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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2025
OR

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

For the transition period from to
Commission file number 001-38150

KALA BIO, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**27-0604595**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1167 Massachusetts Avenue **Arlington, MA** (Address of principal executive offices)	**02476** (Zip Code)

(781) 996-5252
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**KALA**	**The Nasdaq Capital Market**

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 ☒

As of June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the Common Stock held by non-affiliates of the registrant was approximately $24.6 million, based on the closing price of the registrant's common stock on June 30, 2025.

There were 929,491,578 shares of common stock, par value $0.001 per share, outstanding as of April 10, 2026.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this Annual Report on Form 10-K, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Annual Report on Form 10-K include, among other things, statements about:

- our plans and expectations regarding our pursuit of strategic options;
- our ability to obtain additional financing;
- our ability to monetize our assets;
- our ability to continue as a going concern;
- our ability to regain and maintain compliance with the Nasdaq listing standards;
- our ability to retain our remaining employees, consultants, advisors;
- our ability to resume research and development activities for our MSC-S platform if we were to execute a strategic transaction or obtain significant additional funding, and our ability to develop and commercialize the Researgency agentic AI research platform;
- if we were to resume research and development activities, development efforts for KPI-012 and KPI-014 for potential ocular diseases;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- our plans and goals with respect to the AI platform business and the deployment of the Researgency agentic AI research platform, including the development of commercial arrangements with customers in the biotechnology and pharmaceutical industries;
- if we were to resume research and development activities, the rate and degree of market acceptance and clinical utility of our product candidates and our estimates regarding the market opportunity for our product candidates, if approved;
- our expectations regarding our ability to fund our operating expenses, lease and capital expenditure requirements with our cash on hand;
- our intellectual property position;
- our estimates regarding expenses, future revenue, timing of any future revenue, capital requirements and needs for additional financing;
- the impact of government laws and regulations;
- our competitive position;
- developments relating to our competitors and our industry;

- our business and business relationships; and
- the potential impact of global economic and geopolitical developments on our business, operations, strategy and goals.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the "Risk Factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K and have filed as exhibits to this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Annual Report on Form 10-K are made as of the date of filing of this Annual Report on Form 10-K, and we do not assume any obligation to update any forward-looking statements except as required by applicable law.

This Annual Report on Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by us and third parties as well as our estimates of potential market opportunities. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our estimates of the potential market opportunity for the Researgency agentic AI research platform and KPI-012 include several key assumptions based on our industry knowledge, industry publications, third-party research and other surveys, which may be based on a small sample size and may fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions.

Risk Factor Summary

Our business is subject to a number of risks that if realized could materially affect our business, financial condition, results of operations, cash flows and access to liquidity. These risks are discussed more fully in the "Risk Factors" section of this Annual Report on Form 10-K. Our principal risks include the following:

- The Company's auditor has noted substantial doubt about our ability to continue as a going concern.
- We have incurred significant losses from operations and negative cash flows from operations since our inception. We expect to incur additional losses and may never achieve or maintain profitability.
- We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development efforts or cease operations.
- If we were to resume research and development activities with respect to KPI-012, KPI-014 or any other product candidate, such activities would be subject to all of the risks inherent in the development of biologics and other pharmaceutical products, including the risk of clinical trial failure, regulatory rejection, manufacturing challenges, and the absence of adequate financing.
- Our limited operating history and our limited experience in developing AI technology or biologics may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We are shifting our business to focus on developing an AI infrastructure platform for the biotech industry that may present risks to our business. We may not be successful in driving the global deployment and customer adoption of digital offerings, including AI-enabled software solutions.
- We are at an early stage of development of our AI platform business and may be unable to successfully develop, commercialize, or generate revenue from Researgency.
- Our Researgency business depends on an exclusive license for the Researgency platform, and the termination, modification, or invalidity of that license could materially harm our business.
- Regulatory and legislative developments related to the use of AI could adversely affect our use of such technologies in our products, services, and business.
- Data security and privacy risks are heightened in our Researgency business given that our platform may process proprietary biological and clinical data of our customers.
- Our plans to use our KPI-012 clinical development dataset as a proof-of-concept for Researgency may not generate the commercial benefits we expect, and may expose us to additional risks.
- We may be unable to obtain and maintain patent protection for our technology or product candidates, or the scope of the patent protection obtained may not be sufficiently broad or enforceable, such that our competitors could develop and commercialize technology, products and product candidates similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.
- The market for AI platforms serving the biotechnology and pharmaceutical industries is intensely competitive, rapidly evolving, and may develop in ways that are adverse to our business.
- KPI-012 is protected by patent rights exclusively licensed from other companies or institutions. If these third parties terminate their agreements with us or fail to maintain or enforce the underlying patents, or we otherwise lose our rights to these patents, our competitive position and our market share in the markets for any of our products, if any when approved, will be harmed.
- If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate significant revenue will be materially impaired. Although we have suspended active clinical development of KPI-012 following the results of the CHASE Phase 2b clinical trial, we continue to evaluate opportunities to resume preclinical and clinical development activities,

subject to the availability of additional financing and the identification of a suitable development partner. If we were to resume development activities and seek marketing approval for KPI-012 or any other product candidate, the marketing approval process would be expensive, time-consuming and uncertain. As a result, we cannot predict when or if we, or any collaborators we may have in the future, will obtain marketing approval to commercialize KPI-012 or any product candidates we may develop in the future.

- We have recently undertaken a cost reduction plan and may do s again in the future. The assumptions underlying these activities may prove to be inaccurate, or we may fail to achieve the expected benefits therefrom.
- Our pursuit of strategic options with respect to our biologics asset portfolio and the development of our AI platform business may not be successful, and there can be no assurance that either strategy will generate value for our stockholders.
- If we fail to comply with the continued listing requirements of the Nasdaq Capital Market, our Common Stock may be delisted and the price of our Common Stock and our ability to access the capital markets could be negatively impacted.
- The price of our Common Stock is volatile and fluctuates substantially, which could result in substantial losses for purchasers of our Common Stock.
- Cybersecurity risks are heightened for our AI platform business, which is designed to be deployed within customer IT environments and may process sensitive biological and clinical data.

Part I

Item 1. Business

In this Annual Report on Form 10-K, unless the context otherwise requires, references to "we," "us," "our," "our company," "KALA," "KALA BIO" and "Company" refer to KALA BIO, Inc. and its subsidiaries.

Overview

We are a biopharmaceutical company in transition, evaluating the development of a dedicated, on-premises artificial intelligence (AI) infrastructure platform for the biotechnology industry. Our current focus is leveraging our mesenchymal stem cell secretome ("MSC-S") platform to test development of a scalable AI platform-as-a-service business to deploy secure, purpose-built AI systems directly within biotech and pharmaceutical client environments. We have historically been engaged in the research, development and commercialization of innovative therapies for rare and severe diseases of the front and back of the eye. Our lead product candidate was KPI-012, MSC-S, which we acquired from Combangio, Inc. ("Combangio") on November 15, 2021. KPI-012 was in clinical development for the treatment of persistent corneal epithelial defects ("PCED"), a rare disease of impaired corneal healing. Based on the results of a Phase 1b clinical safety and efficacy trial of KPI-012 in patients with PCED, we submitted an investigational new drug application to the U.S. Food and Drug Administration ("FDA"), which was accepted in December 2022. In February 2023, we dosed our first patient in the United States in our CHASE (Corneal Healing After SEcretome therapy) Phase 2b clinical trial of KPI-012 for PCED (the "CHASE trial"). By September 2025, the CHASE trial did not meet its primary endpoints, and we determined to discontinue our development of KPI-012 and the MSC-S platform. We have since expanded upon our business to evaluate strategic alternatives for our legacy MSC-S assets and capitalize on the substantial intellectual property (IP), proprietary biological datasets, and research experience generated during the clinical trials by starting development of an AI platform.

On March 3, 2026 (subsequent to the fiscal year ended December 31, 2025), we entered into an exclusive license for the Researgency AI research platform ("Researgency") from Younet AI ("Younet"), through which we intend to test and assess the feasibility of offering a dedicated AI infrastructure partner for the biotechnology industry. Our goal is to enable companies of all sizes to unlock the value of their proprietary biological data without surrendering control of it through the development of a specialized agentic AI research platform.

Strategic Transition

Suspension of Clinical Trial

On September 28, 2025, the board of directors of the Company (the "Board") determined to cease development of KPI-012 and the MSC-S platform because the CHASE trial did not meet the primary endpoint of complete healing of PCED as measured by corneal fluorescein staining. The CHASE trial also failed to achieve statistical significance for key secondary efficacy endpoints, with no meaningful difference observed between either KPI-012 treatment arm and the placebo arm. In connection with such decision, we implemented a reduction in our workforce of approximately 19 employees, or approximately 51%.

Oxford Foreclosure and Workforce Terminations

On September 29, 2025, we received a notice of default under our senior secured credit facility with Oxford Finance LLC ("Oxford Finance"). Oxford Finance asserted its remedies under the Loan and Security Agreement, dated as of May 4, 2021, by and among us, Combangio and Oxford Finance, as lender and collateral agent (as amended, the "Loan Agreement"), including exercising control over substantially all of our cash, and informed us of its intention to foreclose on our remaining assets. As a result of these restrictions and the anticipated foreclosure process, we terminated substantially all of our remaining employees other than those needed to support limited activities associated with the foreclosure process.

Oxford Finance subsequently paused its foreclosure efforts to permit us to pursue a short-term financing transaction and related negotiations. In November 2025, we entered into a settlement arrangement with Oxford Finance, and in December 2025, we satisfied the amounts due under that arrangement, resolving the obligations under our credit facility with Oxford Finance. Also in November 2025, we entered into a short-term convertible loan arrangement with an individual lender to provide interim liquidity, which was repaid in full in December 2025.

Our current activities comprise of (i) evaluating strategic alternatives for our legacy MSC-S assets and related intellectual property and (ii) early-stage development of a prospective AI platform-as-a-service offering, Researgency, intended for deployment within biotechnology and pharmaceutical customer environments. While we intend to assess the commercial viability of offering dedicated, on-premises AI systems to biotechnology companies, there can be no assurance that we will successfully develop, commercialize or generate revenue from this initiative.

Younet AI Licensing Agreement and the Researgency Platform

Following the decision to suspend the CHASE trial, and as part of our strategic transition, on March 3, 2026 (subsequent to the year-end), we entered into an exclusive licensing agreement with Younet (the "Younet License Agreement"), pursuant to which we secured worldwide exclusive rights to Researgency, specifically adapted for biotechnology applications. Under our license for Researgency, we plan to evaluate whether the platform can be configured to support biotechnology research workflows and data-governance requirements. Specific technical configurations and commercialization plans, including pricing and service levels, remain under development and subject to customer requirements and applicable laws and guidance.

Changes in Leadership

During the fiscal year ended December 31, 2025, and through the date of this filing, the Company experienced significant changes in its executive leadership and the composition of its Board.

On February 11, 2025, Mark Iwicki resigned as Chief Executive Officer. The Board appointed Todd Bazemore as interim Chief Executive Officer and principal executive officer on the same date. On August 29, 2025, Mr. Bazemore was appointed as Chief Executive Officer and President of the Company and was elected as a Class II Director of the Board.

On October 19, 2025, in connection with a workforce reduction, the Board terminated Mr. Bazemore's employment as President and Chief Executive Officer, effective immediately. Mr. Bazemore continued to serve as a director of the Company and as the Company's principal executive officer.

On November 21, 2025, the Board terminated the employment of Mary Reumuth, the Company's Chief Financial Officer and Secretary. On the same date, the Board appointed David Lazar as Chief Executive Officer, principal executive officer, and principal financial officer of the Company, each effective in connection with the closing of the transactions contemplated by the November 2025 Purchase Agreement (as defined herein). Mr. Lazar was also elected as a Class II Director and the Chair of the Board, replacing Mr. Iwicki as Chair. Mr. Iwicki continued to serve as a director.

On December 19, 2025, each of Marjan Farid, M.D., Andrew I. Koven, Mark Iwicki, Todd Bazemore, C. Daniel Meyers, and Howard B. Rosen tendered their resignations as directors of the Company, each effective as of January 30, 2026. Pursuant to the terms of the November 2025 Purchase Agreement (as defined herein), AK Holdings Group Inc. ("AK Holdings") had the right to nominate up to eight individuals to serve as directors of the Company. On January 30, 2026, the Board, upon the recommendation of the Nominating and Corporate Governance Committee, appointed five nominees of AK Holdings as directors: Avi Minkowitz as a Class II Director, Hillel Posen and Chaim (Dovi) Berger as Class I Directors, and Yonatan Colman and Brendan Purdy as Class III Directors.

On February 2, 2026, Mr. Lazar resigned as Chief Executive Officer and Chief Financial Officer of the Company, effective immediately, while remaining a director. On the same date, the Board appointed Avi Minkowitz, a current director, as Chief Executive Officer and Chief Financial Officer. On February 16, 2026, Mr. Lazar resigned from the Board, effective immediately. Mr. Minkowitz currently serves as our Chief Executive Officer and Chief Financial Officer.

The Company's Business Strategy

Our strategy is to pursue two complementary business lines: (i) the monetization of a proprietary biologics asset portfolio centered on the Company's MSC-S platform and its associated IP, and (ii) the development of the Researgency business, through which the Company intends to deploy Researgency to provide a dedicated, on-premises AI infrastructure solution for biotechnology and pharmaceutical companies. Key elements of our current strategy include:

- **Preserve and seek to monetize our MSC-S biologics asset portfolio**. We are preserving our MSC-S platform intellectual property, including the KPI-012 and KPI-014 product candidates and related patents and know-how, and are evaluating strategic options with respect to those assets, including licensing, sale, out-licensing, collaboration, and other arrangements with one or more third parties. We may evaluate preclinical activities in the future if we secure additional funding and identify suitable development partners. We do not have any ongoing clinical trials as of the date of this filing.

- **Develop and aim to deploy Researgency as a dedicated biotechnology industry solution**. Through our exclusive license for Researgency, we intend to serve as a dedicated AI infrastructure partner for biotechnology and pharmaceutical companies. Researgency is designed for on-premises deployment within client environments, enabling customers to leverage advanced AI capabilities while maintaining complete control over their proprietary biological data and intellectual property. We also intend to offer the platform on a platform-as-a-service basis, together with implementation support, maintenance subscriptions, and data analytics services, targeting mid-size biotechnology companies, contract research organizations, and pharmaceutical companies as our primary customer base. Any commercialization, pricing and feature set remain subject to further development, validation, applicable regulatory compliance and customer demand.

