocimab gained an observed average of 7.4 eye chart letters at the primary endpoint (to 72.5 letters) compared with 12.2 letters (to 76.4 letters) for patients treated with aflibercept.

An unexpected increase in cataract adverse events was reported over time in the tarcocimab arms of both GLEAM and GLIMMER, with 19% on tarcocimab versus 9% on aflibercept at the primary endpoint based on the pooled safety population. Kodiak's evaluation suggested that the decline in visual acuity associated with cataracts likely contributed meaningfully to the failure of each study.

Half of tarcocimab treated patients in the GLEAM and GLIMMER studies were on every 24-week dosing at the primary endpoint, two-thirds achieved at least one 6-month dosing interval during the studies, and three-quarters achieved at least one 5-month or longer treatment interval. Intraocular inflammation was rare, occurring in 1.3% and 0.2% of tarcocimab and aflibercept treated patients, respectively. No cases of intraocular inflammation with vasculitis or vascular occlusion were observed.

DAZZLE – Phase 2b/3 Study in Patients with Treatment-Naïve Wet AMD

The DAZZLE study was a global, multi-center, randomized pivotal study designed to evaluate the durability, efficacy and safety of tarcocimab in patients with treatment-naïve wet AMD. In February 2022 Kodiak announced that this initial pivotal study did not meet its primary efficacy endpoint of non-inferior visual acuity gains for subjects dosed on extended regimens every 12-, 16- or 20 weeks with tarcocimab compared to subjects given aflibercept every 8 weeks. Following this announcement, Kodiak discontinued the study and concluded remaining trial-associated activities.

Antibody Biopolymer Conjugate Drug Substance Manufacturing

In August 2020, we entered into a manufacturing agreement with Lonza Ltd ("Lonza") for the clinical and commercial supply of the Company's antibody biopolymer conjugate drug substance which included a custom-built manufacturing facility. The manufacturing agreement has an initial term of 8 years, and the Company has the right to extend the term up to a total of 16 years. The Company and Lonza each have the ability to terminate this agreement upon the occurrence of certain events.

In April 2021, the agreement was amended to provide for greater manufacturing flexibility, to define a comprehensive mandate as an antibody biopolymer conjugates manufacturing facility to be used for the Company's antibody biopolymer conjugates pipeline, at clinical as well as commercial scales, across a broad capacity range under the tight quality controls required for ophthalmology and retinal medicines, and to allow for future process and equipment changes as needed.

Under the agreement, Kodiak and Lonza planned a custom-built facility ("Ursus") dedicated to the commercial-scale manufacturing of Kodiak's drug substance. In January 2023, the custom-built manufacturing suite Ursus was commissioned as a cGMP facility. Kodiak worked together with Lonza and regulatory authorities to obtain approval for Ursus, and we released our first commercial scale cGMP batch of tarcocimab in July 2023. In October 2023, Kodiak made a final payment of $26.8 million to Lonza for final activation of Ursus. Separately, tarcocimab drug product based on our enhanced formulation was released in March 2024 and is being used in the GLOW2 and DAYBREAK pivotal studies.

KSI-501 Clinical Program Update

KSI-501 is an anti-IL-6, VEGF-trap bispecific antibody biopolymer conjugate built on the ABC Platform and is being developed for high prevalence retinal vascular diseases to address the unmet needs of extended durability and targeting disease biology beyond VEGF for differentiated efficacy. KSI-501 is designed to provide high immediacy/efficacy, driven by the enhanced formulation, and high durability, driven by the ABC Platform and our science of durability.

Higher intraocular levels of IL-6 are correlated with poorer BCVA outcomes over time in wet AMD patients treated with anti-VEGF monotherapy, which suggests that IL-6 inhibition in combination with anti-VEGF therapy could lead to improved outcomes. In preclinical models, KSI-501 was shown to be a potent inhibitor of VEGF and IL-6 and, further, was shown to normalize the blood retinal barrier, opening up the possibility that KSI-501 may be a disease-modifying therapy for retinal vascular diseases. A completed Phase 1 multiple ascending dose study demonstrated that repeated monthly dosing of KSI-501 was well tolerated and achieved clinically meaningful and sustained improvement in visual acuity and fluid reduction in patients with diabetic macular edema.

Kodiak has advanced KSI-501 into a Phase 3 study DAYBREAK to evaluate its efficacy and safety in wet AMD. The DAYBREAK study is a non-inferiority study evaluating parallel investigational arms of KSI-501 and tarcocimab against active comparator aflibercept. Patients randomized to KSI-501 will receive fixed every 8-week dosing with additional individualized dosing (up to monthly dosing) on an as needed basis after 4 monthly loading doses. Patients randomized to aflibercept will be dosed per its label. The primary endpoint is non-inferiority in change in visual acuity from baseline to the average of Week 40, 44 and 48. DAYBREAK uses KSI-501's enhanced 50 mg/mL formulation containing both conjugated and unconjugated antibody that is intended to deliver high immediacy and high durability. The objective for KSI-501 in DAYBREAK is to explore the efficacy potential of bispecific VEGF and IL-6 inhibition in a broad treatment-naïve wet AMD population. DAYBREAK is now actively enrolling patients.

KSI-101 Clinical Program Update

KSI-101 is a novel, potent and high strength (100 mg/mL) bispecific protein targeting IL-6 and VEGF. We are developing KSI-101 for patients who have retinal fluid and inflammation. Currently there are no available intravitreal biologic therapies addressing the spectrum of inflammatory conditions of the retina. We believe that retinal inflammatory conditions represent a new market segment separate from the established anti-VEGF market. KSI-101 is a clinical prospect with opportunities and risks uncoupled from the ABC Platform, and as such is an important part of our late-phase portfolio. We have initiated a dose-finding Phase 1b study APEX. The APEX study evaluates KSI-101 in two cohorts, Cohort 1 in patients with diabetic macular edema ("DME") and Cohort 2 in patients with macular edema secondary to inflammation ("MESI"). The goal of the APEX study is to evaluate the safety and tolerability of KSI-101 and to identify two dose levels to progress into dual Phase 2b/3 studies (PEAK and PINNACLE) in MESI.

In January 2025, we presented early APEX data in patients with MESI that demonstrated strong treatment response at all KSI-101 dose levels. We expect to present additional APEX data at an Investor R&D update in June 2025.

KSI-501 and KSI-101 Manufacturing

We have been progressing the manufacturing of KSI-501 and KSI-101 in preparation for the anticipated clinical studies. Clinical material for both KSI-501 (50 mg/mL strength in our enhanced formulation) and KSI-101 (100 mg/mL strength) were successfully manufactured in the first quarter of 2024.

ABC Platform Development

Kodiak is advancing its platform technology to embed small molecules and other active pharmaceutical ingredients ("API") into Kodiak's proprietary biopolymer backbone to enable high drug-antibody-ratio ("DAR") medicines. The diverse APIs are designed to be released over time to achieve targeted, multi-specific and tailored modulation of biological pathways. The unique combination of high DAR and tailored therapeutic benefit offers potential for broad application to multifactorial systemic and ocular diseases and builds directly from our Antibody Biopolymer Conjugate technology and its 15 years of design, development and manufacturing experience. We call this platform extension our Antibody Biopolymer Conjugate Drug ("ABCD") Platform because we are extending our platform capabilities to include the conjugation of small molecule drugs whereas historically we primarily conjugated biologics such as antibodies.

One program is for the treatment of glaucoma, embedding in the biopolymer backbone (i) an NLRP3 small molecule inhibitor, and (ii) a second small molecule that lowers intraocular pressure ("IOP"). The NLRP3 inflammasome is an intracellular complex that drives inflammation and cell death and is known to play a key role in glaucoma progression. The goal of this duet program is to create an intravitreally injected therapy that delivers two mechanisms of action ("MOA") in a sustained release fashion, to fulfill the unmet needs in the glaucoma field for non-topical, long-durability therapy that delivers MOAs beyond IOP lowering and has the potential of quarterly dosing.

The second program is for the treatment of geographic atrophy ("GA"). There are two approved therapies, both complement inhibitors, and they require monthly or every other month intravitreal injections and neither sufficiently halts disease progression. This program at Kodiak explores the potential to embed in the biopolymer backbone (i) a macrocyclic peptide inhibitor of the complement pathway, and (ii) an NLRP3 small molecule inhibitor. The NLRP3 inflammasome is known to play a key role in AMD disease biology. The objective of this duet program is to create an intravitreally injected ABCD platform-enabled therapy with a dual mechanism of action to achieve better efficacy and extended durability, for quarterly dosing, as compared to currently approved therapies for GA.

Digital Health Platform Development

Kodiak also continues to advance its VETi (Visual Engagement Technology and imager) program. VETi is built on Kodiak's suite of proprietary LiDAR (Light Detection and Ranging) sensor technologies. VETi is an autonomous AI- and machine-learning-enabled headset that engages directly into the eye. Kodiak's goal is to commercialize VETi together with Kodiak's emerging portfolio of retinal medicines using apps that apply AI-enabled tools. Kodiak also believes VETi has future potential to be used to build correlations between VETi data and many human diseases outside of retina and then to be used to diagnose disease and monitor treatment. VETi may also have future potential as an AI-enabled device with similarities to a consumer smartwatch but with direct access into the body and the brain through the eye rather than through the skin.

Financial Operations Overview

Since inception in June 2009, we have devoted substantially all of our resources to discovering and developing product candidates and manufacturing processes, building our ABC Platform and assembling our core capabilities in drug development for a broad spectrum of retinal diseases. We do not have any products approved for sale and have not generated any product revenue since inception. We have funded our operations primarily through the issuance of common stock and the sale of future royalties.

Components of Operating Results

Research and Development Expenses

Substantially all of our research and development expenses consist of expenses incurred in connection with the development of our product candidates and ABC Platform. These expenses include certain payroll and personnel expenses, including stock-based compensation, for our research and product development employees; laboratory supplies and facility costs; consulting costs; fees paid to third-party vendors to conduct certain research and development activities on our behalf; and allocated overhead, including rent, equipment, depreciation and utilities. We expense both internal and external research and development expenses as they are incurred. Costs of certain activities, such as manufacturing and preclinical and clinical studies, are generally recognized based on an evaluation of the progress to completion of specific tasks. Payments made prior to the receipt of goods or services that will be used or rendered for future research and development activities are deferred and capitalized. The capitalized amounts are recognized as expense as the goods are delivered or the related services are performed.

We are focusing substantially all of our resources and development efforts on the development of our product candidates. Predicting the timing or the final cost to complete our clinical program or validation of our commercial manufacturing and supply processes is difficult and delays may occur because of many factors, including factors outside of our control. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Furthermore, we are unable to predict when or if our drug candidates will receive regulatory approval with any certainty.

General and Administrative Expenses

General and administrative expenses consist principally of payroll and personnel expenses, including stock-based compensation; professional fees for legal, consulting, accounting and tax services; compliance costs associated with being a public company; allocated overhead, including rent, equipment, depreciation and utilities; and other general operating expenses not otherwise classified as research and development expenses.

Interest Income

Interest income consists primarily of interest income earned on our cash and cash equivalents.

Other Income (Expense), Net

Other income (expense), net consists primarily of the change in fair value and settlement of derivative contracts and tax expense.

Results of Operations

The following table summarizes the results of our operations for the periods indicated (in thousands, except percentages):

	Year Ended December 31,		Change	
	2024	2023	Dollar	Percent
Operating expenses				
Research and development	$ 126,095	$ 206,298	$ (80,203)	(39%)
General and administrative	60,754	71,023	(10,269)	(14%)
Loss from operations	(186,849)	(277,321)	90,472	(33%)
Interest income	11,148	16,733	(5,585)	(33%)
Interest expense	—	(13)	13	*
Other income (expense), net	(506)	110	(616)	*
Net loss	$ (176,207)	$ (260,491)	$ 84,284	(32%)

* Change is not meaningful

Research and Development Expenses

Research and development expenses decreased $80.2 million, or 39%, during the year ended December 31, 2024 as compared to 2023.

The following table summarizes our research and development expenses for the periods indicated (in thousands):

	Year Ended December 31,		
	2024	2023	Change
Tarcocimab program expenses	$ 39,496	$ 90,513	$ (51,017)
KSI-501 and KSI-101 program expenses	8,495	7,264	1,231
ABC Platform and other program expenses	12,915	20,997	(8,082)
Payroll and personnel expenses	45,522	65,382	(19,860)
Facilities and other research and development expenses	19,667	22,142	(2,475)
Total research and development expenses	$ 126,095	$ 206,298	$ (80,203)

Tarcocimab program expenses decreased $51.0 million during the year ended December 31, 2024 as compared to 2023, primarily driven by reduced manufacturing activities and decreased clinical activities for completed trials, partially offset by costs from active clinical trials for the tarcocimab development program.

KSI-501 and KSI-101 program expenses increased $1.2 million during the year ended December 31, 2024 as compared to 2023, stemming from expanding clinical activities for both product candidates.

ABC Platform and other program expenses decreased $8.1 million during the year ended December 31, 2024 as compared to 2023, due to reduced manufacturing activities.

Payroll and personnel expenses decreased $19.9 million during the year ended December 31, 2024 as compared to 2023, mainly attributable to timing of forfeitures of equity awards.

Facilities and other research and development expenses decreased $2.5 million during the year ended December 31, 2024 as compared to 2023, primarily driven by reduced costs for digital transformation activities as well as currency fluctuations in the revaluation of our lease and capital obligations.

General and Administrative Expenses

General and administrative expenses decreased $10.3 million, or 14%, during the year ended December 31, 2024 as compared to 2023, primarily driven by stock-based compensation expense related to previously issued higher value awards becoming fully vested.

Interest Income

Interest income decreased $5.6 million during the year ended December 31, 2024 as compared to 2023, which was mainly attributable to the decrease in cash available to earn interest during 2024.

Other Income (Expense), Net

Other income (expense), net decreased $0.6 million during the year ended December 31, 2024 as compared to 2023, which was mainly attributable to the settlement of foreign currency forward contracts.

Comparison of the Fiscal Years Ended December 31, 2023 and 2022

For a comparison of our results of operations for the fiscal years ended December 31, 2023 and 2022, refer to "Part II, Item 7 — Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on March 28, 2024.

Liquidity and Capital Resources; Plan of Operations

Sources of Liquidity

We have funded our operations primarily through the issuance of common stock and the sale of future royalties. As of December 31, 2024, we had cash and cash equivalents of $168.1 million. We believe that our current cash and cash equivalents will be sufficient to support our current and planned operations into 2026.

Future Funding Requirements

We have incurred net losses and negative cash flows from operations since inception. As of December 31, 2024, we had an accumulated deficit of $1,328.7 million. We expect to continue to incur operating losses and negative operating cash flows for the foreseeable future and as a result, there is substantial doubt regarding our ability to continue as a going concern.

We plan to raise additional capital to maintain current operations and to continue research and development activities. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we are unable to raise additional funds when needed, we may be required to pause, scale back or discontinue one or more of our development programs. We may also be required to sell or license rights to our product candidates or indications in certain territories to others that we would prefer to develop and commercialize ourselves. Adequate additional funding may not be available to us on acceptable terms or at all.

Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. Refer to the section of this report titled "Part I, Item 1A — Risk Factors" for additional risks associated with our substantial capital requirements.

To date, we have not generated any product revenue. We do not expect to generate any product revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates or enter into collaborative agreements with third parties, and we do not know when, or if, either will occur. We expect to continue to incur significant losses for the foreseeable future, and we expect our losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. We are subject to all of the risks typically related to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

The timing and amount of our operating expenditures and capital requirements will depend on many factors, including:

•the scope, timing, rate of progress and costs of our drug discovery, preclinical development activities, laboratory testing and clinical trials for our product candidates;

•the number and scope of clinical programs we decide to pursue;

•the scope and costs of manufacturing development and commercial manufacturing activities;

•the cost, timing and outcome of regulatory review of our product candidates;

•the cost and timing associated with commercializing our product candidates, if they receive marketing approval;

•the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;

•the extent to which we acquire or in-license other product candidates and technologies;

•our ability to establish and maintain collaborations on favorable terms, if at all;

•our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates; and

•the costs associated with being a public company.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans.

Also, the significant uncertainties caused by any public health crises, on-going geopolitical conflicts, inflation, tariffs, rising interest rates, bank failures, on-going supply chain disruptions and volatile equity capital markets may also negatively impact our operations and capital resources. We and our key clinical and manufacturing partners have been able to continue to advance our operations, and we continue to monitor the impact of the aforementioned events on our ability to continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. One or more of these events may ultimately have a material adverse effect on our liquidity and operating plans.

We have based our estimates on assumptions that may prove to be wrong, and we could deplete our available capital resources sooner than we expect. Because of the risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors.

Summary Statement of Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods presented below (in thousands):

	Year Ended December 31,	
	2024	**2023**
Net cash provided by (used in):		
Operating activities	$ (117,319)	$ (154,183)
Investing activities	(755)	249,226
Financing activities	501	31
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (117,573)	$ 95,074

Cash Flows from Operating Activities

Net cash used in operating activities decreased to $117.3 million for the year ended December 31, 2024, based on operational spend of $88.9 million and changes in operating assets and liabilities of $28.4 million.

Material Cash Requirements and Material Known Contractual Obligations and Commitments

Operating Leases

Operating lease payments represent our commitment for future minimum rent made under non-cancelable leases for our corporate offices in Palo Alto, California, office and laboratory space in Visp, Switzerland, and related to our Ursus Facility. Total future undiscounted payments for our operating lease obligations as of December 31, 2024 were $88.6 million, of which $14.9 million is due in the next twelve months.

Manufacturing Agreements

The Company has entered into service and equipment purchase agreements in the normal course of business with various providers, which can contain minimum commitments or other noncancelable obligations.

As of December 31, 2024, future contractual obligations related to these manufacturing agreements that may be subject to cancellation fees were $19.4 million, of which $15.0 million is expected to be due in the next twelve months.

In addition, future manufacturing contractual obligations totaling approximately 105.3 million Swiss Francs may be incurred for the potential clinical and commercial supply of tarcocimab and other antibody biopolymer conjugates medicines based on the agreements with Lonza for production at the Ursus Facility.

For further information on our leases and manufacturing agreements, refer to Note 8 to our consolidated financial statements included in "Part II, Item 8 — Financial Statements and Supplementary Data" of this Annual Report on Form 10-K.

Clinical Agreements

The Company may incur potential contingent payments upon our achievement of clinical, regulatory and commercial milestones, as applicable. Due to the uncertainty of the achievement and timing of the events requiring payment under these agreements, the amounts to be paid by us are not fixed or determinable at this time.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these consolidated financial statements requires us 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, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Accrued Research and Development

Our accrued research and development costs are estimated based on the level of services performed, including the phase or completion of events, and contracted costs. Accrued clinical trial and related costs are estimated using data such as patient enrollment, clinical site activations or information provided by outside service providers regarding their actual costs incurred. Management determined accrual estimates through reports from and discussions with clinical personnel and outside service providers as to the progress of trials, or the services completed. The estimated costs of research and development provided, but not yet invoiced, are included in accrued liabilities and other current liabilities on the consolidated balance sheet. If the actual timing of the performance of services or the level of effort varies from the original estimates, we will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other assets until the services are rendered.

Stock-Based Compensation

We measure and recognize compensation expense for all stock-based awards made to employees, directors and non-employees, based on estimated fair values of the awards on the grant date and recognized using the straight-line method over the requisite service period.

The fair value of options is estimated on the grant date using the Black-Scholes option valuation model or Monte Carlo simulation model. The calculation of stock-based compensation expense requires that we make certain assumptions and judgments about a number of complex and subjective variables used in the valuation model, including the expected term, expected volatility of the underlying common stock and risk-free interest rate. Our stock-based awards are subject to either service, performance-based or market-based vesting conditions. We evaluate whether achievement of the performance conditions is probable and record expense over the appropriate service period based on this assessment.

Changes in these assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require significant analysis and judgment to develop.

Impairment of Long-Lived Assets

We review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amounts of the assets may not be recoverable. Recoverability is measured by comparing the carrying amount of the assets to the estimated undiscounted net cash flows which the assets are expected to generate. If such assets are deemed not recoverable, an impairment loss is recognized in the amount by which the carrying amount of the assets exceeds the estimated fair value of the assets.