- **Evaluate Researgency using our proprietary KPI-012 research dataset**. As an initial step toward potential commercialization of Researgency, we intend to use our accumulated KPI-012 clinical development dataset, which includes data from 79 patients across 37 clinical trial sites together with related regulatory submission materials, as a proof-of-concept validation environment. This self-validation approach is designed to generate reference case studies and to refine platform capabilities using real-world biotechnology research data prior to commercial deployment with external customers. There can be no assurance that these efforts will identify commercially actionable opportunities.

- **Pursue strategic arrangements across both business lines**. We plan to pursue value-driven strategic transactions across both our biologics portfolio and our Researgency business, which may include licensing

arrangements, collaborations, co-development agreements, and other strategic partnerships. With respect to our biologics portfolio, such transactions may include in-licensing or acquisition of complementary product candidates or technologies, particularly for rare ophthalmic diseases. With respect to our Researgency business, such transactions may include strategic partnerships with pharmaceutical companies, academic institutions, and other parties seeking dedicated AI research infrastructure.

Industry Background

The pharmaceutical and biotechnology sectors operate within regulatory frameworks where data management is a matter of compliance. Clinical trial data is governed by the FDA. Patient data must adhere to requirements of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and, where applicable, other domestic and foreign privacy laws, as well as contractual and regulatory obligations applicable to research activities. Regulatory submission documents can be used as evidence in enforcement actions. Intellectual property in active development has commercial value that partly relies on maintaining confidentiality until patent approval or publication. Our goal is to utilize biotechnology research from experimental methods to intelligent, predictive systems designed to minimize risk, speed up timelines, and enhance outcomes throughout the therapeutic development process.

We believe our proposed AI initiatives may address certain operational challenges observed in biotechnology research and development as set forth below:

1. **Data Protection Requirements:** Complex regulatory frameworks governing biological research data, requiring specialized security architectures and compliance monitoring systems.
2. **Patient Data Privacy Obligations:** HIPAA, state privacy laws, the General Data Protection Regulation ("GDPR"), and other privacy regulations thus create stringent requirements for data handling, storage, and processing in clinical research contexts, the scope and application of which continue to evolve.
3. **Intellectual Property Security:** Protection of proprietary research data, therapeutic targets, and competitive intelligence from unauthorized access or disclosure.
4. **Substantial Regulatory Compliance Costs:** FDA submission requirements, clinical trial protocols, and regulatory pathway navigation represent significant operational expenses.
5. **Expensive Research Adaptation Requirements:** Costs associated with modifying research protocols, clinical trial designs, informed consents and other study-related documents and therapeutic approaches based on evolving data and regulatory guidance.
6. **Complex Commercialization Processes:** Multi-stage pathway from research discovery through regulatory approval to market introduction, requiring coordinated expertise across multiple domains.
7. **Extended Development Timelines:** Multi-year development cycles create substantial capital requirements and opportunity costs for biotechnology companies.

We are evaluating AI capabilities, including autonomous task orchestration, integration with internal data sources and auditability, that may support biotechnology research workflows. Potential use cases under consideration include analysis of clinical datasets, literature synthesis and report generation within controlled environments. Any deployment would be designed to align with applicable regulatory expectations regarding clinical development, data integrity, validation and governance, to the extent such expectations are clarified and become applicable to our platform.

We anticipate that customer interest, if any, will focus on private deployments operated within customer infrastructure (on-premises or private cloud) so that proprietary data remain within the customer's control. Features under evaluation include access controls, audit logging, model validation procedures and, where appropriate and permitted, fine-tuning on customer datasets with the customer retaining ownership of model artifacts. The specific

features and capabilities offered may vary based on customer requirements, technical feasibility and applicable regulatory guidance.

Agentic AI and Private Enterprise LLM

One variation of "Agentic" AI is that it describes a system's ability to act on data. A typical AI assistant responds to questions when asked. An agentic AI system is generally designed to autonomously pursue specific goals, breaking down complex objectives into smaller tasks, completing each one step by one, assessing results, and adjusting its strategy based on what it learns along the way. Typical capabilities of agentic AI systems may include goal-directed execution, external tool and database integration, context persistence across extended workflows, self-correction when intermediate outputs fail to meet quality criteria, and multi-agent coordination in which specialized agents perform discrete tasks orchestrated into a unified deliverable.

In biotechnology research, this difference becomes practically important. Analyzing a failed clinical trial dataset for subgroup signals is a complex, multi-step process, involving loading and cleaning data, developing and testing hypotheses, cross-referencing findings with published literature, evaluating statistical significance, ranking results by biological plausibility, and preparing a structured report for scientific review. An agentic system can manage the entire workflow, while a conventional AI tool generally only answers individual questions.

A large language model ("LLM") is a type of artificial intelligence trained on large volumes of text, which may include scientific literature, regulatory filings, clinical records, and financial documents. LLMs are designed to read, summarize, reason about, and generate language across a range of tasks by constructing internal representations of relationships between concepts, enabling them to synthesize information from multiple sources and produce analytical outputs. For example, when a researcher asks an LLM to identify patterns in a clinical dataset, a model maybe able reason through the data's structure, apply domain knowledge encoded during training, and produce interpretations more quickly than a human analyst.

A significant advance in enterprise AI is the development of deployment architectures that allow organizations to use models on their own proprietary data without sending it to external servers. Sending proprietary biological data, regulatory strategy documents, or unpublished efficacy results through a public AI interface introduces legal risks, intellectual property concerns, and potential regulatory non-compliance.

A private enterprise LLM deployment allows an organization to operate these models within its own infrastructure, whether on-premises or in a dedicated private cloud environment, so that proprietary data is not transmitted to external servers. This architecture is intended to mitigates the intellectual property, data sovereignty, and regulatory compliance risks associated with processing sensitive information, including unpublished clinical results, regulatory strategy documents, and other proprietary biological data. A private deployment may also enable, where appropriate and permitted by applicable governance requirements, fine-tuning of the model on the organization's proprietary datasets, with the organization retaining full ownership of any resulting model artifacts. Fine-tuning may allow the model to reason over organization-specific data, such as internal trial documentation, regulatory submissions, and laboratory results, with the same depth applied to publicly available information.

The Researgency Platform

Through our license for Researgency, we plan to evaluate whether the platform can be adapted to meet biotechnology research workflow, data security and governance requirements observed in our historical operations. We are in the early stages of assessment and have not recognized revenue from this initiative.

Younet: The Infrastructure Layer for Private Enterprise AI

Our ability to commercialize Researgency depends in part on Younet's performance of development and infrastructure obligations and our successful integration, validation and deployment of the licensed technology for biotechnology research workflows. Researgency is intended to operate on infrastructure provided by Younet, which provides a technical environment for private enterprise AI deployment. For many biotechnology organizations, this is not a core competency, and the development costs and timelines are prohibitive. Under the Researgency license, Younet may provide certain infrastructure components that support private enterprise AI deployment, including model hosting,

secure environments, data ingestion pipelines, retrieval systems, access controls, audit logging and maintenance. Any commercial offering would be designed to permit customers to control their proprietary data within their own environments. Specific terms and service levels will be finalized if and when we enter into customer agreements.

KPI-012 Dataset for Researgency

We expect to first evaluate the platform using our accumulated research data from the KPI-012 development program. Potential objectives include assessing platform functionality with real-world biotechnology data, informing future development priorities and, if appropriate, preparing internal case studies. This approach offers several expected strategic benefits including: (1) validating platform capabilities with real-world biotechnology data, (2) creating reference case studies for commercial use, (3) refining platform functionality based on actual research needs, and (4) demonstrating value creation from previously unsuccessful therapeutic development programs. These efforts may not result in commercially deployable features.

The KPI-012 dataset includes comprehensive clinical trial data from 79 patients across 37 sites, regulatory submission materials, safety profiles, efficacy metrics, and documentation of interactions with the FDA, which produces a vast amount of biological and clinical data. While the CHASE trial did not outperform placebo on the primary endpoint, we plan to analyze the dataset for potential signals, including subgroup responses, biomarkers, dosing or safety insights. Such analyses are exploratory and may not support further development.

Core features of KALA's goals include:

- Multi-agent orchestration for biotechnology workflows (e.g., elements of regulatory submissions, clinical trial design and data analysis).
- Integration with biomedical databases, regulatory repositories and clinical research datasets.
- Audit trails, access controls and validation procedures designed to support compliance frameworks; accountability for compliance would remain with the sponsor organization.
- On-premises or private-cloud deployment options intended to support data sovereignty.
- Mechanisms for ongoing enhancement based on customer data, with data privacy and isolation.
- Application programming interfaces (APIs) for integration with laboratory information management, clinical trial management and regulatory submission systems.

We are evaluating specialized functional modules potentially applicable to biotechnology and pharmaceutical research, including:

- Clinical Trial Intelligence: AI agents that may specialize in protocol design, patient stratification, site selection, and regulatory submission preparation, potentially drawing on validated clinical development experience.
- Regulatory Pathway Optimization: Analysis of FDA guidance, submission requirements, and approval pathways using predictive modeling that may help to estimate regulatory success likelihood; conclusions will not be guaranteed, and accountability for compliance would remain with the sponsor organization.
- Biological Data Analysis: Advanced pattern recognition and hypothesis generation using biological datasets from KALA's clinical programs and regulatory submissions.
- Intellectual Property Management: Patent landscape analysis, competitive intelligence monitoring, and IP strategy development capabilities that may be integrated with research discovery processes.
- Safety and Efficacy Modeling: Predictive analytics that may help forecast therapeutic safety profiles and efficacy based on validated clinical trial data and regulatory feedback; conclusions will not be guaranteed.

- Commercialization Strategy: Market analysis, competitive positioning, and go-to-market planning tailored specifically for biotechnology therapeutic development.
- Responder Analysis: Exploratory evaluation of biological plausibility in identified subgroups to inform any internal assessment of whether a targeted re-development program is scientifically warranted.
- Investment Recommendation: Evidence-based analyses on whether KPI-012 or KPI-014 warrants additional investment or out-licensing to a strategic partner.
- Partner-Ready Data Package: A structured data set suitable for sharing with potential licensing partners, co-development collaborators, or IP acquirers, subject to appropriate confidentiality and data-protection controls.

Our platform is being designed for use in customer environments that may include proprietary biological datasets, clinical trial data, draft regulatory submissions and other sensitive materials. As such, our product development emphasizes auditability, access controls, logging, and data-handling configurations intended to support customer compliance with applicable privacy, data-governance and research-integrity frameworks. We anticipate that customers will retain ownership and control over their data and, where applicable, any customer-specific model artifacts produced within their environment.

The Placebo Response Question

Our early approach focuses on early testing as to whether the CHASE trial had an unusually high placebo response rate, which is a well-documented phenomenon in eye disease trials. The act of applying any drop, combined with increased clinical attention, can produce meaningful improvement in the control arm, making it difficult for an active treatment to demonstrate statistical superiority. In such event, even a well-conducted responder subgroup analysis will not salvage the program. However, this is what the data review is intended to identify. We believe this analysis is useful to making go/no-go decisions, communicating transparently with future partners or licensors, and avoiding further capital investment in a structurally compromised trial design. There is no assurance that any such assessment will support further development.

Phased Implementation Strategy

Our implementation roadmap adopts a structured, phased approach with internal milestones, metrics and decision points. The timing and scope of each phase will depend on product development progress, funding and customer interest. There can be no assurance that we will be successful in executing any phase of this strategy, and our ability to do so is subject to significant risks and uncertainties, including the risks described in the “Risk Factors” section of this Annual Report on Form 10-K.

Phase 1 Goals: Self-Validation and Platform Refinement (next ~1-6 months)

- Deploy the platform on our KPI-012 dataset for internal evaluation
- Initiate development of internal case studies and assess feasibility of agent-based workflows
- Refine capabilities based on observed research needs and technical performance
- Develop validation and governance documentation aligned with applicable regulatory expectations
- Explore scientific collaborations to reassess potential development pathways
- **Internal Metrics**: Data processing accuracy benchmarks, system performance and documentation completeness

Phase 2 Goals: Strategic Customer Acquisition (next ~12 months)

- Engage with potential pilot customers to evaluate implementation feasibility and develop case studies

- Define pricing, support and customer success metrics
- Expand capabilities based on feedback and market requirements
- **Internal Metrics**: Engagement pipeline, pilot outcomes, satisfaction indicators and utilization measures

Phase 3 Goals: Market Expansion and Scale (~2027 onwards)

1. Grow active customer base across target segments, if Phases 1–2 support commercialization
2. Develop strategic partnerships with pharmaceutical companies and CROs
3. Expand capabilities and market reach through product development and partnerships
4. **Internal Metrics**: Revenue scale, competitive positioning and partnership development

Our Historical Business

KPI-012 and our MSC-S Platform

Prior to our strategic transition, our lead product candidate was KPI-012, a novel, human bone-marrow derived MSC-S composed of biologically active components secreted from mesenchymal stem cells, such as growth factors, protease inhibitors, matrix proteins and neurotropic factors, that had been shown in preclinical studies by Combangio to facilitate corneal healing. KPI-012 had received Orphan Drug and Fast Track designations from the FDA for the treatment of PCED in April 2023.

We have retained worldwide commercial rights for our MSC-S platform, including KPI-012 and KPI-014. We own and/or exclusively license patents and patent applications relating to this platform, including U.S. and foreign issued patents and pending patent applications. The expiration dates of the issued U.S. patents that we control covering KPI-012 are scheduled to expire no earlier than 2040, and a portfolio of additional U.S. and ex-U.S. patent applications covering the MSC-S platform is currently in prosecution.

Our Previous Clinical-Stage Product Candidate

Persistent Corneal Epithelial Defects Overview

PCED is a persistent non-healing corneal defect or wound that is refractory to conventional treatments. PCED is a disease of impaired corneal healing and can be the result of numerous etiologies, including (but not limited to) neurotrophic keratitis, or NK, microbial/viral keratitis, surgical epithelial debridement, corneal transplant surgery, LSCD, mechanical/thermal trauma and exposure keratopathy. Normal healing is a highly regulated multifactorial process that involves numerous biologic pathways and molecules, including growth factors, cell signaling, proliferation, migration and extracellular matrix remodeling. In PCED, the normal healing process is impaired due to an imbalance of the key biomolecules that orchestrate the normal wound healing process. We believe that effective treatment of PCED across the various etiologies requires a multifactorial mechanism of action to address the impaired healing that is responsible for the defects.

PCED is a rare disease with an estimated incidence of 100,000 cases per year in the United States and 238,000 cases per year in the United States, European Union and Japan combined. Clinical symptoms of PCED include pain, foreign body sensation, redness, photophobia and tearing. Clinical signs include non-healing epithelial defects, stromal scarring and stomal thinning. A PCED may lead to infection, corneal ulceration, corneal perforation, scarring, opacification and significant vision loss.