We applied significant judgment in determining we have one asset group and that there is no lower level to group assets for impairment testing. The determination of the asset group primarily considers the interdependencies of our assets, shared cost structure, and the interrelated future cash flow generation. We assessed the recoverability of our asset group during the year ended December 31, 2023 based on our decision to wind-down the tarcocimab program following the topline results from the Phase 3 GLEAM and GLIMMER studies. We determined that the estimated undiscounted net cash flows which the asset group was forecasted to generate exceeded the carrying amount of the asset group and therefore, no impairment loss was recognized in 2023. There was no such impairment of long-lived assets in the year ended December 31, 2024.

Recent Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is discussed under Note 2 to our consolidated financial statements included in "Part II, Item 8 — Financial Statements and Supplementary Data" of this Annual Report on Form 10-K.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of December 31, 2024, we had cash and cash equivalents of $168.1 million, primarily invested in money market funds. As of December 31, 2023, we had cash and cash equivalents of $285.5 million, primarily invested in money market funds. Due to the nature of the cash equivalents, we do not believe that interest rate risk had a material impact on our consolidated financial statements.

We do not believe that other market risks, like foreign currency exchange rate risk, had a significant impact on our results of operations for any periods presented herein.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Kodiak Sciences Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Kodiak Sciences Inc. and its subsidiaries (the "Company") as of December 31, 2024 and 2023, and the related consolidated statements of operations and comprehensive loss, of stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2024, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024 in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred net losses and negative cash flows from operations since inception that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements 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 of these consolidated financial statements 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits 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. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates 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 matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Certain Research and Development Costs

As described in Note 2 to the consolidated financial statements, costs related to research, design and development of products are charged to research and development expense as incurred. Research and development costs include, but are not limited to, payroll and personnel expenses, including stock-based compensation, laboratory supplies, outside services and allocated overhead, including rent, depreciation and utilities. The Company has entered into various agreements with various third parties, including clinical investigator sites, contract research organizations ("CROs") and contract manufacturing organizations ("CMOs"), to provide research and development activities. The Company's research and development expense for the year ended December 31, 2024 was $126.1 million, of which a portion relates to certain research and development costs.

The principal consideration for our determination that performing procedures relating to certain research and development costs is a critical audit matter is a high degree of auditor effort in performing procedures related to the Company's certain research and development costs.

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, among others, testing certain research and development costs on a sample basis by agreeing relevant information and expenses incurred to date to the (i) underlying agreements with outside vendors engaged to conduct preclinical studies, clinical trials, and clinical supply manufacturing; (ii) purchase orders; (iii) invoices received; and (iv) underlying payments made for expenses incurred on the contract.

/s/ PricewaterhouseCoopers LLP

San Jose, California
March 27, 2025

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

Kodiak Sciences Inc.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 168,074	$ 285,507
Prepaid expenses and other current assets	3,862	3,802
Total current assets	171,936	289,309
Restricted cash	6,184	6,324
Property and equipment, net	102,222	120,482
Operating lease right-of-use asset	46,508	54,541
Other assets	8,728	8,716
Total assets	$ 335,578	$ 479,372
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,915	$ 13,608
Accrued and other current liabilities	11,030	18,351
Operating lease liability	10,628	9,770
Total current liabilities	25,573	41,729
Operating lease liability, net of current portion	59,717	71,862
Liability related to sale of future royalties	100,000	100,000
Total liabilities	185,290	213,591
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized; 0 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	—	—
Common stock, $0.0001 par value, 490,000,000 shares authorized at December 31, 2024 and December 31, 2023; 52,726,916 and 52,508,602 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	5	5
Additional paid-in capital	1,479,021	1,418,307
Accumulated deficit	(1,328,738)	(1,152,531)
Total stockholders' equity	150,288	265,781
Total liabilities and stockholders' equity	$ 335,578	$ 479,372

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

Kodiak Sciences Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Year Ended December 31,		
	2024	**2023**	**2022**
Operating expenses			
Research and development	$ 126,095	$ 206,298	$ 267,591
General and administrative	60,754	71,023	73,788
Total operating expenses	186,849	277,321	341,379
Loss from operations	(186,849)	(277,321)	(341,379)
Interest income	11,148	16,733	7,071
Interest expense	—	(13)	(18)
Other income (expense), net	(506)	110	503
Net loss	$ (176,207)	$ (260,491)	$ (333,823)
Net loss per common share, basic and diluted	$ (3.35)	$ (4.97)	$ (6.39)
Weighted-average shares of common stock outstanding used in computing net loss per common share, basic and diluted	52,583,148	52,414,256	52,249,620
Other comprehensive income (loss)			
Change in unrealized gains (losses) related to available-for-sale debt securities, net of tax	—	1,307	(1,307)
Total other comprehensive income (loss)	—	1,307	(1,307)
Comprehensive loss	$ (176,207)	$ (259,184)	$ (335,130)

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

Kodiak Sciences Inc.
Consolidated Statements of Stockholders' Equity
(in thousands, except share and per share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2021	51,826,257	$ 5	$ 1,221,532	$ —	$ (558,217)	$ 663,320
Issuance of common stock upon exercise of stock options	126,999	—	1,770	—	—	1,770
Issuance of common stock upon vesting of restricted stock units	103,032	—	—	—	—	—
Issuance of common stock pursuant to employee stock purchase plan	27,863	—	174	—	—	174
Issuance of common stock upon exercise of common stock warrants	249,699	—	—	—	—	—
Stock-based compensation expense	—	—	106,033	—	—	106,033
Other comprehensive loss	—	—	—	(1,307)	—	(1,307)
Net loss	—	—	—	—	(333,823)	(333,823)
Balances at December 31, 2022	52,333,850	5	1,329,509	(1,307)	(892,040)	436,167
Issuance of common stock upon exercise of stock options	7,528	—	60	—	—	60
Issuance of common stock upon vesting of restricted stock units	116,403	—	—	—	—	—
Issuance of common stock pursuant to employee stock purchase plan	50,821	—	182	—	—	182
Stock-based compensation expense	—	—	88,556	—	—	88,556
Other comprehensive income	—	—	—	1,307	—	1,307
Net loss	—	—	—	—	(260,491)	(260,491)
Balances at December 31, 2023	52,508,602	5	1,418,307	—	(1,152,531)	265,781
Issuance of common stock upon exercise of stock options	82,790	—	394	—	—	394
Issuance of common stock upon vesting of restricted stock units	86,559	—	—	—	—	—
Issuance of common stock pursuant to employee stock purchase plan	48,965	—	107	—	—	107
Stock-based compensation expense	—	—	60,213	—	—	60,213
Net loss	—	—	—	—	(176,207)	(176,207)
Balances at December 31, 2024	52,726,916	$ 5	$ 1,479,021	$ —	$ (1,328,738)	$ 150,288

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

Kodiak Sciences Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2024	**2023**	**2022**
Cash flows from operating activities			
Net loss	$ (176,207)	$ (260,491)	$ (333,823)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation	18,710	18,298	3,796
Stock-based compensation	60,213	88,556	106,033
Loss on disposal of long-lived assets	—	2	—
Net amortization (accretion) of premium (discount) on marketable securities	—	(846)	(1,068)
Settlement of derivative contracts	355	—	(616)
Amortization of operating lease right-of-use asset	7,996	7,649	7,205
Amortization of issuance costs	—	4	53
Changes in assets and liabilities:			
Prepaid expenses and other current assets	(60)	8,451	(2,744)
Other assets	(12)	426	7,384
Accounts payable	(9,693)	5,597	1,660
Accrued and other current liabilities	(7,371)	(12,907)	(2,246)
Operating lease liability	(11,250)	(8,922)	7,907
Net cash provided by (used in) operating activities	(117,319)	(154,183)	(206,459)
Cash flows from investing activities			
Purchase of property and equipment	(375)	(41,350)	(37,021)
Deposits on property and equipment	(25)	(77)	(10,342)
Purchase of marketable securities	—	(49,347)	(427,766)
Maturities of marketable securities	—	340,000	138,000
Settlement of derivative contracts	(355)	—	616
Net cash provided by (used in) investing activities	(755)	249,226	(336,513)
Cash flows from financing activities			
Proceeds from issuance of common stock upon options exercise	394	60	1,770
Proceeds from issuance of common stock pursuant to employee stock purchase plan	107	182	174
Principal payments of tenant improvement allowance payable	—	(211)	(49)
Net cash provided by (used in) financing activities	501	31	1,895
Net increase (decrease) in cash, cash equivalents and restricted cash	(117,573)	95,074	(541,077)
Cash, cash equivalents and restricted cash, at beginning of period	291,831	196,757	737,834
Cash, cash equivalents and restricted cash, at end of period	$ 174,258	$ 291,831	$ 196,757
Reconciliation of cash, cash equivalents and restricted cash to consolidated balance sheets			
Cash and cash equivalents	$ 168,074	$ 285,507	$ 190,433
Restricted cash	6,184	6,324	6,324
Total cash, cash equivalents and restricted cash in consolidated balance sheets	$ 174,258	$ 291,831	$ 196,757
Supplemental cash flow information:			
Cash paid for interest	$ —	$ 13	$ 18
Supplemental disclosures of non-cash investing and financing information:			
Operating lease right-of-use asset obtained in exchange for operating lease liability	$ (49)	$ 2,668	$ (170)
Purchase of property and equipment under accounts payable and accruals	$ 50	$ —	$ 2,917
Reclassification of deposits to property and equipment	$ 25	$ 44,300	$ 5,363

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

1. The Company

Kodiak Sciences Inc. (the "Company") is a clinical stage biopharmaceutical company committed to researching, developing and commercializing transformative therapeutics to treat a broad spectrum of retinal diseases. The Company devotes substantially all of its resources to the research and development of its platform and product candidates including activities to conduct clinical studies of its product candidates, manufacture product candidates and provide general and administrative support for these operations.

Liquidity

As of December 31, 2024, the Company had cash and cash equivalents of $168.1 million. The Company has incurred net losses and negative cash flows from operations since inception. The Company has incurred net losses of $176.2 million, $260.5 million and $333.8 million for the years ended December 31, 2024, 2023 and 2022, respectively. The net cash used in operating activities was $117.3 million, $154.2 million and $206.5 million for the years ended December 31, 2024, 2023 and 2022, respectively.