Limitations of Existing Treatments for Persistent Corneal Epithelial Defects

There is currently a significant unmet need for therapies to effectively treat PCED. Conventional therapies, which include bandage contact lenses, autologous serum and surgery, are usually ineffective in overcoming the dysregulation present in multiple cellular pathways that may need to be addressed to heal a PCED. Surgical procedures used in the treatment of PCED include tarsorrhaphy, corneal epithelial stem cell transplants and corneal transplants which are used to aid in restoration and maintenance of vision capabilities.

The only currently approved prescription product in the PCED space is Oxervate®, indicated for the treatment of NK, which we believe to be the primary etiology for approximately one-third of PCED cases. Oxervate contains a single growth factor – nerve growth factor (NGF) – and has been demonstrated to be effective in only the subgroup of PCED cases whose underlying etiology is neurotrophic disease. Oxervate is a topical eye drop that is administered six times per day at two-hour intervals for eight weeks. Each administration of Oxervate requires the use of a vial containing the drug product, a vial adapter, a single-use pipette and disinfectant wipes.

KPI-012 Opportunity in Persistent Corneal Epithelial Defects

KPI-012 is a novel, human bone-marrow derived MSC secretome composed of biologically active components secreted from the MSCs, such as growth factors, protease inhibitors, matrix proteins and neurotropic factors, that have been shown in preclinical studies by Combangio to facilitate corneal healing. KPI-012 is cell-free and produced from a proprietary cell bank. The drug substance for KPI-012 is produced as a chemically-defined cell-free solution followed by formulation and filling of the drug product in non-preserved single dose units. Key biological factors contained in KPI-012 and their potential wound healing functions are shown below:

Key KPI-012 Components	**Ocular Surface Wound-Healing Function**
Protease Inhibitors (TIMP-1, TIMP-2, Serpin E)	Inhibit destructive proteases that degrade matrix in the wound bed
Matrix Proteins (Fibronectin)	Build a molecular scaffold in the wound bed for cells to migrate and adhere to
Growth Factors (HGF)	Suppress inflammation and promote corneal epithelium repair
Neurotrophic Factors (PEDF)	Promote maintenance of neurons to support corneal health

CHASE 2b Clinical Trial of KPI-012

Our initial goal was to develop KPI-012 for the treatment of PCED. Combangio completed a Phase 1b clinical efficacy trial in nine patients with PCED in Mexico City, Mexico. Based on the results of this Phase 1b clinical trial, we had initiated a full preclinical development program and submitted an Investigational New Drug (“IND”) application to the FDA for KPI-012, which was accepted in December 2022. In February 2023, we dosed the first patient in the CHASE trial of KPI-012 in patients with PCED in the United States. The CHASE trial was comprised of two patient cohorts. On March 27, 2023, we announced positive safety data from the first cohort of the CHASE trial, which was an open-label study to evaluate the safety of the high dose of KPI-012 ophthalmic solution (3 U/mL) dosed topically QID in two patients. Both patients in the first cohort successfully completed eight weeks of dosing with no safety issues observed.

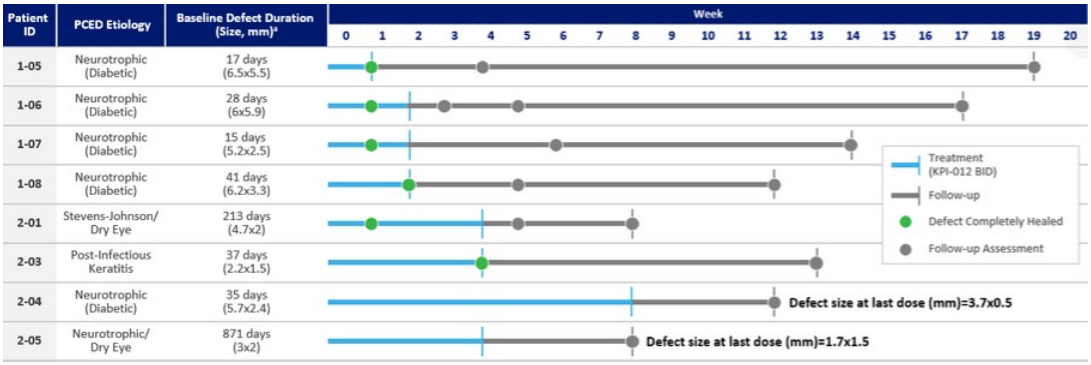
The second cohort of the CHASE trial was a multicenter, randomized, double-masked, vehicle-controlled, parallel-group trial to evaluate the safety and efficacy of two doses of KPI-012 ophthalmic solution (3 U/mL and 1 U/mL) versus vehicle dosed topically QID for 56 days in approximately 90 adult patients with PCED. The trial had an 8-week treatment period with evaluations at frequent times during the dosing period and at 10 weeks and 26 weeks. We previously opened 45 trial sites for the CHASE trial in the United States and initiated clinical trial sites in Argentina . The primary endpoint of the CHASE trial was the complete healing of the PCED as measured by corneal fluorescein staining using a central-reading center assessment of corneal fluorescing staining photographs.

Phase 1b Clinical Trial Results of KPI-012

Combangio had conducted a Phase 1b clinical trial of KPI-012 in Mexico City, Mexico during 2020 and 2021, consisting of three subjects without active corneal disease, or the safety cohort, who were dosed twice a day (1 U/mL) for one week and nine patients with PCED, or the PCED cohort, who were dosed twice a day (1 U/mL) for up to eight weeks. Key inclusion criteria for the PCED cohort included subjects with bilateral corneal burns who could only have one eye entered into the clinical trial; subjects whose previous treatment were stopped except for the study medication; and subjects with PCED of at least 10 days without improvement from one or more conventional non-surgical treatments in the study eye due to any of the following: NK (provided there was no active herpetic infection of the eye in the prior three months), corneal burns (alkali, acid, and thermal), post-photorefractive keratectomy, post-corneal transplant surgery, corneal epithelial debridement resulting from diabetic vitrectomy surgery, trauma, keratoconjunctivitis sicca, Sjögren's, or corneal cross-linking.

The participants in the Phase 1b trial were treated with KPI-012 topically twice a day, with the subjects in the safety cohort treated for one week and patients in the PCED cohort treated between one to eight weeks. KPI-012 was generally well tolerated in both cohorts, with only one subject experiencing treatment-related adverse events (mild and transient itching, red eye and blurred vision after study drug administration). There were no deaths or treatment-related serious adverse events during either cohort. One subject in the PCED cohort had to withdraw from the trial due to a protocol screening violation.

As depicted in Figure 1 below, six of the eight patients in the PCED cohort (75%) who completed the trial achieved complete healing of the lesion after four weeks of treatment, with the two other patients experiencing some clinical improvement but not complete healing. Four of eight patients in the PCED cohort (50%) achieved complete healing of the lesion after one week of treatment and the other two patients achieved complete healing within two to four weeks of initiation of treatment with KPI-012. All six of the patients who achieved complete healing remained healed through the follow-up period of the trial, which ranged between eight to 19 weeks. Of the two patients who did not show complete healing in the trial, clinical investigators noted some clinical improvement in both patients, but the corneal staining images did not show complete healing of the defect.



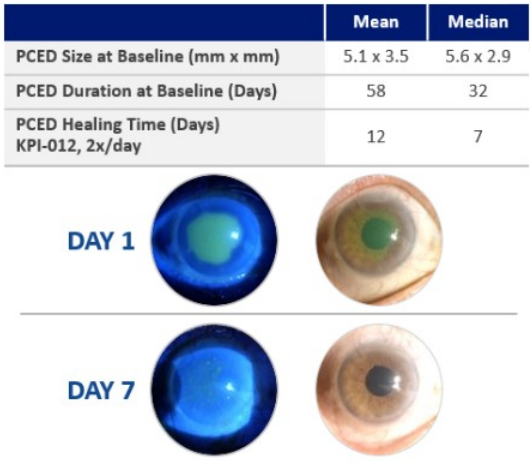


Figure 1. Summary of Phase 1b clinical trial of KPI-012 for PCED, including representative images for a healed patient study eye. The Day 1 images were taken on the first day of treatment, prior to first KPI-012 administration, with the fluorescein (green) stain demarking the corneal wound boundary of the study eye image. The Day 7 images were taken on the last day of KPI-012 treatment showing the PCED completely healed. The images on the left depict the study eye viewed under blue light to visualize the PCED with fluorescein stain.

Significant pain relief was reported by patients in the PCED cohort within one week of treatment with KPI-012, as shown in Figure 2 below. Of the six patients who reported pain at the baseline, all six patients reported a reduction in pain after one week of treatment, four patients reported a pain score of zero after one week of treatment and all six patients reported a pain score of zero after three weeks of treatment.

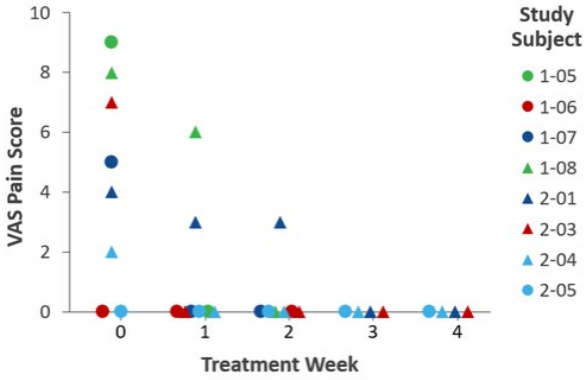


Figure 2. PCED cohort patient-reported score of pain level due to defect using a visual analogue scale, or VAS, which is a subjective rating of pain levels on a scale of 0 to 10 where a score of 0 represents no pain at all and a score of 10 represents the worst possible pain.

KPI-012 Preclinical Studies and Results

KPI-012 was previously evaluated by Combangio in a number of preclinical studies. In these studies, KPI-012 promoted rapid ocular re-epithelialization and mitigated scarring and neovascularization in a number of well-established animal models.

In vitro Human Corneal Epithelial Wound Closure Assay

The therapeutic mechanism of action of KPI-012 involves stimulating corneal re-epithelialization and ocular surface healing. Combangio evaluated KPI-012 in an *in vitro* wound gap assay developed using human corneal epithelial cells. In this assay, a mechanical defect (cell-free region) was introduced into a two-dimensional monolayer of epithelial cells to create a wound. The 'injured' monolayer was then treated with KPI-012 and the cell free region was monitored for wound closure as show in Figure 3 below. In this assay, KPI-012 exhibited a dose-dependent and potent wound closure response.

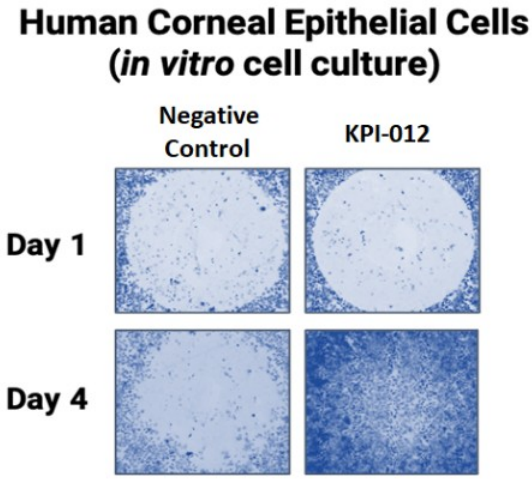


Figure 3. Representative images from an in vitro human corneal epithelial wound closure assay. A mechanical wound instilled to a corneal epithelial cell monolayer on Day 1 healed after treatment with KPI-012 (Day 4 of treatment), but not negative control (vehicle). Depicted images are wounded cell monolayers stained with Gentian Violet.

In vivo Mechanical Wound Studies of Activity

Combangio also previously evaluated the activity of KPI-012 in a mechanical corneal injury mouse model. In this model, a circular area on the surface of the cornea was debrided (mechanically scraped) to remove the epithelial layer and create a circular wound.

Topical formulations of vehicle or KPI-012 were administered twice daily to the wounded eyes. As shown in Figure 4 below, mice treated with KPI-012 exhibited prominent wound healing at day four of the treatment period, while the vehicle-treated wounded eyes remained largely unhealed. Further, treatment with KPI-012 resulted in reduced corneal haze and scarring relative to treatment with vehicle. Results of this mouse model suggested that at Day 4 of treatment KPI-012 promoted *in vivo* closure of cornea mechanical wounds relative to vehicle control.

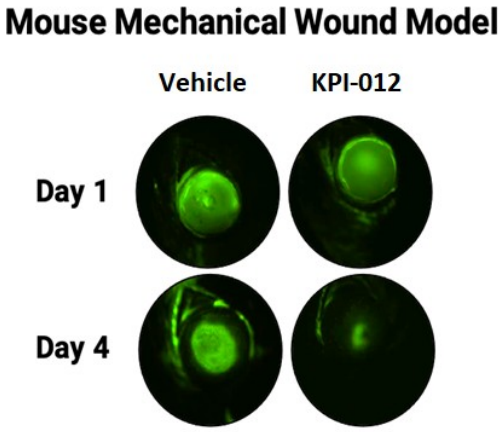


Figure 4. Representative images of wounded mouse corneas after mechanical injury (Day 1). Depicted is the fluorescein (green) stain, which demarks the corneal wound boundary. Treatment with KPI-012 rapidly healed the wound size (as indicated by the disappearance of the green stain by Day 4) relative to vehicle control-treated eyes.

A second confirmatory mechanical corneal injury mouse model study was performed according to the method described above using a different lot of KPI-012. The study yielded similar results, with KPI-012 promoting wound healing relative to vehicle as well as exhibiting dose-dependent potency dynamics. After four days of treatment, KPI-012 treated eyes exhibited more pronounced reduction in wound staining relative to vehicle-treated eyes, as shown in Figure 5A below, and after five days most KPI-012 treated eyes completely healed, as shown in Figure 5B below. Further, a KPI-012 formulation lacking key biologic factors known to mediate wound healing exhibited reduced healing capacity in the study, supporting the selection of KPI-012's critical quality attributes.