The Company has historically funded its operations primarily through the issuance of common stock and the sale of future royalties. The Company's ability to achieve and sustain profitability will depend on the successful development, approval and commercialization of its product candidates and on the achievement of sufficient revenue to support its cost structure and, unless and until it does, the Company will need to raise additional capital to maintain current operations and to continue research and development activities. The Company continues to monitor and reduce certain expenditures and plans to raise additional capital through approaches that include equity or debt financings, collaborations or a combination of similar transactions. While the Company has been able to raise multiple rounds of financing, there can be no assurance that such financing will be available on terms which are favorable or at all. The Company could be required to pause, scale back or discontinue one or more of its development programs, which could adversely affect the Company's business, financial condition and results of operations.

The Company believes that the existing cash and cash equivalents may not be sufficient to meet the anticipated operating and capital expenditure requirements for the 12 months following the date of this Annual Report on Form 10-K. As a result, there is substantial doubt regarding the Company's ability to continue as a going concern. The consolidated financial statements have been prepared assuming that the Company will continue to operate as a going concern, which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("US GAAP").

Reclassification

Certain prior period amounts in the consolidated financial statements have been reclassified to conform to the current period presentation.

Principles of Consolidation

The consolidated financial statements include the Company's accounts and its subsidiaries. All intercompany accounts and transactions have been eliminated. The functional and reporting currency of the Company and its subsidiaries is the U.S. dollar. The aggregate foreign currency transaction gain (loss) included in determining net loss was $0.3 million, $(0.1) million, and $0.3 million for the years ended December 31, 2024, 2023 and 2022, respectively.

Segment Information

The Company operates and manages its business as one operating and reportable segment. Refer to Note 13.

Use of Estimates

The preparation of consolidated financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the date of the consolidated financial statements and expenses during the reporting period. Such estimates include, but are not limited to, accrued research and development, stock-based compensation and impairment of long-lived assets. Actual results could differ from those estimates.

Risks and Uncertainties

Global economic and business activities continue to face widespread macroeconomic uncertainties, including health epidemics, labor shortages, bank failures, inflation and monetary supply shifts, tariffs, recession risks and potential disruptions from the geopolitical conflicts. The Company continues to actively monitor the impact of these macroeconomic factors on its financial condition, liquidity, operations, and workforce. The extent of the impact of these factors on the Company's operational and financial performance, including its ability to execute its business strategies and initiatives in the expected timeframe, will depend on future developments, which are uncertain and cannot be predicted; however, any continued or renewed disruption resulting from these factors could negatively impact the Company's business.

The Company's future results of operations involve a number of risks and uncertainties common to clinical stage companies in the biotechnology industry. The Company's product candidates are in development and the Company operates in an environment of rapid change in technology and substantial competition from other pharmaceutical and biotechnology companies. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company's potential drug candidates, uncertainty of market acceptance of any of the Company's product candidates that receive regulatory approval, competition from new technological innovations, substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals and vendors.

Products developed by the Company require approvals from the U.S. Food and Drug Administration ("FDA") or other international regulatory agencies prior to commercial sales. There can be no assurance that any of the Company's product candidates will receive the necessary approvals. If the Company is denied approval, approval is delayed or the Company is unable to maintain approvals, it could have a materially adverse impact on the Company. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales.

The Company expects to incur substantial operating losses for the next several years and will need to obtain additional financing in order to complete clinical trials, launch and commercialize any product candidates for which it receives regulatory approval. There can be no assurance that such financing will be available or will be on terms acceptable by the Company.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. As of December 31, 2024 and 2023, cash and cash equivalents were invested primarily in money market funds through highly rated financial institutions. Investments are restricted, in accordance with the Company's investment policy, to a concentration limit per issuer or sector.

Cash and Cash Equivalents

The Company considers all highly liquid investments with stated maturities of three months or less at the date of purchase to be cash equivalents.

Marketable Securities

The Company may invest excess cash balances in marketable securities. The investments in marketable securities are classified as either held-to-maturity or available-for-sale based on facts and circumstances present at the time of purchase. Marketable securities with a remaining maturity date greater than one year are classified as non-current. The Company's marketable securities can consist of U.S. treasury securities, commercial paper, and corporate bonds. Marketable debt securities that are available for sale, are carried at fair value with the unrealized gains and losses included in other comprehensive income (loss) as a component of stockholders' equity until realized. Any premium or discount arising at purchase of marketable debt securities is amortized and/or accreted to interest income or expense over the life of the instrument. Realized gains and losses are determined using the specific identification method and are included in other income (expense), net.

Restricted Cash

As of December 31, 2024, and 2023, the Company had $6.2 and $6.3 million of long-term restricted cash deposited with financial institutions. The entire amount is held in separate bank accounts to support letter of credit agreements related to the Company's U.S. corporate offices.

Derivatives and Hedging

Derivative instruments that do not qualify for hedge accounting are recognized on the consolidated balance sheet at fair value, with changes in the fair value recognized on the consolidated statement of operations and comprehensive loss as a component of other income (expense), net. The cash flows associated with these derivatives are reflected as cash flows from investing activities in the consolidated statement of cash flows.

Fair Value of Financial Instruments

Accounting Standards Codification ("ASC") 820, *Fair Value Measurement*, establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances.

Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tier fair value hierarchy that distinguishes between the following:

Level 1—Observable inputs, such as quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs which reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and inputs to the model.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The carrying amounts of the Company's financial instruments consisting of cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued liabilities and other current liabilities, approximate fair value due to their relatively short maturities.

Leases

The Company determines if an arrangement is, or contains, a lease at inception and then classifies the lease as operating or financing based on the underlying terms and conditions of the contract. Leases with terms greater than one year are initially recognized on the consolidated balance sheet as right-of-use assets and lease liabilities based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes the incremental borrowing rate, which is the rate incurred to borrow, on a collateralized basis, an amount equal to the lease payments over a similar term and in a similar economic environment of the applicable country or region. Variable lease payments are excluded from the right of use assets and operating lease liabilities and are recognized in the period in which the obligation for those payments is incurred.

Property and Equipment, Net

Property and equipment are stated at cost, net of accumulated depreciation. Construction in progress reflects amounts incurred for construction or improvements of property or equipment that have not been placed in service. Construction in progress is transferred to specific property and equipment and depreciated when these assets are ready for their intended use. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which generally follows:

Asset Category	Useful Lives
Furniture and Fixtures	5 years
Machinery and Equipment	3 to 10 years
Computer Software and Hardware	3 to 5 years
Leasehold improvements	Lesser of the useful life or the term of the respective lease

Upon sale or retirement of assets, the costs and related accumulated depreciation are removed from the consolidated balance sheet and the resulting gain or loss is reflected in operations. Maintenance and repairs are charged to operations as incurred.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amounts of the assets may not be recoverable. Recoverability is measured by comparing the carrying amount of the assets to the estimated undiscounted net cash flows which the assets are expected to generate. If such assets are deemed not recoverable, an impairment loss is recognized in the amount by which the carrying amount of the assets exceeds the estimated fair value of the assets.

The Company applied significant judgment in determining it has one asset group and that there is no lower level to group assets for impairment testing. The determination of the asset group primarily considers the interdependencies of its assets, shared cost structure, and the interrelated future cash flow generation. The Company assessed the recoverability of its asset group during the year ended December 31, 2023 based on the Company's decision to wind-down the tarcocimab program following the topline results from the Phase 3 GLEAM and GLIMMER studies. The Company determined that the estimated undiscounted net cash flows which the asset group was forecasted to generate exceeded the carrying amount of the asset group. Therefore, no impairment loss was recognized in 2023. There was no such impairment of long-lived assets in the year ended December 31, 2024.

Research and Development Expenses

Costs related to research, design and development of products are charged to research and development expense as incurred. Research and development costs include, but are not limited to, payroll and personnel expenses, including stock-based compensation, laboratory supplies, outside services and allocated overhead, including rent, depreciation and utilities.

Accrued Research and Development

The Company has entered into various agreements with various third parties, including clinical investigator sites, contract research organizations ("CROs") and contract manufacturing organizations ("CMOs"), to provide research and development activities. The Company's accrued research and development costs are estimated based on the level of services performed, including the phase or completion of events, and contracted costs. Accrued clinical trial and related costs are estimated using data such as patient enrollment, clinical site activations or information provided by outside service providers regarding their actual costs incurred. Management determines accrual estimates through reports from and discussions with clinical personnel and outside service providers as to the progress of trials, or the services completed. The estimated costs of research and development provided, but not yet invoiced, are included in accrued and other current liabilities on the consolidated balance sheet. If the actual timing of the performance of services or the level of effort varies from the original estimates, the Company will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the performance of the related services are recorded as prepaid expenses or other assets until the services are rendered.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with the provisions of ASC 718, *Compensation-Stock Compensation*. The Company measures stock-based compensation expense for stock options and restricted stock units granted to its employees, directors and non-employees based on the estimated fair value of the awards on the grant date. The fair value of options is calculated using the Black-Scholes valuation model or the Monte Carlo simulation model, which requires the input of subjective assumptions, including (i) the calculation of expected term of the award, (ii) the expected stock price volatility, (iii) the risk-free interest rate, and (iv) expected dividends.

The expected term is determined based on hypothetical exercise data for unexercised stock options.

The expected volatility is estimated based on the Company's historical information for its common stock and supplemented by the historical stock price volatility of a representative peer group over a period equivalent to the expected term of the equity award.

The risk-free interest rate is estimated based on the U.S. Treasury securities with maturity dates commensurate with the expected term of the equity award.

The Company has never paid, and does not expect to pay, dividends in the foreseeable future.

The expense is recorded on a straight-line basis over the requisite service period, which is generally the vesting period, for the entire award. The Company accounts for forfeitures as they occur.

The Company has certain stock options and restricted stock units that vest in conjunction with certain performance conditions. At each reporting date, the Company is required to evaluate whether achievement of the performance conditions is probable. Compensation expense is recorded over the appropriate service period based upon the Company's assessment of accomplishing each performance provision. Refer to Note 12.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires, among other things, that deferred income taxes be provided for temporary differences between the tax basis of the Company's assets and liabilities and their financial statement reported amounts. In addition, deferred tax assets are recorded for the future benefit of utilizing net operating losses ("NOLs") and research and development credit carryforwards and are measured using the enacted tax rates and laws that will be in effect when such items are expected to reverse. A valuation allowance is provided against deferred tax assets unless it is more likely than not that they will be realized.