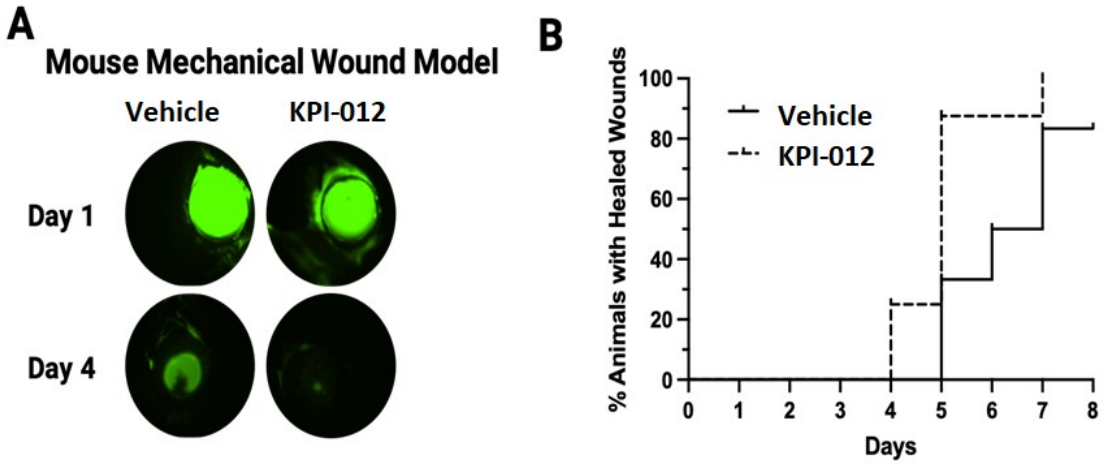


Figure 5. Summary of second mouse corneal mechanical study. (A) Representative images of wounded mouse corneas after mechanical injury (Day 1) and after four days of treatment with KPI-012 or vehicle (Day 4). Depicted is the fluorescein (green) stain, which demarks the corneal wound boundary. Treatment with KPI-012 rapidly healed the wound size (as indicated by the disappearance of the green stain by Day 4) relative to vehicle control-treated eyes; (B) Treatment with KPI-012 resulted in more rapid complete healing and a greater percentage of completely healed eyes (dashed line), relative to vehicle-treated eyes (solid line).

Potential Indications for KPI-014

Based on the manufacturing and delivery expertise gained from KPI-012 development, we had also initiated preclinical studies under our KPI-014 program to evaluate the utility of our MSC-S platform for inherited retinal degenerative diseases, such as Retinitis Pigmentosa and Stargardt Disease. These preclinical activities have since been suspended in connection with our determination to cease development of KPI-012 and our MSC-S platform.

MSC-S therapies have shown great promise to treat inherited retinal diseases ("IRDs"), with the recognition that they function through their secretome (i.e., the secretion of paracrine factors that enhance retinal cell function and survival). We believe an MSC-S engineered for intravitreal delivery may provide an improved treatment option for IRDs as compared to the traditional MSC-based approach.

IRDs are associated with mutations in over 280 different genes, where each IRD has one or more mutations that cause disease onset and results in vision loss. It is projected that over 200,000 individuals in the United States alone suffer from IRDs. While significant progress has been made with gene therapies, these are typically limited to a single gene or mutation. With over 280 different IRD-associated genes, a therapy broadly effective for most IRDs does not currently exist, leaving patients with little-to-no options to slow disease progression and vision loss. We were previously developing KPI-014 with the goal of providing a broad, genotype-agnostic, therapeutic benefit to reduce vision loss and improve quality of life for patients suffering from inherited retinal degenerative diseases.

Competition

Competition in Artificial Intelligence Platform Services

The market for artificial intelligence platforms serving the biotechnology and pharmaceutical industries is rapidly evolving and intensely competitive. We expect to face competition from companies that have developed, or are developing, AI platforms and tools specifically designed for drug discovery and development, as well as from large technology companies offering general-purpose AI infrastructure solutions. Many companies that have developed AI-enabled drug discovery and research platforms have developed computational platforms designed to accelerate drug discovery and development. Many of these companies have significantly greater financial resources, larger research and development teams, and more established commercial relationships than we do. We believe that the key competitive factors in the AI platform market for biotechnology include data sovereignty architecture, depth of domain expertise in biotechnology regulatory affairs and clinical development, breadth of functional platform capabilities, pricing, and the availability of validated reference use cases. We believe that our on-premises deployment architecture, combined with the domain expertise and proprietary biological datasets we have accumulated through our own clinical development programs, provides meaningful differentiation from existing competitors. However, there can be no assurance that we will be able to successfully compete in this market or that competitors will not develop superior technologies or capabilities before we are able to establish a commercial presence.

Biotechnology and Pharmaceutical Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technologies, knowledge, experience and scientific resources provide us with competitive advantages, we face competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Our competitors include large pharmaceutical and biotechnology companies, and specialty pharmaceutical and generic drug companies. Many of our competitors 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. These competitors also compete with us in recruiting and retaining qualified scientific, sales and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies

may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The key competitive factors affecting the success of KPI-012 and any other product candidates that we develop are the product candidate's efficacy, safety, method of administration, convenience, price, the level of generic competition and the availability of insurance coverage and reimbursement from government and other third-party payors.

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 our products. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. In addition, our ability to compete may be affected because in many cases insurers or other third-party payors seek to encourage the use of generic products.

Sales and Marketing

We have not yet established a commercial organization or distribution capabilities. With respect to our AI platform business, we intend to develop a direct sales capability targeting biotechnology and pharmaceutical companies, contract research organizations, and academic research institutions. We intend to supplement our direct sales efforts with strategic partnerships and channel arrangements as the AI platform business matures. With respect to any biologics product candidates that we may develop or acquire in the future, we would seek to establish appropriate sales and marketing capabilities at the time of any regulatory approval, either directly or through third-party arrangements.

Intellectual Property

Our success depends significantly on our ability to obtain and maintain proprietary protection for our products, product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. We seek to protect our proprietary position by, among other methods, filing U.S. and certain foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business, where patent protection is available. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

As of March 13, 2026, we owned eight U.S. issued patents and seven U.S. patent applications, as well as two foreign patents and 49 foreign patent applications (including pending Patent Cooperation Treaty, or PCT, applications). We exclusively licensed one U.S. patent, as well as one foreign patent and one foreign patent application including original filings, continuations and divisional applications. Our patent portfolio includes the following patents and patent applications that we own or exclusively license:

- Eight U.S. patents, seven U.S. patent applications, and two foreign patents and 49 related foreign patent applications, all relating to pharmaceutical compositions including KPI-012 for treating ocular conditions, which are owned by us, and which, if granted with respect to the patent applications, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, are expected to expire beginning in 2040; and

- One U.S. patent, one foreign patent, and one foreign patent application, all related to secreted stem cell factors for tissue repairment and regeneration, and which are exclusively in-licensed from Stanford University, and which, if granted with respect to the patent applications, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, are expected to expire beginning in 2038;

The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in examining and granting a patent, or may be shortened if a patent is terminally

disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration date of a U.S. patent as partial compensation for the length of time the drug is under regulatory review while the patent is in force. 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 applicable to each regulatory review period 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. We cannot provide any assurance that any patent term extension with respect to any U.S. patent will be obtained and, if obtained, the duration of such extension.

Similar provisions are available in the European Union and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our product candidates receive approval by the FDA or foreign regulatory authorities, we expect to apply for patent term extensions on issued patents covering those products, if permitted under the applicable laws, regulations, and rules and depending upon the length of the clinical trials for each drug and other factors. The expiration dates referred to above are without regard to potential patent term extension or other market exclusivity that may be available to us. However, we cannot provide any assurances that any such patent term extension of any patent will be obtained and, if obtained, the duration of such extension.

Trade Secrets

In addition to patents, we may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, and obtain and maintain ownership of certain technologies, in part, by confidentiality and invention assignment agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Licensing and Other Arrangements

EYSUVIS and INVELTYS Milestone Payments

We previously developed and commercialized two marketed products, EYSUVIS® (loteprednol etabonate ophthalmic suspension) 0.25% (“EYSUVIS”), for the short-term (up to 2 weeks) treatment of the signs and symptoms of dry eye disease, and INVELTYS® (loteprednol etabonate ophthalmic suspension) 1% (“INVELTYS”), a topical twice-a-day ocular steroid for the treatment of post-operative inflammation and pain following ocular surgery. Both products applied a proprietary mucus-penetrating particle drug delivery technology (the “AMPPLIFY® Drug Delivery Technology”).

On July 8, 2022, we sold to Alcon Pharmaceuticals Ltd. and Alcon Vision, LLC (together, “Alcon”), the rights to manufacture, sell, distribute, market and commercialize EYSUVIS and INVELTYS and to develop, manufacture, market and otherwise exploit the AMPPLIFY Drug Delivery Technology (collectively, the “Commercial Business”) pursuant to an asset purchase agreement (the “Alcon Asset Purchase Agreement”). We are eligible to receive from Alcon up to four commercial-based sales milestone payments related to the aggregate worldwide net sales of EYSUVIS and INVELTYS in time frames ranging from 2023 to 2029. Each milestone payment is payable once upon the first time such milestone is achieved, and only one milestone payment may be paid with respect to a calendar year. To date, no milestones have been achieved, and we have not received any milestone payments from Alcon.

Stanford University License Agreement

As part of our acquisition of Combangio, we acquired Combangio’s exclusively in-licensed patent portfolio from Stanford University. In October 2019, Combangio entered into a license agreement with The Board of Trustees of The Leland Stanford Junior University (“Stanford”), which was amended in February 2020 (as amended, the “Stanford Agreement”). Pursuant to the license agreement with Stanford, or the Stanford Agreement, we hold a worldwide, exclusive, sublicensable license under certain patent rights, or licensed patents, directed to methods to promote eye wound healing, to make, have made, use, import, offer to sell and sell products that are covered by the licensed patents, or licensed products, for use in all fields.

Under the Stanford Agreement, we owe Stanford certain milestone payments upon the achievement of specified development and regulatory milestones and specified sales milestones, as well as certain fees and royalties. A milestone payment to Stanford was triggered by the commencement of the CHASE trial in the United States. Stanford is also entitled to receive tiered royalties from us in a low single digit percentage range of our, our affiliates' and our sublicensees' net sales of licensed products that are covered by a valid claim of a licensed patent. Our obligation to pay royalties will continue, on a country-by-country and licensed product-by-licensed product basis, until the last-to-expire valid claim of a licensed patent covering such licensed product in the country of manufacture and sale. Additionally, we are required to pay Stanford a low double-digit percentage of certain consideration we receive as a result of granting sublicenses to the licensed patents.

Pursuant to the Stanford Agreement, Stanford retains the right, on behalf of itself, Stanford Health Care, Lucile Packard Children's Hospital at Stanford, and all other non-profit research institutions, to practice the licensed patents for any non-profit purpose. In addition, the United States government retains nonexclusive rights under the licensed patents to practice or have practiced the licensed patents by or on behalf of the United States government or on behalf of any foreign government or international organization pursuant to treaty or agreement.

Combangio Merger Agreement

Pursuant to the Agreement and Plan of Merger (the "Combangio Merger Agreement"), we entered into with Combangio in connection with the acquisition of Combangio in November 2021, the former Combangio stockholders or other equityholders (the "Combangio Equityholders"), are entitled to receive from us up to $105.0 million in payments that are contingent upon the achievement of specified development, regulatory and commercialization milestones (the "Contingent Consideration")..

Upon dosing of the first patient in our CHASE trial for PCED in the United States in February 2023, we paid the former Combangio Equityholders an aggregate of $2.5 million in cash and $2.4 million in shares of our Common Stock (representing an aggregate of 105,038 shares of our Common Stock) in March 2023. The remaining amount of $0.1 million was paid in cash in January 2024. Any Contingent Consideration payable under the Merger Agreement in the future will be paid only in cash as follows:

- (i) $5.0 million payable upon the first patient dosed with any product candidate whose active ingredient comprises one or more biological factors secreted by MSCs or their progenitors, including KPI-012, or the Product Candidate, in a pivotal clinical trial, (ii) $12.5 million payable upon regulatory approval by the FDA of marketing and sale of a Product Candidate in the United States, subject to certain specified reductions; (iii) $17.5 million payable upon the first commercial sale of a Product Candidate in the United States, subject to certain specified reductions and (iv) an aggregate of up to $65.0 million payable upon the achievement of specified sales milestones;

- tiered cash royalties at percentage rates in the mid-to-high single digits payable on annual net sales of all Product Candidates; and

- a cash payment at a percentage rate in the high single digits of all income, including earnout payments, received by us or any of our affiliates from a product license granted by us to a third party to sell or otherwise commercialize the Product Candidate in countries where neither we nor our affiliates conduct sales of such Product Candidate, subject to certain exceptions set forth in the Merger Agreement.

If the aggregate amount of Contingent Consideration payable in any calendar year exceeds $2.5 million, or the Excess Cash Cap, such excess portion, or the Carry Forward Contingent Cash Consideration, will be carried forward and, subject to application of the Excess Cash Cap in the following calendar year, become payable on the first business day of the following calendar year. Any Carry Forward Contingent Cash Consideration outstanding on June 1, 2026 is payable in full on June 1, 2026.

CIRM Award

Our development of KPI-012 was funded, in part, by an award from the California Institute for Regenerative Medicine ("CIRM"). On August 2, 2023, Combangio entered into an award agreement with CIRM for a $15.0 million grant (the "CIRM Award"), to support the KPI-012 program for the treatment of PCED as well as product and process characterization and analytical development for the program. The CIRM Award was subject to a co-funding requirement to spend a specified minimum amount on the development of KPI-012 to obtain the full award amount, with a significant portion of the award is payable upon the achievement of specified milestones that are primarily related to the progress in conducting the CHASE clinical trial. Additionally, there were significant compliance requirements associated with the CIRM Award, such as reporting, notification, recordkeeping and audit requirements, for which internal and external resources may be needed and which may increase our costs of doing business.

Under the CIRM Award, if we fail to satisfy the co-funding requirement under the CIRM Award or fail to achieve the milestones within the timeframe required by the CIRM Award, we may not receive full funding under the CIRM Award. CIRM may permanently cease disbursements under the CIRM Award if the milestones are not met within four months of their scheduled completion dates or if the delay is not addressed to CIRM's satisfaction, as determined by CIRM in its sole discretion. Additionally, if CIRM determines, in its sole discretion, that Combangio has not complied with the terms and conditions of the CIRM Award, CIRM may suspend or permanently cease disbursements. Moreover, disbursements under the CIRM Award are contingent upon the availability of funds in the state of California's Stem Cell Research and Cures Fund, which is outside of our control.

On September 29, 2025, we announced that the CHASE trial of KPI-012 for the treatment of PCED did not meet the primary endpoint of complete healing of PCED as measured by corneal fluorescein staining. The CHASE trial also failed to achieve statistical significance for key secondary efficacy endpoints and did not show any meaningful difference between either KPI-012 treatment arm and the placebo arm. Based on the CHASE trial results, we determined to cease development of KPI-012 and our MSC-S platform. As of December 31, 2025, no more funding is expected under the CIRM Award.