The Company accounts for uncertain tax positions by assessing all material positions taken in any assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

Comprehensive Loss

Comprehensive loss is composed of net loss and other comprehensive income (loss). Other comprehensive income (loss) consists primarily of unrealized gains and losses on debt securities.

Liability related to Sale of Future Royalties

On December 1, 2019, the Company and its subsidiary Kodiak Sciences GmbH entered into a funding agreement with Baker Bros. Advisors, LP ("BBA"), which holds more than 5% of the Company's stock, pursuant to which BBA purchased the right to receive a capped 4.5% royalty on future net sales of tarcocimab, the Company's anti-VEGF antibody biopolymer conjugate therapy, in exchange for $225.0 million. Under the terms of the funding agreement, there is no obligation to repay any funding amount received, other than through the capped royalty payments on future product revenues. The Company recorded the funding amount paid by BBA as a liability on the consolidated balance sheet net of issuance costs, in accordance with ASC 730, *Research and Development*. Under ASC 730, the significant related party relationship between the Company and BBA creates an implicit obligation to repay the funding amount paid to the Company. Once royalty payments to BBA are determined to be probable and estimable, and if such amounts exceed the liability balance, the Company will impute interest to accrete the liability on a prospective basis based on such estimates. If and when the Company makes royalty payments under the funding agreement, it would reduce the liability balance at such time. In July 2021, the funding agreement was amended, at the Company's request, that the remaining funding amount of $125.0 million would not be paid. Refer to Note 16.

Net Loss per Share

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock and potentially dilutive securities outstanding for the period. Since the Company has reported net loss for all periods presented, diluted net loss per share is the same as basic net loss per common share for those periods.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB"), under its ASC or other standard setting bodies, and adopted by the Company as of the specified effective date.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires disclosure of incremental segment information on an annual and interim basis. The ASU was adopted by the Company for the annual period ended December 31, 2024 and for the interim periods beginning January 1, 2025. Refer to Note 13.

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which enhances the disclosures required for income taxes in annual consolidated financial statements. The ASU is effective for fiscal years beginning after December 15, 2024, and early adoption is permitted. The Company is assessing the impact of this amendment on its consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-03, *Disaggregation of Income Statement Expenses*, which requires additional disclosure of the nature of expenses included in the income statement. The ASU is effective for annual periods beginning after December 15, 2026 and interim periods within fiscal years beginning after December 15, 2027, and early adoption is permitted. The Company is assessing the impact of this standard on its consolidated financial statements and related disclosures.

3. Property and Equipment, net

Property and equipment, net consists of the following (in thousands):

	December 31, 2024	December 31, 2023
Furniture and fixtures	$ 2,042	$ 2,042
Machinery and equipment	40,326	39,709
Computer software and hardware	378	378
Leasehold improvement	96,534	96,534
Construction in progress	4,204	4,371
Total property and equipment	143,484	143,034
Less: Accumulated depreciation	(41,262)	(22,552)
Total property and equipment, net	$ 102,222	$ 120,482

The Company's property and equipment are maintained in the United States and Switzerland with net book values of $35.6 million and $66.6 million, respectively, as of December 31, 2024 compared to $40.2 million and $80.3 million, respectively, as of December 31, 2023. Depreciation expense was $18.7 million, $18.3 million and $3.8 million for the years ended December 31, 2024, 2023 and 2022, respectively.

4. Accrued and Other Current Liabilities

Accrued and other current liabilities consist of the following (in thousands):

	December 31, 2024	December 31, 2023
Accrued salaries and benefits	$ 5,266	$ 6,078
Accrued clinical trial and related costs	2,803	2,701
Accrued manufacturing and research & development costs	2,148	8,662
Accrued legal fees and professional fees	443	196
Accrued other liabilities	370	714
Total accrued and other current liabilities	$ 11,030	$ 18,351

5. Fair Value Measurements

The following tables present the Company’s fair value hierarchy for assets measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements at December 31, 2024			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 166,464	$ —	$ —	$ 166,464
Total	$ 166,464	$ —	$ —	$ 166,464

	Fair Value Measurements at December 31, 2023			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 274,466	$ —	$ —	$ 274,466
Total	$ 274,466	$ —	$ —	$ 274,466

As of December 31, 2024 and 2023, the fair value of the liability related to sale of future royalties is based on the Company's current estimates of future royalties expected to be paid to BBA, which are considered Level 3 inputs. Refer to Note 16.

There were no transfers of assets or liabilities between the fair value measurement levels during the years ended December 31, 2024 and 2023.

6. Marketable Securities

As of December 31, 2024 and 2023, there were no marketable securities. There were no reclassifications out of accumulated other comprehensive income (loss), impairment charges or recoveries and no allowance for credit losses recorded for the years ended December 31, 2024, 2023 and 2022, respectively.

7. Derivatives

The Company uses certain derivative instruments, that are not designated as hedges for accounting purposes, which include foreign currency forward contracts. As of December 31, 2024 and 2023, the Company did not have any outstanding derivative instruments.

8. Commitments and Contingencies

Leases

Palo Alto, California Leases

In June 2020, the Company entered into lease agreements for two buildings at 1200 and 1250 Page Mill Road in Palo Alto, California, which are now the Company's U.S. corporate offices. The facilities are approximately 82,662 square feet and 72,812 square feet, respectively and include office and laboratory space. For 1200 Page Mill Road, the monthly rent during the initial 6.5-year term will be approximately $0.6 million, with annual year-over-year increases of 3% plus certain operating expenses and taxes and total rent abatement of approximately $7.2 million. The Company has an option to extend the lease term for a period of 6.5 years. For 1250 Page Mill Road, the monthly rent during the initial 13-year term will be approximately $0.5 million, with annual year-over-year increases of 3% plus certain operating expenses and taxes and total rent abatement of approximately $6.3 million. The Company has two options to extend the lease term for a period of 5 years each. The Company determined that the renewal options were not reasonably certain at lease inception for the two buildings. The Company executed a $10.9 million cash-collateralized letter of credit, which was subsequently reduced to $6.2 million as a result of meeting certain reduction requirements specified therein in 2020. The cash collateralizing the letter of credit is classified as restricted cash on the Company's consolidated balance sheet. The Landlord will provide a tenant improvement allowance of approximately $1.2 million for 1200 Page Mill Road and $10.6 million for 1250 Page Mill Road. The Company has fully utilized $10.6 million of the tenant improvement allowance for 1250 Page Mill Road. Under ASC 842, the Company classified these leases as operating leases and recorded right-of-use assets and lease liabilities on the lease commencement date.

Switzerland Lease

In April 2020, the Company entered into a lease agreement for office and laboratory space at Rottenstrasse 5 in Visp, Switzerland. The space is approximately 1,000 square meters. The initial lease term is 5 years, with automatic renewals every 5 years for a maximum lease term of 15 years. The monthly rent during the initial 5-year term will be approximately 32.0 thousand Swiss Francs plus certain operating expenses and taxes. Under ASC 842, the Company classified this lease as an operating lease and recorded a right-of-use asset and lease liability on the lease commencement date.

Ursus Facility

In August 2020, the Company and its wholly owned subsidiary Kodiak Sciences GmbH entered into a manufacturing agreement with Lonza Ltd ("Lonza") for the clinical and commercial supply of the Company's antibody biopolymer conjugate drug substance which included a custom-built manufacturing facility. The manufacturing agreement has an initial term of 8 years, and the Company has the right to extend the term up to a total of 16 years. The Company and Lonza each have the ability to terminate this agreement upon the occurrence of certain events.

In April 2021, the agreement was amended to provide for greater manufacturing flexibility, to define a comprehensive mandate as an antibody biopolymer conjugates manufacturing facility to be used for the Company's antibody biopolymer conjugates pipeline, at clinical as well as commercial scales, across a broad capacity range under the tight quality controls required for ophthalmology and retinal medicines, and to allow for future process and equipment changes as needed.

The Company concluded that this agreement contained an embedded lease as the custom-built manufacturing suite would be dedicated for the Company's use. On January 31, 2023, the custom-built manufacturing suite was commissioned as a cGMP facility. The consideration was allocated to lease and non-lease components as this agreement contained a significant service component (manufacturing services). Under ASC 842, the Company classified the lease portion as an operating lease and recorded a right-of-use asset and lease liability on the lease commencement date.

Fixed assets of $81.7 million, in leasehold improvements and machinery and equipment, were placed in service and capitalized as of January 31, 2023. In October 2023, payment was made for the remaining $26.8 million of these fixed assets.

The maturities of the operating lease liabilities, including the Ursus Facility lease, as of December 31, 2024 were as follows (in thousands):

Year ending December 31,	As of December 31, 2024
2025	$ 14,910
2026	16,537
2027	9,809
2028	8,606
2029	8,832
Thereafter	29,931
Total undiscounted lease payments	88,625
Less: imputed interest	(18,280)
Total operating lease liabilities	$ 70,345

The minimum lease payments above do not include any related common area maintenance charges or real estate taxes. The operating lease expenses for the years ended December 31, 2024, 2023 and 2022 were $13.0 million, $13.2 million and $12.8 million, respectively. Variable lease expenses, including common area maintenance charges and real estate taxes, for the years ended December 31, 2024, 2023 and 2022 were $3.3 million, $3.6 million and $3.1 million, respectively.

The weighted-average remaining lease terms and weighted-average discount rates were as follows:

	December 31, 2024	December 31, 2023
Weighted-average remaining lease term (in years)	6.8	7.5
Weighted-average discount rate	6.8%	6.8%

Manufacturing Agreements

The Company has entered into service and equipment purchase agreements in the normal course of business with various providers, pursuant to which such providers agreed to perform activities in connection with the manufacturing process of certain materials. These agreements, and any related amendments, state that planned activities and purchases that are included in the signed work orders are, in some cases, binding and, hence, obligate the Company to pay the full price of the work order upon satisfactory delivery of products and services or obligate the Company to the binding amount regardless of whether such planned activities are in fact performed. Per the terms of the agreements, the Company has the option to cancel signed orders at any time upon written notice, which may or may not be subject to payment of a cancellation fee. The level of cancellation fees may be dependent on the timing of the written notice in relation to the commencement date of the work, with the maximum cancellation amount dependent on the agreement or the work order.