Government Regulation

Our business is subject to an evolving regulatory landscape. Although we do not currently believe Researgency constitutes a medical device, customer use of AI-generated analyses to inform drug discovery, clinical trial design, or regulatory submissions may implicate FDA expectations for credibility, reproducibility and explainability of analyses used in regulated activities the scope of which remains uncertain. In addition, deployment within customer environments may involve personal data subject to U.S. federal and state privacy laws (including HIPAA and the CCPA/CPRA) and foreign privacy regimes (including the GDPR), as well as emerging U.S. federal and state AI-specific statutes and regulations, each of which is subject to ongoing interpretation and enforcement priorities that may change over time.

In addition, our existing clinical trial data and IP, and any future clinical trial development is governed by government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, pricing, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, reimbursement and import and export of biopharmaceutical products and certain artificial intelligence and machine learning platforms intended for use in life sciences. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure.

U.S. Government Regulation of Artificial Intelligence in Life Sciences

In connection with our strategic decision to prioritize our Researgency business through the Researgency License, we are subject to a rapidly evolving regulatory environment governing the use of artificial intelligence and machine learning in life sciences applications. Although we do not believe Researgency would be considered a medical device, it is expected to be designed for deployment within biotechnology and pharmaceutical client environments to process proprietary biological data and clinical trial datasets, and its outputs may be used to inform or support drug discovery, clinical trial design, and regulatory submissions by our customers. As a result, both the platform itself and its use cases may implicate a range of existing and emerging regulatory frameworks.

The FDA has issued guidance on the use of artificial intelligence and machine learning in drug development and in medical devices, including a framework for AI/ML-based software as a medical device (SaMD). Although we do not currently believe that our AI platform constitutes a medical device or SaMD, the FDA's regulatory framework in this area is evolving, and future guidance or rulemaking could expand the scope of FDA oversight to encompass AI platforms used in connection with drug discovery or clinical development activities. In October 2023, the FDA issued a discussion paper on the use of AI in drug manufacturing, and in March 2024, the FDA published a draft guidance on the use of AI and machine learning in the development of drug and biological products. These and other regulatory initiatives may impose requirements on AI platforms that are used to generate outputs in support of regulatory submissions, clinical trial design, or other activities subject to FDA, or similar state or foreign regulatory authority, oversight.

In addition, because Researgency is designed for on-premises deployment within client environments and may process proprietary biological data, clinical trial datasets, and other sensitive information of our biotechnology and pharmaceutical customers, the platform may be subject to data privacy and security requirements, including obligations that may arise under HIPAA, the GDPR, the CCPA, and other applicable federal, state, and international privacy laws that govern the handling of protected health information and other sensitive personal data. The regulatory landscape for data privacy is rapidly evolving, with numerous states having enacted or considering consumer data privacy statutes. We may also be subject to emerging state and federal legislation specifically governing the use of artificial intelligence, including requirements related to algorithmic transparency, bias testing, and disclosure obligations. The regulatory landscape for AI products is rapidly evolving in the United States and internationally, including through the EU Artificial Intelligence Act which establishes a risk-based governance framework for AI in the EU market, and there is significant uncertainty regarding the nature and scope of future AI-related regulation.

Furthermore, our customers' use of outputs generated by Researgency in their own regulatory submissions, clinical trial protocols, or product development activities may subject those outputs to scrutiny by the FDA and other regulatory authorities. To the extent the FDA or other regulators require that AI-generated analyses or recommendations used in regulatory submissions meet specific standards of credibility, reproducibility, or explainability, our platform may need to be designed and validated to satisfy those standards. If we are unable to meet such requirements, or if the regulatory environment develops in a manner that restricts the use of AI-generated outputs in drug development, our ability to commercialize the AI platform and generate revenue from our target customers could be adversely affected. We intend to monitor regulatory developments and adapt our platform capabilities as appropriate, but there can be no assurance that we will be able to anticipate or respond to all applicable requirements in a timely or cost-effective manner..

Our AI platform may incorporate or rely upon third-party LLMs or other machine learning technologies. LLMs process large amounts of data, including potentially sensitive customer information. Unauthorized access to or a breach of LLM software or related systems could lead to significant legal and financial repercussions. LLMs may produce incorrect, inaccurate or misleading outcomes, sometimes referred to as “hallucinations,” and the ongoing accuracy and reliability of AI-generated outputs is critical for the effectiveness of our platform. Inaccurate or unreliable outputs could lead to customer dissatisfaction, reputational harm, reduced demand for our platform and potential legal liabilities. Furthermore, rapid advancements in AI technology could render our existing LLM-powered tools obsolete, requiring the licensing or development of replacement technologies at significant cost.

LLMs and other AI models are typically trained on large datasets that may contain biases, and these biases can be reflected in the output of AI systems, potentially leading to ethical concerns, reputational harm, unfair or discriminatory outcomes, and potential liability. There may also be real or perceived social harm or other outcomes that undermine public confidence in the use and deployment of AI technologies. Any of the foregoing may result in decreased demand for our platform, harm to our reputation, regulatory scrutiny or legal action.

Our platform involves the collection, storage and transmission of confidential and proprietary information belonging to our customers, including personal identifying information, clinical trial data and other sensitive business data. Our systems may be targeted in cyber-attacks, including computer viruses, phishing attacks, malicious software programs, distributed denial of service attacks and other information security breaches, which could result in unauthorized access to, or release, monitoring, misuse, loss or destruction of, sensitive data. If threat actors are able to circumvent our security measures, sensitive data may be compromised. Because the techniques used to obtain unauthorized access or to sabotage systems change frequently and may utilize advanced technologies including AI, we

may not be able to anticipate these techniques and implement adequate preventative or protective measures. Any actual or perceived breach of our security could damage our reputation, cause existing customers to discontinue the use of our platform, prevent us from attracting new customers, or subject us to third-party lawsuits, regulatory investigations, fines or other actions or liabilities.

U.S. Government Regulation of Biological Products

In the United States, biological products, or biologics, are licensed for marketing by the FDA under the Public Health Service Act, or the PHSA, and regulated by the FDA under the Food, Drug and Cosmetic Act, or FDCA. A company, institution, or organization which takes responsibility for the initiation and management of a clinical development program for such products, and for their regulatory approval, is typically referred to as a sponsor. Although the Company has suspended active clinical development of KPI-012 and its MSC-S platform following the results of the CHASE Phase 2b clinical trial, the Company retains its biologics intellectual property portfolio, including its existing IND, and continues to evaluate opportunities to resume preclinical and clinical development activities, subject to the availability of additional financing and the identification of a suitable development partner. Accordingly, the regulatory framework governing biological products remains relevant to the Company's business. A sponsor seeking approval to market and distribute a new biologic in the United States must satisfactorily complete each of the following steps:

- completion of preclinical laboratory tests, animal studies and formulation studies according to good laboratory practices, or GLP, regulations or other applicable regulations;
- design of a clinical protocol and submission to the FDA of an IND, which must become effective before human clinical trials may begin and must be updated when certain changes are made;
- approval by an independent institutional review board, or IRB, or ethics committee representing each clinical trial site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practices, or GCPs, and other clinical-trial related regulations to evaluate the safety, potency and purity of the investigational product for each proposed indication;
- preparation and submission to the FDA of a BLA, demonstrating the safety, purity and potency of the proposed product and requesting marketing approval for one or more proposed indications, including payment of application and program fees pursuant to the Prescription Drug User Fee Act, or PDUFA;
- review of the BLA by an FDA advisory committee, where applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the biologic is produced to assess compliance with current good manufacturing practice, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the product’s identity, strength, quality and purity;
- satisfactory completion of any FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data submitted in support of the BLA;
- FDA review and approval of the BLA authorizing marketing of the new biologic product for particular indications 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 any post-approval studies required by the FDA.

Regulatory Exclusivity Governing Biologics

When a biological product is licensed for marketing by the FDA with approval of a BLA, the product may be entitled to certain types of market and data exclusivity barring the FDA from approving competing products for certain

periods of time. In March 2010, the Patient Protection and Affordable Care Act was enacted in the United States and included the Biologics Price Competition and Innovation Act of 2009, or the BPCIA. The BPCIA amended the PHSA to create an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. To date, the FDA has approved a number of biosimilar products and interchangeable biosimilar products.

Under the BPCIA, a manufacturer may submit an application for a product that is "biosimilar to" a previously approved biological product, which the statute refers to as a "reference product." In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and the proposed biosimilar product in terms of safety, purity and potency. The biosimilar sponsor may demonstrate that its product is biosimilar to the reference product on the basis of data from analytical studies, animal studies and one or more clinical studies to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the sponsor must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity and potency.

For the FDA to approve a biosimilar product as interchangeable with a reference product, the FDA must find not only that the product is biosimilar to the reference product but also that it can be expected to produce the same clinical results as the reference product such that the two products may be switched without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Upon licensure by the FDA, an interchangeable biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product. Following approval of the interchangeable biosimilar product, the FDA may not grant interchangeability status for any second biosimilar until one year after the first commercial marketing of the first interchangeable biosimilar product. In December 2022, Congress clarified through FDORA that FDA may approve multiple first interchangeable biosimilar biological products so long as the products are all approved on the first day on which such a product is approved as interchangeable with the reference product.

A reference biological product is granted 12 years of 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. Even if a product is considered to be a reference product eligible for exclusivity, however, another company could market a competing version of that product if the FDA approves a full BLA for such 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 BPCIA also includes provisions to protect reference products that have patent protection. The biosimilar product sponsor and reference product sponsor may exchange certain patent and product information for the purpose of determining whether there should be a legal patent challenge. Based on the outcome of negotiations surrounding the exchanged information, the reference product sponsor may bring a patent infringement suit and injunction proceedings against the biosimilar product sponsor. The biosimilar applicant may also be able to bring an action for declaratory judgment concerning the patent.

The FDA maintains a publicly-available online database of licensed biological products, which is commonly referred to as the "Purple Book." The Purple Book lists product names, dates of licensure, and applicable periods of exclusivity. Further, the reference product sponsor must provide patent information and patent expiry dates to FDA following the exchange of patent information between biosimilar and reference product sponsors. This information is then published in the Purple Book.

In an effort to increase competition in the drug and biologic product marketplace, Congress, the executive branch, and FDA have taken certain legislative and regulatory steps. For example, the 2020 Further Consolidated Appropriations Act included provisions requiring that sponsors of approved drug and biologic products, including those subject to REMS, provide samples of the approved products to persons developing biosimilar products within specified timeframes, in sufficient quantities, and on commercially reasonable market-based terms. Failure to do so can subject the approved product sponsor to civil actions, penalties, and responsibility for attorney's fees and costs of the civil action. There have been recent government proposals to reduce the 12-year reference product exclusivity period, but none have been enacted to date. In addition, since passage of the BPCIA, many states have passed laws or amendments to laws, which address pharmacy practices involving biosimilar products.

Orphan Drug Designation and Exclusivity

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for treatment of rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the product for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation qualifies a company for tax credits and potentially market exclusivity for seven years following the date of the product's approval if granted by the FDA. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. A product becomes an orphan when it receives orphan drug designation from the Office of Orphan Products Development at the FDA based on acceptable confidential requests. The product must then go through the review and approval process like any other product.

A sponsor may request orphan drug designation of a previously unapproved product or new orphan indication for an already marketed product. In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first approved product. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation.

If a product with orphan designation receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve another sponsor's marketing application for the same product for the same disease or condition for seven years, except in certain limited circumstances. If a product designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to exclusivity.

The period of market exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the disease or condition for which the product has been designated. Orphan drug exclusivity will not bar approval of another product under certain circumstances, including if the company with orphan drug exclusivity is not able to meet market demand or the subsequent product is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care. This is the case despite an earlier court opinion holding that the Orphan Drug Act unambiguously required the FDA to recognize orphan drug exclusivity regardless of a showing of clinical superiority. Under Omnibus legislation passed in December 2020, the requirement for a product to show clinical superiority applies to drug products that received orphan drug designation before enactment of amendments to the FDCA in 2017 but have not yet been approved by the FDA.

In September 2021, the Court of Appeals for the 11th Circuit, in *Catalyst Pharms, Inc. v. Becerra*, or *Catalyst*, held that, for the purpose of determining the scope of orphan drug exclusivity, the term "same disease or condition" in the statute means the designated "rare disease or condition" and could not be interpreted by the FDA to mean the "indication or use." Thus, the court concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the approved "indication or use." Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, the FDA announced that, in matters beyond the scope of the *Catalyst* court order, the FDA will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug is approved. More recently however, on February 14, 2025, a federal district court in Washington, D.C. fully embraced the reasoning of the *Catalyst* decision in another decision challenging the scope of orphan drug exclusivity. The implications of this decision, and its impact on the FDA's implementation of the Orphan Drug Act, are unclear at this point.

Patent Term Restoration and Extension

In the United States, a patent claiming a new product, its method of use or its method of manufacture may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent extension of up to five years for patent term lost during product development and FDA regulatory review. Assuming grant of the patent for

which the extension is sought, the restoration period for a patent covering a product is typically one-half the time between the effective date of the IND involving human beings is begun and the submission date of the BLA, plus the time between the submission date of the application and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date in the United States. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The U.S. Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Healthcare Laws and Regulations

Arrangements with providers, consultants, third-party payors and customers may be subject to numerous federal and state healthcare laws, including broadly applicable fraud and abuse, anti-kickback, false claims, transparency, patient privacy, and other healthcare laws and regulations that may constrain business and/or financial arrangements. These laws include, among others, the federal Anti-Kickback Statute; federal civil and criminal false claims laws, including the False Claims Act; HIPAA and related privacy and security regulations; the federal false statements statute; the Foreign Corrupt Practices Act; the Physician Payments Sunshine Act; and analogous state and foreign laws. Further, some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. The scope and enforcement of federal and state healthcare laws and regulations are broad and often uncertain and subject to change. Violations of any such federal and state healthcare laws and regulations may include, among other things, penalties such as civil or criminal penalties, monetary damages, or exclusion from participation in government contracting, healthcare reimbursement or other government programs.

Federal and State Data Privacy Laws

There are multiple privacy and data security laws that may impact our business activities, in the United States and in other countries where we may conduct trials or where we may do business in the future. These laws are evolving and may increase both our obligations and our regulatory risks in the future. In the health care industry generally, under HIPAA, HHS has issued regulations to protect the privacy and security of protected health information used or disclosed by covered entities including certain healthcare providers, health plans and healthcare clearinghouses. HIPAA also imposes certain obligations on the business associates of covered entities that obtain protected health information in providing services to or on behalf of covered entities. HIPAA may apply to us in certain circumstances and may also apply to our business partners in ways that may impact our relationships with them. Our clinical trials are regulated by the Common Rule, which also includes specific privacy-related provisions. In addition to possible federal civil and criminal penalties for HIPAA violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. Additionally, state attorney generals (along with private plaintiffs) have brought civil actions seeking injunctions and damages resulting from alleged violations of HIPAA's privacy and security rules. Further, there are a number of state laws governing confidentiality and security of health information and personal information that may be applicable to our business including any new laws and regulations governing privacy and security may be adopted in the future as well.