As of December 31, 2024, future contractual obligations related to these manufacturing agreements that may be subject to cancellation fees, was $19.4 million. This amount represents our minimal contractual obligations, excluding the commitments under the Ursus Facility arrangement. Purchases under these manufacturing agreements for the years ended December 31, 2024, 2023 and 2022 were $25.8 million, $59.7 million and $47.4 million, respectively.

In addition, future manufacturing contractual obligations totaling approximately 105.3 million Swiss Francs may be incurred for the potential clinical and commercial supply of tarcocimab and other antibody biopolymer conjugates medicines based on the agreements with Lonza for production at the Ursus Facility.

Other Funding Commitments

In the normal course of business, the Company enters into agreements with third-parties for services to be provided to the Company. Generally, these agreements provide for termination upon notice, with specified amounts due upon termination based on the timing of termination and the terms of the agreement. The actual amounts and timing of payments under these agreements are uncertain and contingent upon the initiation and completion of services to be provided to the Company.

The Company has also entered into various cancellable license agreements for certain technology. The Company may be obligated to make payments on future sales of specified products associated with such license agreements. Such payments are dependent on future product sales and are not estimable.

Legal Proceedings

From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities. Management is currently not aware of any matters that could have a material adverse effect on the its financial position, results of operations or cash flows. The Company records a legal liability when it believes that it is both probable that a liability may be imputed, and the amount of the liability can be reasonably estimated. Significant judgment by the Company is required to determine both probability and the estimated amount.

Indemnification

To the extent permitted under Delaware law, the Company has agreed to indemnify its directors and officers for certain events or occurrences while the director or officer is, or was serving, at the Company's request in such capacity. The indemnification period covers all pertinent events and occurrences during the director's or officer's service. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is not specified in the agreements; however, the Company has director and officer insurance coverage that reduces its exposure and enables the Company to recover a portion of any future amounts paid. The Company believes the estimated fair value of these indemnification agreements in excess of applicable insurance coverage is minimal.

9. Income Taxes

The components of loss before income taxes were as follows (in thousands):

	Year Ended December 31, 2024	Year Ended December 31, 2023	Year Ended December 31, 2022
United States	$ (118,783)	$ (143,256)	$ (163,240)
Foreign	(57,404)	(117,176)	(170,550)
Total loss before income taxes	$ (176,187)	$ (260,432)	$ (333,790)

The provision (benefit) for income taxes consists of the following (in thousands):

	Year Ended December 31, 2024	Year Ended December 31, 2023	Year Ended December 31, 2022
Current:			
Federal	$ —	$ —	$ —
State	—	—	—
Foreign	20	33	33
Total current	20	33	33
Deferred:			
Federal	—	—	—
State	—	—	—
Foreign	—	—	—
Total deferred	—	—	—
Provision (Benefit) for income taxes	$ 20	$ 33	$ 33

The tax effects of temporary differences that give rise to significant components of the net deferred tax assets are as follows (in thousands):

	December 31, 2024	December 31, 2023
Deferred tax assets:		
Net operating loss carryforwards	$ 146,537	$ 133,919
Intangible assets	11,902	163,841
Research and development tax credits	32,641	29,630
Stock-based compensation	27,904	24,344
Accruals	1,085	1,086
Operating lease liability	13,748	15,845
Sec. 174 Capitalized R&D	23,683	16,992
Total deferred tax assets	257,500	385,657
Valuation allowance	(247,216)	(373,474)
Net deferred tax assets	10,284	12,183
Deferred tax liabilities:		
Operating lease right-of-use asset	(8,822)	(10,362)
Property and equipment	(1,462)	(1,821)
Total deferred tax liabilities	(10,284)	(12,183)
Total net deferred tax assets	$ —	$ —

The Company has recorded a full valuation allowance against its net deferred tax assets due to the uncertainty as to whether such assets will be realized. The net change in the total valuation allowance for the years ended December 31, 2024 and 2023, was a decrease of approximately $126.3 million and an increase of $25.7 million, respectively. The decrease in the year ended December 31, 2024 was due to the expiration of a foreign intangible asset.

NOLs and tax credit carry-forwards are subject to review and possible adjustment by the Internal Revenue Service ("IRS") and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50% as defined under Sections 382 and 383 in the Internal Revenue Code, which could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the Company's value immediately prior to the ownership change. The Company periodically completes a Section 382 analysis. Subsequent ownership changes since the most recent study may further affect the limitation in future years.

As of December 31, 2024, the Company had $111.5 million of federal and $616.3 million of state net operating loss available to offset future taxable income. A portion of the federal net operating loss carryforwards begin to expire in 2035 and the state net operating loss carryforwards begin to expire in 2035, if not utilized. $93.4 million of the federal net operating loss are not subject to expiration.

As of December 31, 2024, the Company also had federal and state research and development credit carryforwards of approximately $31.5 million and $9.9 million, respectively. The federal research and development credit carryforwards expire beginning 2035. The California tax credit can be carried forward indefinitely.

A reconciliation of the Company's effective tax rate to the statutory U.S. federal rate is as follows:

	December 31, 2024	December 31, 2023	December 31, 2022
Federal statutory income tax rate	21.0%	21.0%	21.0%
State taxes	0.3	(2.6)	5.8
Foreign tax rate differential	(3.0)	(4.3)	(4.7)
Intangible valuation	(86.2)	(0.8)	-
Research tax credit	1.3	1.4	1.8
Stock-based compensation	(5.1)	(4.1)	(3.9)
Other	-	(0.1)	-
Change in valuation allowance	71.7	(10.5)	(20.0)
Provision for income taxes	0.0%	0.0%	0.0%

The decrease in the intangible valuation in the year ended December 31, 2024 was due to the expiration of a foreign intangible asset.

The Company recognizes benefits of uncertain tax positions if it is more likely than not that such positions will be sustained upon examination based solely on their technical merits, as the largest amount of benefit that is more likely than not to be realized upon the ultimate settlement. As of December 31, 2024, 2023 and 2022, none of the unrecognized tax benefits would affect income tax expense with consideration of the valuation allowance. The Company does not anticipate the uncertain tax positions will materially change in the next 12 months. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

The beginning and ending unrecognized tax benefits amounts are as follows (in thousands):

	December 31, 2024	December 31, 2023	December 31, 2022
Unrecognized tax benefits at beginning of period	$ 8,245	$ 7,578	$ 6,729
Increases related to current year tax positions	558	667	849
Unrecognized tax benefits at end of period	$ 8,803	$ 8,245	$ 7,578

The Company files income tax returns in the United States and Switzerland. The Company is not currently under examination by income tax authorities in federal, state or other jurisdictions. All US tax returns remain open for examination by the federal and state authorities for three and four years, respectively, from the date of utilization of any net operating loss or credits.

10. Preferred Stock

As of December 31, 2024 and 2023, the Company's amended and restated certificate of incorporation authorized the Company to issue up to 10,000,000 shares of preferred stock at the par value of $0.0001 per share. As of December 31, 2024, there are no shares of the Company's preferred stock issued or outstanding.

11. Common Stock

As of December 31, 2024 and 2023, the Company's amended and restated certificate of incorporation authorized the Company to issue 490,000,000 shares of common stock at the par value of $0.0001 per share. Each share of common stock is entitled to one vote. The board of directors may declare and pay dividends to holders of common stock. The Company has never declared or paid any dividends on common stock.

The Company had reserved common stock for future issuances as follows:

	December 31, 2024	December 31, 2023
Exercise of options outstanding and release of restricted shares	19,994,733	17,766,283
Issuance of common stock under the 2018 Equity Incentive Plan	1,862,920	2,460,375
Issuance of common stock under the 2018 Employee Share Purchase Plan	325,393	374,358
Total	22,183,046	20,601,016

12. Stock-Based Compensation

2018 Equity Incentive Plan

In August 2018, the Company adopted the 2018 Equity Incentive Plan ("2018 Plan"), which became effective on the business day prior to the effectiveness of the registration statement relating to the IPO. The 2018 Plan initially reserved 4,300,000 shares of common stock for the issuance of incentive stock options ("ISOs"), nonstatutory stock options ("NSOs"), restricted stock, restricted stock units ("RSUs"), stock appreciation rights, performance units and performance shares to employees, directors and consultants of the Company. The number of shares available for issuance increases annually on the first day of each fiscal year equal to the least of (1) 4,300,000 shares, and (2) 4% of outstanding shares of common stock as of the last day of the immediately preceding year, and (3) such other amount as determined by the board of directors. The exercise price of options must be equal to at least the fair market value of the common stock on the grant date. For ISOs, the term may not exceed ten years, except in respect to any participant with more than 10% of voting power of all classes of stock, then the term may not exceed five years and the exercise price must be equal to at least 110% of the fair market value of the common stock on the grant date. Options and RSUs granted generally vest over four years.

The number of shares available for issuance increased by 2,100,344 shares in 2024 and there were 1,862,920 shares available for grant under the 2018 Plan as of December 31, 2024.

2021 Long-Term Performance Incentive Plan

The 2021 Long-Term Performance Incentive Plan ("2021 LTPIP") was designed to be a long-term, pay-for-performance, incentive plan that would further align the interests of management and other eligible employees with the creation of substantial long-term value for the Company's stockholders. During 2021, eligible employees were provided a one-time opportunity to "opt-in" and forgo a portion of their annual equity incentive awards in exchange for a one-time grant of performance-based stock options from the 2021 LTPIP and 2018 Plan, collectively referred to as the "LTPIP Program". There were no options granted under the LTPIP Program for the year ended December 31, 2024.

Shares underlying the options granted under the LTPIP Program may be earned based on the achievement of the performance-based requirement based on stock price goals and/or certain operational milestones based on approval by the U.S. Food and Drug Administration of a Biologics License Application in respect of a first, second, and third major indication and based on sales. The performance-based requirement and operational milestones were not achieved as of December 31, 2024.