Because of the breadth of these laws, it is possible that some of our current or future business activities, including certain clinical research, sales and marketing practices, our AI platform development, and the provision of certain items and services to our customers, could be subject to challenge under one or more of such privacy and data security laws. The heightening compliance environment and the need to build and maintain robust and secure systems to comply with different privacy compliance and/or reporting requirements in multiple jurisdictions could increase the possibility that a healthcare company may fail to comply fully with one or more of these requirements. If our operations are found to be in violation of any of the privacy or data security laws or regulations described above that are applicable to us, or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal, civil and administrative penalties, damages, fines, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a consent decree or similar

agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Human Capital

Our ability to sustain and grow our business requires us to hire, retain and develop a highly skilled workforce. As of December 31, 2025 and March 31, 2026, we had a total of 6 full-time employees. As of the date of this Annual Report on Form 10-K, we have 3 full-time employees. We continually evaluate our business needs and opportunities and balance in-house expertise and capacity with outsourced expertise and capacity.

Following the reduction in our employees in September 2025, we focus our human-capital objectives on (i) recruiting and retaining personnel with expertise in AI engineering and architecture, data governance and security, quality and compliance, and biotechnology informatics; (ii) maintaining an ethical, compliance-oriented culture appropriate for companies operating in regulated life-sciences environments; and (iii) providing role-appropriate training related to data integrity, privacy and security, and workplace safety. We believe these measures are important to our ability to execute our strategic transition. We also engage third-party service providers, as needed, for specialized development and regulatory support. We value the health, safety and wellbeing of our employees and their families.

Our Corporate Information

We were incorporated under the laws of the State of Delaware in July 2009. On August 2, 2023, we changed our name from Kala Pharmaceuticals, Inc. to KALA BIO, Inc. Our website address is www.kalarx.com. The information on our website is not incorporated by reference into this Annual Report on Form 10-K and should not be considered to be a part of this Annual Report on Form 10-K. Our website address is included in this Annual Report on Form 10-K as an inactive technical reference only.

Available Information

Through our website, we make available free of charge our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Exchange Act. We make these reports available through our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to the SEC. You can review our electronically filed reports and other information that we file with the SEC on the SEC's web site at http://www.sec.gov. We also make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. In addition, we regularly use our website to post information regarding our business, product development programs and governance, and we encourage investors to use our website, particularly the information in the section entitled "Investors," as a source of information about us.

The information on our website is not incorporated by reference into this Annual Report on Form 10-K and should not be considered to be a part of this Annual Report on Form 10-K. Our website address is included in this Annual Report on Form 10-K as an inactive technical reference only.

Item 1A Risk Factors

Investing in our Common Stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Annual Report on Form 10-K, including our financial statements and the related notes appearing at the end of this Annual Report on Form 10-K, before deciding to invest in our Common Stock. These risks, some of which have occurred and any of which may occur in the future, can have a material adverse effect on our business, prospects, operating results and financial condition. In such event, the trading price of our Common Stock could decline and you might lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business, prospects, operating results and financial condition.

Risks Related to Our Financial Position and Need for Additional Capital

The Company's predecessor auditor noted substantial doubt about our ability to continue as a going concern.

The Company has a history of recurring losses and negative cash flows from operations, and experienced significant liquidity constraints in 2025, including in connection with its debt arrangement with Oxford Finance LLC, which required management to evaluate the Company's ability to continue as a going concern. Our consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the discharge of liabilities in the normal course of business. As described in Note 2 to the consolidated financial statements, the Company had an accumulated deficit of $694.9 million as of December 31, 2025 and had previously disclosed going concern uncertainty during the first, second, and third quarters of 2025. As of the date of this annual report, management concluded that, after considering its plans and recent developments, substantial doubt about the Company's ability to continue as a going concern was alleviated for the twelve months following the date the consolidated financial statements were issued.

There can be no assurance, however, that management's plans will be successfully implemented or that the Company will be able to generate sufficient cash flows to meet its obligations as they become due. If the Company is unable to maintain sufficient unrestricted cash and working capital, satisfy or refinance existing obligations, or otherwise obtain additional capital when needed on acceptable terms (or at all), it may be required to delay, reduce or terminate planned activities, pursue strategic alternatives on unfavorable terms, or seek protection under applicable insolvency laws. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

We have incurred significant losses from operations and negative cash flows from operations since our inception. We expect to incur additional losses and may never achieve or maintain profitability.

Since inception, we have incurred significant losses from operations and negative cash flows from operations. Our net losses were $27.0 million and $38.5 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $694.9 million. We have financed our operations primarily through proceeds from the sale of our Commercial Business to Alcon in July 2022, our initial public offering ("IPO"), follow-on public offerings of Common Stock and sales under our at-the-market offering facilities, private placements of Common Stock and/or preferred stock, borrowings under credit facilities, disbursements under a grant from CIRM, convertible promissory notes and warrants. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials. We have no revenue-generating commercial products, our cash flows have diminished as a result of the sale of our Commercial Business to Alcon and, as a result of our acquisition of Combangio, we may be required to pay certain milestones and royalty payments to former equityholders of Combangio. Although we are eligible to receive up to $325.0 million in payments from Alcon based upon the achievement of specified commercial sales-based milestones with respect to EYSUVIS and INVELTYS, there can be no assurance as to when we may receive such milestone payments or of the amount of milestone payments we may receive, if any. We expect to continue to incur significant expenses and operating losses for the foreseeable future, including in connection with our expanded business strategy. We may never achieve or maintain profitability. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year.

We anticipate that our research and development expenses will increase substantially in the future as compared to prior periods as we develop and commercialize Researgency.

Because of the new direction of our business strategy, the discontinued clinical trials and the evaluation and development of Researgency, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate revenue from Researgency, KPI-012 or any product candidate we may develop for the foreseeable future, if at all. Achieving and maintaining profitability will require us to be successful in a range of challenging activities, including successfully developing, commercializing and marketing Researgency.

As a company, we have limited experience commercializing products, and we may not be able to commercialize a product successfully in the future. There are numerous examples of unsuccessful product launches and failures to meet expectations of market potential, including by pharmaceutical companies and AI-powered biotech companies with more experience and resources than us.

We may never succeed in the foregoing activities and we may never generate revenue that is sufficient to achieve profitability. 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 would 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 product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development efforts or cease operations.

We expect to devote substantial financial resources to our ongoing and planned activities, including the exploration of strategic options relating to our MSC-S platform IP and dataset and the development, commercialization and marketing of Researgency. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts or cease operations and, potentially, wind down the company under the bankruptcy laws or otherwise. If we were to cease operations and wind down the company under the bankruptcy laws or otherwise, we cannot assure our stockholders or other stakeholders of any specific level of recovery, or any recovery at all on their specific claims or interest.

Our future capital requirements will depend on many factors, including:

- the timing and amount of milestone payments we ultimately receive from Alcon under the Alcon Asset Purchase Agreement;
- development efforts for Researgency;
- if we were to resume research and development activities, development efforts for KPI-012 and KPI-014 for potential ocular diseases;
- the costs and timing of process development and manufacturing scale-up activities associated with KPI-012 for PCED and any other indications we determine to pursue;
- our ability to establish and maintain strategic collaborations, licensing or other agreements and the financial terms of such agreements;
- the scope, progress, results and costs of research and development of any other product candidates that we may develop;

- the extent to which we successfully advance and/or in-license or acquire rights to other products, product candidates or technologies; and

- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against any intellectual property-related claims.

We expect to continue to incur expenses and operating losses. Net losses may fluctuate significantly from quarter-to-quarter and year-to-year. We expect that our cash and cash equivalents of $7.6 million as of December 31, 2025 will enable us to fund our operations, lease and capital expenditure requirements into the first quarter of 2027. We expect that our existing cash resources will be sufficient to enable us to fund our strategic initiative to deploy and continue to develop the AI platform for the biotech industry. We have based our estimates on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. As a result, we could deplete our available capital resources sooner than we currently expect.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete. Completion dates and completion costs can vary significantly for each product candidate and are difficult to predict. We may never generate the necessary data or results required to obtain marketing approval and achieve product sales from KPI-012 or any other product candidate we may develop. Also, even if we continue clinical testing and successfully develop KPI-012 or any product candidate and one or more of those are approved, we may not achieve commercial success with them. Accordingly, we will require additional financing to achieve our business objectives. In addition, we may opportunistically raise additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. Adequate additional financing may not be available to us on acceptable terms, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize any product candidate for which we obtain approval.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, royalty agreements, and marketing and distribution arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other rights and preferences that adversely affect the rights of our Common Stock holder. Debt financing and preferred equity financing, if available, may involve agreements that include pledging of assets as collateral and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

In addition, if we raise additional funds through collaborations, strategic alliances, licensing arrangements, royalty agreements, or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or current or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves or cease operations and, potentially, wind down the company under the bankruptcy laws or otherwise. If we were to cease operations and wind down the company under the bankruptcy laws or otherwise, we cannot assure our stockholders or other stakeholders of any specific level of recovery, or any recovery at all on their specific claims or interest.

The milestone consideration we are eligible to receive in connection with the sale of our Commercial Business to Alcon is subject to various risks and uncertainties.

The milestone consideration we are eligible to receive for the sale of our Commercial Business to Alcon is subject to various risks and uncertainties. We are eligible to receive up to four commercial-based sales milestone

payments from Alcon as follows: (1) $25.0 million upon the achievement of $50.0 million or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2028, (2) $65.0 million upon the achievement of $100.0 million or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2028, (3) $75.0 million upon the achievement of $175.0 million or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2029 and (4) $160.0 million upon the achievement of $250.0 million or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2029. To date, we have not received any such milestone payments.

We cannot predict what success, if any, Alcon and its affiliates may have with respect to sales of EYSUVIS and INVELTYS and, therefore, it is uncertain as to when we may receive the milestone payments, which milestone payments we may receive and if we will receive any milestone payments at all. If we do not receive some or all of the milestone payments, our business will be harmed.

If our estimates or judgments relating to our critical accounting policies, or any of our projections, prove to be inaccurate or financial reporting standards or interpretations change, our results of operations could be adversely affected.

The preparation of financial statements in conformity with generally accepted accounting principles in the United States requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities and expenses. Such estimates and judgments include the present value of lease liabilities and the corresponding right-of-use assets, the fair value of warrants, stock-based compensation, accrued expenses, contingent consideration, grant income and deferred grant income, the valuation of embedded derivatives and the recoverability of our net deferred tax assets and related valuation allowance. We base our estimates and judgments on historical experience, expected future experience and on various other assumptions that we believe to be reasonable under the circumstances. In addition, from time to time, we may rely on projections regarding our expected future performance that represent our management's then-current estimates. However, any of these estimates, judgments or projections, or the assumptions underlying them, may change over time or may otherwise prove to be inaccurate. Our results of operations may be adversely affected if our estimates, assumptions or projections change or if actual circumstances differ from those in our estimates or assumptions, which could cause our results of operations to fall below the expectations of securities analysts and investors, resulting in a decline in the trading price of our Common Stock.

Additionally, we regularly monitor our compliance with applicable financial reporting standards and review new pronouncements and drafts thereof that are relevant to us. As a result of new standards, changes to existing standards and changes in their interpretation, we might be required to change our accounting policies, alter our operational policies and implement new or enhance existing systems so that they reflect new or amended financial reporting standards, or we may be required to restate our published financial statements. Such changes to existing standards or changes in their interpretation may have an adverse effect on our reputation, business, financial position and results of operations.

Our limited operating history and our limited experience in developing AI technology or biologics may make it difficult to evaluate the success of our business to date and to assess our future viability.

Our operations to date have been limited to organizing and staffing our company, acquiring rights to intellectual property, business planning, raising capital, conducting research and development activities, and prior to the sale of our Commercial Business to Alcon in July 2022, developing and commercially launching EYSUVIS and INVELTYS. While we have had experience with obtaining marketing approval for and commercially launching two commercial products, we no longer have any commercial products following the sale of our Commercial Business to Alcon, and we have only no product candidates in clinical development. We cannot be certain that we will be able to develop, obtain marketing approval for and commercialize a product in the future if we were to continue our clinical trials. If we are successful in developing and obtaining marketing approval for any product candidate we may develop in the future, we will again have to transition from a company with a research and development focus to a company capable of supporting commercial activity. We may not be successful in such a transition. In addition, prior to our acquisition of KPI-012 in November 2021, we had no prior experience developing biological product candidates.

In addition, we do not have experience developing, validating, deploying or supporting a commercial AI platform. Our strategy depends in part on third-party licensed technology and will require new competencies that we have not previously demonstrated, including data-engineering, model evaluation and monitoring, security-by-design, on-premises or private-cloud deployment, service-level support and customer success functions. We may face delays and unanticipated costs as we hire or contract for specialized technical talent, build processes appropriate for regulated life-sciences environments, integrate licensed components, and establish and document controls over data governance, privacy and cybersecurity. Even if we are able to develop the platform as planned, customers may be slow to adopt on-premises AI solutions, require features we do not have or cannot build on our expected timelines, or require validation packages and audit trails that increase our costs and lengthen sales cycles. Our lack of experience in these areas increases the risk that we will not achieve technical milestones, product-market fit, or commercialization on the schedule or at the cost levels currently contemplated deployment.

Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had prior experience developing biological product candidates or a longer operating and commercialization history.

We expect our financial condition and operating results to fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

Risks Related to Product Development and Monetization of our Biologics Assets

Our ability to monetize our biologics asset portfolio is subject to significant uncertainty, and we may be unable to enter into any licensing, collaboration, sale, or other strategic arrangement with respect to our KPI-012 or KPI-014 product candidates or related intellectual property on acceptable terms, or at all.

We have ceased active clinical development of our KPI-012 and KPI-014 product candidates following the failure of the CHASE Phase 2b clinical trial of KPI-012 to meet its primary or key secondary endpoints. We are actively evaluating strategic options with respect to our MSC-S platform intellectual property, which may include licensing arrangements, out-licensing, collaborations, sale transactions, or other monetization strategies. However, we may be unable to identify a suitable counterparty for any such arrangement on terms that are acceptable to us, or at all. The value that any third party may be willing to ascribe to our biologics intellectual property is inherently uncertain and may be significantly diminished by the negative results of the CHASE trial. Even if we enter into a licensing or collaboration arrangement, there can be no assurance that any such arrangement will generate revenue or value for our stockholders at the level we anticipate, or at all. Any such transactions are also subject to complex negotiations, extensive due diligence processes, and may be subject to third-party consents or conditions that we cannot control. If we are unable to execute on our monetization strategy for our biologics assets, our business, financial condition, and results of operations could be materially harmed.

If we were to resume research and development activities with respect to KPI-012, KPI-014 or any other product candidate, such activities would be subject to all of the risks inherent in the development of biologics and other pharmaceutical products, including the risk of clinical trial failure, regulatory rejection, manufacturing challenges, and the absence of adequate financing.

While we have suspended active clinical development, we continue to evaluate the potential to resume preclinical and clinical development activities for our MSC-S platform, including for potential additional indications for KPI-012 such as limbal stem cell deficiency, or LSCD, and for KPI-014 for inherited retinal degenerative diseases. Any resumption of research and development activities would be subject to the availability of additional financing, the identification of a suitable development or co-development partner, and the successful completion of additional preclinical studies and regulatory filings to support a new IND or amendment to our existing IND. There can be no assurance that we will be able to resume development activities or that, if resumed, any future clinical trials will achieve their primary or secondary endpoints. The negative results of the CHASE trial may make it more difficult for us to raise the financing required to resume development or to attract a suitable development partner. If we are unable to resume development activities on acceptable terms or at all, the value of our biologics intellectual property may continue to decline.

We are shifting our business to focus on developing an AI infrastructure platform for the biotech industry that may present risks to our business. We may not be successful in driving the global deployment and customer adoption of digital offerings, including AI-enabled software solutions.

Our increasing focus on and investment in AI and software offerings present risks to our business. We may not be successful in driving the global deployment and customer adoption of an AI platform.

A growing part of our business involves cloud, edge computing, AI (including generative AI), and software solutions, and we are devoting significant resources to developing and deploying such strategies. Our success with these solutions will depend on the level of adoption of our offerings. We may incur costs to develop AI solutions and to build and maintain infrastructure to support cloud and edge computing offerings. Success with these solutions depends on execution in many areas, including:

- establishing and maintaining the utility, compatibility, and performance of our cloud, edge computing, AI, and software solutions (including the reliability of our third-party software vendors, network, and cloud providers) on a growing array of medical devices, software, and equipment;

- continuing to enhance the attractiveness of our solutions to our customers in the face of increasing competition from a significant number of existing and new entrants in the market, while meeting reliability and security expectations for these solutions; and

- meeting regulatory requirements for the development, testing, marketing, and implementation of these solutions in a fast-moving space disrupted by changing regulations around data and the need for innovation, including obtaining marketing authorizations when required.

It is uncertain whether our strategies will attract customers or generate revenue required to succeed in this highly competitive and rapidly changing global market. We plan to commit substantial efforts, funds, and other resources to R&D and IT infrastructure for AI platform, and the risk of failure is inherent. Even where our digital offerings satisfy applicable regulations and reimbursement policies, customers may not adopt them due to concerns about the security of personal data or the customers' absence of digital infrastructure to support and effectively use the offerings, a hesitancy to embrace new technology, or for other reasons. We also may not effectively execute organizational and technical changes to accelerate innovation and execution. In a number of countries, some AI and software solutions are restricted areas of foreign investment. Collaborating with a domestic, qualified third party will increase costs and may create uncertainties in such jurisdictions. The legality or validity of any collaboration may be challenged or subjected to scrutiny in such jurisdictions and the relevant governmental authorities have broad discretion in addressing such arrangements. Any of these risks could have a material adverse effect on our business, results of operations, cash flows, financial condition, or prospects.

AI solutions in the biotech and pharmaceutical industry must comply with stringent regulations, including certification requirements, in many of the countries in which our customers are located, particularly in relation to obtaining, using, storing, and transferring personal data. Our platform must be compliant with applicable regulations in the country in question before we can launch our offerings. In some jurisdictions, we must obtain marketing authorizations before commercializing software solutions. Such regulatory compliance may take longer or cost more than expected or require that design changes be incorporated into our offerings. In addition, changes to reimbursement policies for digital healthcare offerings could potentially lead to delays and additional expense. The inability of customers to obtain adequate reimbursement from private and governmental third-party payers could adversely affect purchasing decisions and prices and cause our revenue and profitability to suffer.

Additionally, we are making significant investments in AI initiatives and are building AI into our digital offerings. We are planning to use AI, including generative AI, throughout our portfolios to build differentiated products and solutions and deploy those solutions through various modalities for our customers, including on the device, via edge computing or data centers, and/or via the cloud. Using AI in this manner presents risks and challenges that could affect its adoption, acceptance, and effectiveness, including flawed AI algorithms; insufficient, overly-broad, or biased datasets; unauthorized use or access to personal data; lack of acceptance from our customers; difficulties in obtaining or maintaining the necessary regulatory approvals or clearances; or failure to deliver positive outcomes. As we seek to build clinical applications that leverage AI models built by third parties, we may have limited rights to access the

underlying intellectual property used to create these models, and, if requested, this may limit or impair our ability to independently verify the explainability, transparency, and reliability of the underlying model. The use of AI in healthcare offerings also poses clinical risks resulting from potential misdiagnosis or misinformation provided from AI applications, diminishing critical judgment, or loss of interpersonal care from clinicians. These deficiencies could undermine the decisions, predictions, or analysis AI applications produce, as well as their adoption, subjecting us to competitive harm; legal liability, including under new legislation regulating AI in jurisdictions such as the EU or ongoing evolution in how data protection, privacy, IP, and other laws are interpreted; regulatory actions; and reputational harm. Additionally, our obligations to comply with the evolving legal and regulatory landscape could entail significant costs or limit our ability to incorporate some AI capabilities into our offerings. In addition, some AI scenarios present ethical, privacy, or other social issues, risking reputational harm and/or reduced market demand or acceptance of AI solutions. The safeguards we have designed to promote the ethical implementation of AI may not be sufficient to protect us against negative outcomes. Furthermore, we contract with numerous third parties to offer our digital content to customers as well as to assist with the development of their own software applications and services, and our reliance on access to these third parties' healthcare digital applications, which may not continue to be available to us on commercially reasonable terms or at all, could impact our ability to offer a wide variety of our own digital offerings at reasonable prices with acceptable usage tools or continue to expand our geographic reach. These risks are amplified by the critical nature of healthcare decisions and the sensitivity of health-related information, and the occurrence of any of the above could have a material adverse effect on our business, results of operations, cash flows, financial condition, or prospects.

We have invested and expect to continue to invest in research and development efforts that further enhance our computational platform. Such investments may affect our operating results, and, if the return on these investments is lower or develops more slowly than we expect, our revenue and operating results may suffer

We have invested and expect to continue to invest in research and development efforts that further enhance our computational platform, often in response to our customers' requirements. These investments may involve significant time, risks, and uncertainties, including the risk that the expenses associated with these investments may affect our margins and operating results and that such investments may not generate sufficient revenues to offset liabilities assumed and expenses associated with these new investments. The software industry changes rapidly as a result of technological and product developments, which may render our solutions less desirable. For example, in recent years, a number of companies have entered the drug discovery industry utilizing different AI approaches. While we believe we compete favorably and are meaningfully differentiated from such approaches with the combination of our physics-based computational platform and machine learning capabilities, the success of other such AI approaches to drug discovery could impact the demand for our solutions. We believe that we must continue to invest a significant amount of time and resources in our platform and software solutions to maintain and improve our competitive position. If we do not achieve the benefits anticipated from these investments, if the achievement of these benefits is delayed, if technological developments render our solutions less desirable, or if a slowdown in general computing power impacts the rate at which we expect our physics-based simulations to increase in power and domain applicability, our revenue and operating results may be adversely affected.

Risks Related to Our Dependence on Third Parties

The involvement of third-party vendors and partners in developing and delivering our AI platform services introduces risks to quality control that could result in service failures, reputational harm, or liability.

We have entered into a collaboration and licensing agreement with Younet regarding the development and operation of Researgency. As a result of this agreement, certain functions, systems, and deliverables related to Researgency are subject to Younet's engineering decisions, development timelines, and technical capacity. We do not have direct control over Younet's internal processes, personnel, or development priorities, and we may have limited ability to influence or oversee the manner in which Younet performs its obligations under the agreement. Delays, errors, or changes in Younet's approach could materially impair our ability to deliver services to our customers, achieve development milestones, or maintain the performance standards expected by our clients. There can be no assurance that Younet will perform its obligations in a manner consistent with our requirements, expectations, or business objectives, and any failure by Younet to do so could have a material adverse effect on our business, financial condition, and results of operations.

In addition, we rely on third-party vendors and partners in connection with the development and delivery of our AI platform services, and we may have limited visibility into, or ability to audit or otherwise oversee, the processes, methodologies, and outputs of such third-party collaborators. Deficiencies in third-party performance, including errors in code, inadequate testing protocols, failure to adhere to agreed-upon specifications, or other quality lapses, could result in service failures, delays in platform deployment, reputational harm, or claims of liability against us. Our quality assurance measures may not be sufficient to identify or remediate all deficiencies arising from third-party involvement on a timely basis, or at all. Any such deficiency could have a material adverse effect on our business, financial condition, and results of operations.

Our AI platform services depend, in part, on access to graphics processing unit ("GPU") infrastructure and other specialized computational resources. The availability, cost, and performance of these resources are subject to factors beyond our control, including global supply constraints, vendor pricing adjustments, changes in hardware standards, and the allocation policies of third-party infrastructure providers. Technological limitations inherent in current GPU architecture may constrain the scope, speed, or scalability of our platform's processing capabilities. There can be no assurance that adequate computational capacity will be available to us on commercially reasonable terms, or at all, to meet our current or future operational requirements. Any prolonged shortage, cost increase, or technological limitation affecting our access to necessary computational resources could delay our platform development, impair the quality of our services, and have a material adverse effect on our business, financial condition, and results of operations.

If we resume research and development activities and enter into arrangements with third-party manufacturers for the production of any of our product candidates, we will be exposed to risks associated with reliance on third-party manufacturers, including risks related to regulatory compliance, supply chain disruptions, manufacturing quality, and our ability to secure adequate quantities at acceptable cost.

The manufacture of biologics is inherently complex. Any resumption of manufacturing activities for KPI-012 or any other product candidate would require us to re-establish manufacturing arrangements and potentially conduct comparability studies if manufacturing processes or manufacturers have changed. We may not be able to establish or maintain manufacturing arrangements on acceptable terms, or at all, which could delay or prevent any resumption of development or commercialization activities.

If we continue to pursue development of our MSC-S platform, we may enter into collaborations with third parties for the development or commercialization of our clinical product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

Although we have discontinued clinical development of KPI-012 and currently have no product candidates in clinical development, if we pursue any future product candidates or seek to out-license, co-develop or commercialize assets that may arise from our pipeline, we may rely on a variety of collaboration, distribution and other marketing arrangements with third parties to develop and commercialize KPI-012 or any other product candidate we develop and for which we seek or obtain marketing approval in markets outside the United States. We also may enter into arrangements with third parties to perform these services in the United States if we do not establish our own sales, marketing and distribution capabilities in the United States for our product candidates or if we determine that such third-party arrangements are otherwise beneficial. We also may seek third-party collaborators for development and commercialization of our product candidates. For example, we may consider potential collaborative partnership opportunities prior to initiating IND-enabling studies on product candidates we may develop.

Our likely collaborators for any sales, marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We are not currently party to any such arrangement. However, if we do enter into any such arrangements with any third parties in the future, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements.

Collaborations that we enter into may pose a number of risks, including the following:

- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development of our product candidates or may elect not to continue or renew development programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may not pursue commercialization of our product candidates that receive marketing approval or may elect not to continue or renew commercialization programs based on changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, 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;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own products or product candidates, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would divert management attention and resources, be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates or products in the most efficient manner, or at all. If any collaborations that we enter into do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our product candidates could be delayed, and we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval and commercialization described herein also apply to the activities of our collaborators.

Additionally, subject to its contractual obligations to us, if a collaborator of ours were to be involved in a business combination, it might de-emphasize or terminate the development or commercialization of any product or

product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be harmed.

If we are not able to establish collaborations or strategic partnerships relating to our AI platform, we may have to alter our development and commercialization plans and our business could be adversely affected.

We intend to pursue strategic partnerships with biotechnology and pharmaceutical companies, academic institutions, and contract research organizations for the deployment and adoption of our Researgency agentic AI research platform. We face significant competition in seeking appropriate collaborators. Potential partners may evaluate the maturity and functionality of our platform, the availability of competing AI solutions, and the cost and complexity of on-premises deployment relative to cloud-based alternatives. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of Researgency, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our AI product platform.

Risks Related to Our AI Platform Business

We are at an early stage of development of our AI platform business and may be unable to successfully develop, commercialize, or generate revenue from Researgency.

We recently entered into an exclusive license for the Researgency platform and have announced our intention to deploy the platform as a dedicated, on-premises AI infrastructure solution for biotechnology and pharmaceutical companies. However, we have not yet completed commercial development of the platform, have not entered into any commercial arrangements with customers, and have not generated any revenue from the Researgency business. We have limited experience developing and commercializing AI platform products, and there can be no assurance that we will be able to successfully develop a commercially viable version of the platform, attract and retain customers, generate recurring revenue, or compete effectively in the rapidly evolving market for AI platforms serving the life sciences industry. The development and commercialization of the AI platform will require significant financial resources, technical expertise, and commercial infrastructure that we do not currently possess. If we are unable to successfully build and commercialize the AI platform, our business and financial condition will be materially harmed.

Our Researgency business depends on an exclusive license for the Researgency platform, and the termination, modification, or invalidity of that license could materially harm our business.

Our ability to operate our Researgency business depends on our exclusive license for the Researgency platform. If the licensor were to terminate the license agreement, assert that we have breached our obligations under the license, or otherwise challenge our rights to the platform, our ability to develop and commercialize Researgency would be materially impaired. We may also be required to make milestone, royalty, or other payments under the license that could strain our financial resources. Any changes to the platform's underlying technology that are outside of our control could also affect the commercial viability of our business. In addition, if the intellectual property underlying the Researgency platform is found to be invalid or unenforceable, or if a third party asserts that the platform infringes its intellectual property rights, we could be subject to substantial litigation costs and may be required to cease using or licensing the platform.

Issues relating to the use of artificial intelligence and machine learning in our offerings could adversely affect our business and operating results.