The Company determined the exchange of the original award of annual equity incentive awards with the modified award of options granted under the LTPIP Program represented a change in the original terms and conditions. The modification resulted in additional compensation cost equal to the incremental value between the original and modified awards to be recognized. For the annual equity incentive awards, the Company continues to record the unrecognized compensation expense over the original vesting period. For the options granted under the LTPIP Program, the stock-based compensation expense recognized during the years ended December 31, 2024, 2023 and 2022 was $42.9 million, $53.7 million and $65.1 million, respectively.

As of December 31, 2024, there was $96.3 million of unrecognized stock-based compensation expense related to the 5,659,816 options granted under the LTPIP Program, but not yet earned or vested, to be recognized over a weighted-average period of 2.07 years.

Stock Options

Stock option activity, including stock options and performance-based stock options under the 2021 LTPIP, 2018 Plan and 2015 Plan is summarized as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	17,601,466	$ 43.86	7.29	$ 933
Granted	4,249,650	$ 2.59		
Exercised	(82,790)	$ 4.75		
Forfeited or canceled	(1,895,253)	$ 34.78		
Outstanding at December 31, 2024	19,873,073	$ 36.06	6.88	$ 51,018
Shares exercisable December 31, 2024	11,334,432	$ 33.97	5.94	$ 22,755
Vested and expected to vest December 31, 2024	19,873,073	$ 36.06	6.88	$ 51,018

The weighted-average grant date fair value of the time-vested stock options granted for 2024, 2023 and 2022 was $1.74, $4.51 and $6.31 per share, respectively. The total intrinsic value of stock options exercised during 2024, 2023 and 2022 was $0.3 million, not significant, $6.1 million, respectively. The intrinsic value represents the amount by which the market price of the underlying stock exceeds the exercise price of an option.

Employee Stock Options

The Company estimated the fair value of employee stock options using the Black-Scholes valuation model. The fair value of time-vested employee stock options was estimated using the following weighted-average assumptions:

	Year Ended December 31,		
	2024	2023	2022
Expected volatility	92%	86%	83%
Risk-free interest rate	3.91%	3.55%	2.86%
Dividend yield	0%	0%	0%
Expected term	3.99	4.00	5.98

The Company granted 4,195,650 options to employees in 2024. The total fair value of employee options vested during the years ended December 31, 2024, 2023 and 2022 was $13.4 million, $25.6 million and $28.9 million, respectively. Stock-based compensation expense recognized during the years ended December 31, 2024, 2023 and 2022 for options granted to employees, including the options granted under the LTPIP Program, was $56.7 million, $80.8 million and $93.8 million, respectively.

Restricted Shares

Restricted share activity, including restricted stock awards, restricted stock units, and performance-based restricted stock units, under the 2018 Plan is summarized as follows:

	Number of Restricted Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2023	164,817	$ 49.87
Granted	75,100	$ 3.23
Vested	(86,559)	$ 59.68
Canceled	(31,698)	$ 42.27
Unvested at December 31, 2024	121,660	$ 16.08

Employee Restricted Stock Units

The Company granted 75,100 RSUs to employees in 2024. The total fair value of RSUs vested during the year ended December 31, 2024, 2023, and 2022 was $3.5 million, $4.8 million and $4.9 million, respectively. Stock-based compensation expense recognized during the years ended December 31, 2024, 2023 and 2022 for RSUs was $2.4 million, $4.5 million, and $4.6 million, respectively.

Non-Employee Awards

The Company granted 54,000 stock options to non-employees during the year ended December 31, 2024. The Company granted 22,500 stock options and 1,500 RSUs to non-employees during the year ended December 31, 2023. The fair value of non-employee stock options was estimated using the following weighted-average assumptions:

	Year Ended December 31, 2024	Year Ended December 31, 2023	Year Ended December 31, 2022
Expected volatility	92%	88%	—
Risk-free interest rate	4.44%	3.82%	—
Dividend yield	0%	0%	—
Expected term	3.28	4.11	—

Stock-based compensation expense recognized during the years ended December 31, 2024, 2023 and 2022 for equity awards granted to non-employees was $0.2 million, $0.9 million and $1.2 million, respectively.

Performance-Based Awards

In December 2019, the Company granted 170,150 performance-based stock options and 128,900 performance-based RSUs (collectively "2019 PSA"). These equity awards would vest 25% upon the achievement of specific clinical development milestones. The remaining awards would then vest in three equal annual installments after that date. The performance criteria for 2019 PSA was achieved in June 2021. 37,925 of the performance-based stock options and 21,570 of the performance-based restricted stock vested during 2024. The total fair value of the performance-based stock options and RSUs vested during the years ended December 31, 2024, 2023 and 2022 was $3.4 million, $3.7 million and $3.9 million, respectively.

The Company estimated the fair value of the 2019 PSA using the Black-Scholes valuation model and significant assumptions included an expected volatility of 72%, a risk-free rate of 1.67%, expected dividend yield of 0%, and expected term of 6.31 years.

In February 2021, the Company granted 190,831 performance-based stock options ("2021 Feb PSO"). These stock options will vest 25% upon the achievement of specific clinical development milestones. The remaining awards would then vest in 36 successive equal monthly installments after the performance criteria is achieved. The performance criteria for 2021 Feb PSOs was achieved in February 2022. 44,695 of the performance-based stock options vested during 2024. The total fair value of the performance-based stock options vested during the year ended December 31, 2024, 2023 and 2022 was $3.5 million, $3.1 million and $6.2 million, respectively.

The Company estimated the fair value of the 2021 Feb PSO using the Black-Scholes valuation model. Significant assumptions utilized in estimating the fair value of 2021 Feb PSO include an expected volatility of 66%, a risk-free rate of 0.66%, expected dividend yield of 0%, and expected term of 5.94 years.

In August 2021, the Company granted 478,750 performance-based stock options ("2021 Aug PSO"). These stock options will vest upon the achievement of specific clinical development milestones with the percentage of shares earned being dependent on the relative total stockholder return over the performance period. As of December 31, 2023, the requisite performance criteria for the 2021 Aug PSO was not achieved and the shares were cancelled and returned to the plan. No stock-based compensation expense was recognized related to these stock options.

Performance-based awards are recorded as expense beginning when vesting events are determined to be probable. Stock-based compensation expense recognized during the years ended December 31, 2024, 2023 and 2022 for the performance-based equity awards was $0.8 million, $2.2 million and $6.3 million, respectively.

2018 Employee Share Purchase Plan

In August 2018, the Company adopted the 2018 Employee Share Purchase Plan ("ESPP"), which became effective on the business day prior to the effectiveness of the registration statement relating to the IPO. A total of 460,000 shares of common stock were initially reserved for issuance under the ESPP. The initial offering period of the ESPP was authorized by the Company's board of directors and commenced on January 4, 2021. Each offering period is twelve months long, with two purchase periods. ESPP participants will purchase shares of common stock at a price per share equal to 85% of the lesser of (1) the fair market value per share of the common stock on the enrollment date or (2) the fair market value of the common stock on the exercise date.

The Company issued 48,965 shares under the ESPP during the year ended December 31, 2024. Stock-based compensation expense recognized during the year ended December 31, 2024, 2023 and 2022 for the ESPP was $0.1 million, $0.2 million and $0.2 million, respectively.

Stock-Based Compensation Expense

Stock-based compensation is classified in the consolidated statements of operations and comprehensive loss as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Research and development	$ 24,162	$ 44,014	$ 59,288
General and administrative	36,051	44,542	46,745
Total stock-based compensation	$ 60,213	$ 88,556	$ 106,033

As of December 31, 2024, the Company had $115.7 million of unrecognized compensation expense related to unvested share-based awards including options granted under the LTPIP Program and ESPP, which is expected to be recognized over a weighted-average period of 2.08 years.

Shares Subject to Repurchase

The Company has a right of repurchase with respect to unvested shares issued upon early exercise of options at an amount equal to the lower of (1) the exercise price of each restricted share being repurchased and (2) the fair market value of such restricted share at the time the Company's right of repurchase is exercised. The Company's right to repurchase these shares lapses as those shares vest over the requisite service period.

Shares purchased by employees pursuant to the early exercise of stock options are not deemed, for accounting purposes, to be issued until those shares vest according to their respective vesting schedules. Cash received for early exercised stock options is recorded as accrued liabilities and other current liabilities on the consolidated balance sheet and is reclassified to common stock and additional paid-in capital as such shares vest. At December 31, 2024, there were no early exercised stock options subject to the Company's right of repurchase.

13. Segment Information

The Company operates and manages its business as one operating and reportable segment, which is the business of researching, developing and commercializing transformative therapeutics to treat a broad spectrum of retinal diseases. The chief operating decision maker ("CODM") is the Chief Executive Officer. The CODM uses net loss to allocate resources and assess performance when making decisions on the timing and extent of the Company's development programs for its product candidates. The assets are managed on a consolidated basis as reported on the consolidated balance sheets.

The significant expense categories within net loss are presented on the consolidated statements of operations. The research and development expenses have been disaggregated as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Tarcocimab program expenses	$ 39,496	$ 90,513	$ 132,953
KSI-501 and KSI-101 program expenses	8,495	7,264	6,964
ABC Platform and other program expenses	12,915	20,997	27,409
Payroll and personnel expenses	45,522	65,382	79,314
Facilities and other research and development expenses	19,667	22,142	20,951
Total research and development expenses	$ 126,095	$ 206,298	$ 267,591

14. Net Loss per Common Share

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders (in thousands, except share and per share data):

	Year Ended December 31,		
	2024	2023	2022
Numerator:			
Net loss attributable to common stockholders	$ (176,207)	$ (260,491)	$ (333,823)
Denominator:			
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	52,583,148	52,414,256	52,249,620
Net loss per share attributable to common stockholders, basic and diluted	$ (3.35)	$ (4.97)	$ (6.39)

The following common share equivalents were excluded from the computation of diluted net loss per common share for the periods presented because their inclusion would have been antidilutive:

	As of December 31,		
	2024	2023	2022
Outstanding stock options	19,873,073	17,601,466	16,542,107
Unvested restricted shares	121,660	164,817	280,522
Total	19,994,733	17,766,283	16,822,629

15. 401(k) Plan

In 2011, the Company adopted a 401(k) retirement and savings plan covering all employees. The 401(k) plan allows employees to make pre- and post-tax contributions up to the maximum allowable amount set by the Internal Revenue Service. The 401(k) plan was amended to include an employer matching provision in 2019. The Company will make matching contributions of 100% of employee contributions up to a maximum of $10,250. For the years ended December 31, 2024, 2023 and 2022, the expense related to the matching contributions was $0.9 million, $0.9 million and $0.9 million, respectively.

16. Liability related to Sale of Future Royalties

On December 1, 2019, the Company and its subsidiary Kodiak Sciences GmbH entered into a funding agreement with BBA, which holds more than 5% of the Company's stock, pursuant to which BBA purchased the right to receive a capped 4.5% royalty on future net sales of tarcocimab, the Company's anti-VEGF antibody biopolymer conjugate therapy, in exchange for $225.0 million. Under the terms of the funding agreement, there is no obligation to repay any funding amount received, other than through the capped royalty payments on future product revenues. The royalty terminates upon the date that BBA has received an aggregate amount equal to 4.5 times the funding amount paid to the Company, unless earlier terminated or repurchased by the Company. The Company has the option, exercisable at any point during the term of the funding agreement, to repurchase 100% of the royalties due to BBA for a purchase price equal to 4.5 times the funding amount paid to the Company as of such time, less amounts paid by the Company to BBA.

The closing of the funding agreement was subject to certain conditions and occurred in February 2020. The Company received $100.0 million of the funding on February 4, 2020. The remaining $125.0 million, subject to delivery of notice by the Company, was payable upon enrollment of 50% of the patients in the RVO clinical program. In July 2021, the funding agreement was amended, at the Company's request, that the remaining funding amount of $125.0 million would not be paid.

The Company recorded the initial $100.0 million payment as a liability on the consolidated balance sheet net of issuance costs. Once royalty payments to BBA are determined to be probable and estimable, and if such amounts exceed the liability balance, the Company will impute interest to accrete the liability on a prospective basis based on such estimates. If and when the Company makes royalty payments under the funding agreement, it would reduce the liability balance at such time. As of December 31, 2024, royalty payments are not probable and estimable. For the years ended December 31, 2024, 2023, and 2022, no interest expense was recognized for the liability related to the sale of future royalties.

17. Subsequent Event

In March 2025, the Company entered into a sublease agreement for the corporate office space located at 1200 Page Mill Road for the remainder of the initial lease term until February 2027. The Company retains the option to reoccupy the space and to extend the lease term of the building located at 1200 Page Mill Road for a period of 6.5 years.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Management's Evaluation of our Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of the Company's disclosure controls and procedures as of December 31, 2024. Based upon such evaluation, our principal executive officer and principal financial officer concluded that the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2024.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act). Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements and 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. Under the supervision of and with the participation of our principal executive officer and principal financial officer, our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2024 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in "Internal Control—Integrated Framework" (2013). Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2024.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended December 31, 2024, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Auditor Attestation

We are a non-accelerated filer under the Exchange Act and not required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002. Therefore, this Annual Report does not include an attestation report of our registered public accounting firm regarding the effectiveness of internal control over financial reporting as of December 31, 2024.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item will be contained in our definitive proxy statement to be filed with the SEC in connection with the Annual Meeting of Stockholders within 120 days after December 31, 2024, or the Proxy Statement, under the captions "Executive Officers" and "Board of Directors and Corporate Governance", and is incorporated in this Annual Report on Form 10-K by reference.

Our board of directors has adopted a Code of Business Conduct and Ethics that applies to all of our employees, officers and directors, including our Chief Executive Officer, Chief Financial Officer, and other executive and senior financial officers. The full text of our Corporate Governance Guidelines and Code of Business Conduct and Ethics is posted on the Corporate Governance portion of our website at ir.kodiak.com/corporate-governance/governance-overview. We intend to satisfy the disclosure requirements under Item 5.05 of the SEC Form 8-K regarding an amendment to, or waiver from, a provision of our Code of Conduct by posting such information on our website at the website address and location specified above.

Our board of directors has adopted insider trading policies and procedures that govern the purchase, sale, and other dispositions of our securities by our directors, officers, and employees. We believe these policies and procedures are reasonably designed to promote compliance with insider trading laws, rules, and regulations, and applicable listing standards. A copy of our insider trading policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be contained in the Proxy Statement under the captions "Executive Compensation" (excluding the information presented under the subheading "Pay Versus Performance") and "Non-Employee Director Compensation" and is incorporated in this Annual Report on Form 10-K by reference.

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

The information required by this item will be contained in the Proxy Statement under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance Under Equity Compensation Plans" and is incorporated in this Annual Report on Form 10-K by reference.

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

The information required by this item will be contained in the Proxy Statement under the captions "Related-Person Transactions" and "Board of Directors and Corporate Governance – Director Independence" and is incorporated in this Annual Report on Form 10-K by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will be contained in the Proxy Statement under the caption "Ratification of Appointment of Independent Registered Public Accounting Firm" and is incorporated in this Annual Report on Form 10-K by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) FINANCIAL STATEMENTS

The consolidated financial statements are filed as part of this Annual Report on Form 10-K under Item 8.

(2) FINANCIAL STATEMENT SCHEDULES

All schedules to the consolidated financial statements are omitted as the required information is either inapplicable or presented in the consolidated financial statements.

(3) EXHIBITS

EXHIBIT INDEX

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of Kodiak Sciences Inc.	10-Q	001-38682	3.1	11/16/2018
3.2	Amended and Restated Bylaws of Kodiak Sciences Inc.	10-Q	001-38682	3.2	11/16/2018
4.1	Form of Common Stock Certificate	S-1/A	333-227237	4.1	9/24/2018
4.2	Investors' Rights Agreement, dated September 8, 2015, as amended, by and among the registrant and the investors and founders named therein	S-1/A	333-227237	4.2	9/24/2018
4.5	Form of Class B Share Warrant	S-1/A	333-227237	4.5	9/7/2018
4.6	Description of Securities	10-K	001-38682	4.6	3/16/2020
4.7	Registration Rights Agreement, dated March 1, 2021, by and among the registrant and the investors named therein	10-K	001-38682	4.7	3/1/2021
10.1+	Form of Director and Officer Indemnification Agreement	S-1/A	333-227237	10.1	9/24/2018
10.2+	2009 Options and Profits Interest Plan	S-1	333-227237	10.2	9/7/2018
10.3+	2015 Share Incentive Plan	S-1	333-227237	10.3	9/7/2018
10.4+	Form of Notice of Stock Option Grant and Stock Option Agreement under the 2009 Option and Profits Interest Plan	S-1	333-227237	10.4	9/7/2018
10.5+	Form of Notice of Stock Option Grant and Stock Option Agreement under the 2015 Share Incentive Plan	S-1	333-227237	10.5	9/7/2018
10.6+	2018 Equity Incentive Plan	S-1/A	333-227237	10.6	9/24/2018
10.7+	Form of Notice of Stock Option Grant and Stock Option Agreement under the 2018 Equity Incentive Plan	S-1/A	333-227237	10.7	9/24/2018
10.8+	Form of Notice of Restricted Stock Unit Grant and Terms and Conditions of Restricted Stock Unit Grant under the 2018 Equity Incentive Plan	S-1/A	333-227237	10.8	9/24/2018
10.9+	2018 Employee Stock Purchase Plan	S-1/A	333-227237	10.9	9/24/2018

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.10+	Form of Subscription Agreement under the 2018 Employee Stock Purchase Plan	S-1/A	333-227237	10.10	9/24/2018
10.11+	Executive Employment Agreement, effective as of September 6, 2018, between the Registrant and Victor Perlroth	S-1/A	333-227237	10.11	9/24/2018
10.12+	Amended Executive Employment Agreement, effective as of September 6, 2018, between the Registrant and John Borgeson	S-1/A	333-227237	10.12	9/24/2018
10.13+	Executive Incentive Compensation Plan	S-1/A	333-227237	10.15	9/24/2018
10.14	Funding Agreement, dated as of December 1, 2019, between Kodiak Sciences Inc., Kodiak Sciences GmbH and Baker Bros. Advisors, LP	8-K	001-38682	10.1	12/2/2019
10.15	Lease Agreement for 1200 Page Mill Road, Building 3, by and between the Registrant and 1050 Page Mill Road Property, LLC, dated June 19, 2020	10-Q	001-38682	10.1	8/10/2020
10.16	Lease Agreement for 1250 Page Mill Road, Building 4, by and between the Registrant and 1050 Page Mill Road Property, LLC, dated June 19, 2020	10-Q	001-38682	10.2	8/10/2020
10.17	Letter Agreement, dated July 22, 2021	8-K	001-38682	10.1	7/23/2021
10.18	2021 Long-Term Performance Incentive Plan	10-Q	001-38682	10.1	11/9/2021
19.1*	Kodiak Sciences Inc. Insider Trading Policy				
21.1*	Subsidiaries of the Company				
23.1*	Consent of Independent Registered Public Accounting Firm				
24.1*	Power of Attorney (included in signature page)				
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
31.2*	Certification of Principal Financial and Accounting Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2*	Certification of Principal Financial and Accounting Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
97.1	Incentive Compensation Recoupment Policy	10-K	001-38682	97.1	3/28/2024
101.INS	Inline XBRL Instance Document				
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbases Document				
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				

* Filed herewith.

+ Indicates management contract or compensatory plan.

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 Annual Report on Form 10-K to be signed on its behalf by the undersigned thereunto duly authorized.

KODIAK SCIENCES INC.

Date: March 27, 2025 By:

/s/ Victor Perlroth
Victor Perlroth, M.D.
Chairman and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Victor Perlroth and John Borgeson, jointly and severally, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K 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/ Victor Perlroth Victor Perlroth, M.D.	Chairman and Chief Executive Officer *(Principal Executive Officer)*	March 27, 2025
/s/ John Borgeson John Borgeson	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 27, 2025
/s/ Felix J. Baker Felix J. Baker, Ph.D.	Director	March 27, 2025
/s/ Charles Bancroft Charles Bancroft	Director	March 27, 2025
/s/ Bassil I. Dahiyat Bassil I. Dahiyat, Ph.D.	Director	March 27, 2025
/s/ Richard S. Levy Richard S. Levy, M.D.	Director	March 27, 2025
/s/ Robert A. Profusek Robert A. Profusek, J.D.	Director	March 27, 2025
/s/ Taiyin Yang Taiyin Yang, Ph.D.	Director	March 27, 2025