We incorporate AI and machine learning solutions into our platform, in applications that are important to our operations and our drug discovery processes. There are significant risks involved in utilizing AI. Issues relating to the use of new and evolving technologies such as AI and machine learning may cause us to experience brand or reputational harm, competitive harm, legal liability, and new or enhanced governmental or regulatory scrutiny, and we may incur additional costs to resolve such issues. Known risks of AI currently include inaccuracy, bias, toxicity, intellectual property infringement or misappropriation, privacy, data protection and cybersecurity issues, and data provenance disputes. Perceived or actual technical, legal, compliance, privacy, data protection, cybersecurity, ethical or other issues relating to the use of AI may cause public confidence in AI to be undermined, which could slow our customers' adoption of our products and services that use AI. In addition, litigation or government regulation related to the use of AI may also adversely impact our and others' abilities to develop and offer products that use AI, as well as increase the cost and complexity of doing so. Developing, testing and deploying AI systems may also increase the cost profile of our product offerings due to the nature of the computing costs involved in such systems, which could impact our project margin and adversely affect our business and operating results. In addition, AI may have or produce errors or inadequacies that are not easily detectable. If the data used to train AI or the content, analyses, or recommendations that AI applications assist in producing are or are alleged to be deficient, inaccurate, incomplete, overbroad or biased, our business, financial condition, and results of operations may be adversely affected. The legal landscape and subsequent legal protection for the use of AI and the collection and use of data used to train AI models remains uncertain, and development of the law in this area could impact our ability to enforce our proprietary rights or protect against infringing uses. If we do not have sufficient rights to collect or use the data on which our AI relies or to the outputs produced by AI applications, we may incur liability through the alleged violation of certain laws, third-party privacy rights, online terms of service, or other contracts.

We may use, and our vendors may incorporate AI, both in our own development and implementation of AI and through the adoption of commercially available tools. The use of AI presents risks and challenges that could adversely affect our business and reputation, including cybersecurity, data privacy, IT, confidentiality, regulatory, legal, operational, competitive, reputational, intellectual property and other risks. Specifically, risks related to accuracy, bias, AI hallucinations, discrimination, harmful content, misinformation, fraud, scams, targeted attacks (including model poisoning or data poisoning), surveillance, data leakage, bias and inequality, environmental and other harms may flow from our development or use of AI technologies. For example, use of certain AI tools may lead to false or misleading information being used, relied upon or referenced by us or our vendors. Furthermore, use of certain AI tools may increase the risk of unauthorized disclosure of confidential information, compromise of proprietary intellectual property, or inadvertent inclusion of third-party intellectual property or other protected material, which could result in disputes or claims of infringement.

Our vendors may in turn incorporate AI tools into their offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy, data security and data integrity. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. In addition, the use of generative AI models in our internal or third-party systems may create new attack surfaces or methods for adversaries, which could impact us and our vendors. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

We are committed to implementing governance and control measures to mitigate these risks, but there can be no assurance that such measures will adequately prevent or mitigate the adverse effects that the integration and use of AI may have on our business, financial conditions and results of operations.

Regulatory and legislative developments related to the use of AI could adversely affect our use of such technologies in our products, services, and business.

We use AI throughout our business, including in our drug discovery processes and technology. As the regulatory framework for AI (including generative AI) evolves, our business, financial condition and results of operations may be adversely affected. The regulatory framework for AI and similar technologies is changing rapidly. It is possible that new laws and regulations will be adopted in the United States and in non-U.S. jurisdictions, or that existing laws and regulations may be interpreted in ways that would affect the operation of our drug discovery platform and data analytics and the way in which we use AI and similar technologies. We may not be able to adequately anticipate or respond to these evolving laws and regulations, and we may need to expend additional resources to adjust our offerings in certain jurisdictions if applicable legal frameworks are inconsistent across jurisdictions. In addition, because these technologies are themselves highly complex and rapidly developing, it is not possible to predict all of the legal or regulatory risks that may arise relating to our use of such technologies. Further, the cost to comply with such laws or regulations could be significant and would increase our operating expenses, which could adversely affect our business, financial condition and results of operations.

For example, in Europe, the European Union's Artificial Intelligence Act (AI Act) entered into force on August 1, 2024. The AI Act establishes a risk-based governance framework for regulating high-risk AI systems operating in or being used by the EU market. The AI Act could impact our products, business, and use of AI, even if we do not have a direct presence in the EU. This framework categorizes AI systems based on the risks associated with such AI systems' intended purposes as creating "unacceptable", "high" or "limited" risks. While the AI Act has not yet been enforced, there is a risk that our current or future AI-powered software or applications may be categorized as "high" risk or "limited" risk, obligating us to comply with the applicable requirements of the AI Act, which may impose additional costs on us, increase our risk of liability, or adversely affect our business. For example, "high" risk AI systems are required, amongst other things, to implement and maintain certain risk and quality management systems, conduct certain conformity and risk assessments, use appropriate data governance and management practices, including in development and training, and meet certain standards related to testing, technical robustness, transparency, human oversight, and cybersecurity. Even if our AI systems are not categorized as "high" risk we may be subject to additional transparency and other obligations for "low" risk AI system providers. The AI Act sets forth certain penalties, including fines of the greater of EUR 35 million or 7% of worldwide annual turnover (as defined in the AI Act) for the prior year for violations related to offering prohibited AI-systems or data governance, fines of the greater of EUR 15 million or 3% of worldwide annual turnover for the prior year for violations related to the requirements for "high" risk AI systems, and fines of the greater of EUR 7.5 million or 1.5% of worldwide annual turnover for the prior year for violations related to supplying incorrect, incomplete or misleading information to the EU and member state authorities. The AI Act's regulatory framework is expected to have a material impact on the way AI is regulated in the EU and across the world. Other jurisdictions also have proposed, and in certain cases enacted, laws and regulations addressing the use and development of AI. For example, in the United States, numerous states have proposed or have enacted laws addressing these matters, and in the United Kingdom, the government has published a white paper calling for existing regulators to implement certain specific principles to guide and inform the responsible development and use of AI. The AI Act and other evolving laws and regulations addressing AI, together with developing guidance and/or decisions in this area, may affect our use of AI and our ability to provide and to improve our services, require additional compliance measures and changes to our operations and processes, result in increased compliance costs and potential increases in civil claims against us, and could adversely affect our business, financial condition and results of operations.

Additionally, government and supranational regulation related to AI is evolving as new laws and regulations are implemented globally and could increase the burden and operational cost of compliance, including through requirements related to transparency, accountability, risk management, human oversight, and data governance. We expect to see increasing regulation related to AI governance, use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. The EU's Artificial Intelligence Act, or the AI Act, started entered into force on August 1, 2024, with important sections scheduled to come into effect in August 2026. As currently enacted, the AI Act imposes significant obligations on providers and deployers of high-risk AI systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles when developing and using AI technology. The scope of requirements depends on legal and risk determinations that rely on legal provisions that have not yet been fully interpreted by courts or regulators, and non-compliance can lead to significant fines.

In the U.S., the regulatory environment is complex and uncertain. Over the past year, states have advanced, and in some cases passed, dozens of laws focusing on AI governance and regulation, including on deployment of AI in healthcare settings. At the federal level, the current administration has endorsed a federal moratorium on the enforcement of state AI laws, including through a December 11, 2025, executive order on "Ensuring a National Policy Framework for Artificial Intelligence." So far, these efforts have not been successful at curtailing state action on AI regulation, contributing to a complicated legislative patchwork, which may be litigated in state and federal courts. In addition, there is continued uncertainty regarding the application of existing federal and state legal frameworks to uses and development of AI, and legal norms and market standards regarding AI continue to evolve. For example, various federal and state regulators have issued guidance and focused enforcement efforts on the use of AI in regulated sectors. The U.S. Food and Drug Administration, for example, issued guidance on the use of artificial intelligence in medical devices, requiring detailed risk management and review processes to obtain approvals. If we develop or use AI systems that are governed by the these laws or regulations, we will need to meet higher standards of data quality, transparency, and human oversight, and we would need to adhere to specific, potentially burdensome and costly ethical, accountability, and administrative requirements. We may also be subject to significant enforcement or litigation in the event of any perceived non-compliance.

The rapid evolution of AI will require the application of significant resources to design, develop, test and maintain our products and services to help ensure that AI is implemented in accordance with applicable law and regulation and to minimize any real or perceived unintended harmful impacts. The use of certain AI technologies can also give rise to intellectual property risks, including by disclosing or otherwise compromising confidential or proprietary intellectual property, or by undermining our ability to assert or defend ownership rights in intellectual property created with the assistance of AI tools.

The market for AI platforms serving the biotechnology and pharmaceutical industries is intensely competitive, rapidly evolving, and may develop in ways that are adverse to our business.

Our prospective AI platform will compete in a market characterized by rapid technological change, short innovation cycles and significant incumbent and emerging competition. We will face actual and potential competition from specialized AI-enabled drug discovery and research companies, large technology companies offering general-purpose AI infrastructure and tooling, open-source model communities and toolchains that can reduce barriers to entry, incumbent life-sciences software vendors that may add AI features to established offerings (including ELN/LIMS, data-management and workflow tools), systems integrator, and biotechnology and pharmaceutical companies that choose to build or extend their own internal AI platforms.

Many of these competitors have substantially greater financial, technical, data, marketing, sales, regulatory and procurement resources than we do, as well as longer operating histories, broader brand recognition and deeper relationships with our target customers. They may be able to innovate more quickly, secure advantageous pricing or bundling arrangements, invest more heavily in validation and compliance features required in regulated environments, and obtain or generate datasets and benchmarks that improve perceived performance. Existing and potential customers may prefer competing offerings that are more fully featured, more integrated with their existing systems, bundled with other capabilities, available on commercial terms we cannot match, or validated through prior deployments and references that we do not yet have.

Our strategy emphasizes on-premises or private-cloud deployment, data-sovereignty and customer control. The market may not value these attributes, or may view them as outweighed by perceived benefits of multi-tenant or fully managed solutions. Rapid advances in AI models, tooling and hardware may diminish or eliminate any early advantages we achieve, and competitors may replicate our features more quickly or at lower cost than we anticipate. In addition, our platform depends in part on technology we license from third parties; if comparable or superior capabilities become widely available from alternative vendors or open-source communities, our ability to differentiate may erode and our costs may increase.

If we are unable to compete effectively, keep pace with technological change, win procurement processes, achieve and demonstrate the levels of validation and compliance customers require, or otherwise differentiate our offerings, we may be unable to attract or retain customers or generate revenue on acceptable terms. Adverse developments in the competitive landscape could therefore materially and adversely affect our business, financial condition and results of operations.

Our Researgency business model depends on market acceptance of on-premises AI deployment architectures by biotechnology and pharmaceutical companies, and there is no assurance that sufficient market demand will develop.

Our Researgency business model is predicated on the premise that a meaningful number of biotechnology and pharmaceutical companies will prefer or be required by their internal data governance policies or regulatory considerations, to deploy AI infrastructure on-premises within their own facilities rather than using cloud-based solutions. This market thesis may prove incorrect. Cloud-based AI solutions offered by large technology companies may offer cost advantages, ease of implementation, or other benefits that make them more attractive to our target customers than our on-premises deployment model, notwithstanding the data sovereignty and intellectual property protection advantages that we believe our model provides. In addition, the addressable market for the software and services we offer may be smaller than we currently estimate, or potential customers may not perceive a sufficient need for the capabilities our platform provides to justify the costs of on-premises deployment. Demand for our services may also be influenced by shifts in customer priorities, budgetary constraints, or the availability of alternative solutions that customers consider adequate for their needs. Our assumptions regarding customer adoption rates and the size of the addressable market may prove to be incorrect. The market for life sciences AI platform solutions is early-stage and evolving, and customer adoption patterns are difficult to predict. If sufficient market demand for on-premises biotechnology AI infrastructure does not develop in the timeframes we anticipate, or if market preferences shift toward cloud-based or other alternatives, our business model could be materially impaired, and our revenue, financial condition, and results of operations could be materially and adversely affected.

We may not be able to protect our proprietary AI platform technology, and third parties may be able to develop competing products that use similar methods.

Our ability to compete in the AI platform market depends in part on our ability to protect our proprietary platform technology and the unique features of the Researgency platform. We may not be able to obtain or maintain adequate intellectual property protection for the AI platform. The legal framework for protecting AI-related inventions remains unsettled, and we cannot assure you that patent applications we may file, or patents we may obtain through our license arrangements, will be adequate to prevent competitors from developing substantially similar products. In addition, AI platform technology may be susceptible to reverse engineering, and confidential information related to our platform architecture or capabilities could be misappropriated. If we are unable to adequately protect our AI platform technology, our competitive position could be harmed.

Our use of artificial intelligence and machine learning in our AI platform business may be subject to methodological and processing limitations that could expose us to regulatory, legal, and reputational risks.

The research and analytical processes underlying Researgency may be subject to confirmation bias or other methodological limitations, which could adversely affect the reliability and commercial viability of platform outputs. The processes may be influenced, whether consciously or unconsciously, by a predisposition toward outcomes that confirm our existing assumptions, hypotheses, or business model. When researchers or developers design methodologies to verify a specific hypothesis, there is an inherent risk that such methodologies may produce results that reflect confirmation bias rather than an objective evaluation of the available data. Any such bias could compromise the reliability of outputs generated by our platform and the validity of conclusions derived from those outputs by our customers. We have implemented internal review processes intended to mitigate the risk of confirmation bias in our research and development activities; however, we cannot assure you that such processes will be effective in identifying or eliminating all instances of bias. If our platform outputs are perceived as unreliable or biased, our reputation and customer relationships could be harmed, and our business, financial condition, and results of operations could be materially and adversely affected.

Further, the costs of processing and analyzing data within Researgency may exceed our estimates, and we may be unable to deliver results within commercially viable timelines. The volume, complexity, or format of data supplied by our customers or sourced by us for use on our AI platform may exceed our anticipated parameters, resulting in higher computational costs, longer processing times, or diminished output quality. There can be no assurance that our current pricing model or operational budget will be sufficient to accommodate all potential data processing scenarios that may arise as our platform is deployed commercially. Our failure to deliver platform outputs within acceptable cost parameters and timeframes could result in customer dissatisfaction, contract terminations, or claims for damages, any of which could have a material adverse effect on our business, financial condition, and results of operations.

The regulatory environment for artificial intelligence and machine learning products is rapidly evolving in the United States and internationally. Although there are no comprehensive federal healthcare AI laws at this time, there are increasing legislative efforts and regulatory scrutiny of the use of AI in healthcare and life sciences applications. In particular, the FDA has issued guidance on the use of AI and machine learning in medical devices and drug development, and future regulatory actions may apply to aspects of our AI platform. We may also face potential liability if our Researgency platform generates outputs that are used in clinical decision-making and that contribute to adverse patient outcomes, even if our platform is not itself classified as a medical device or diagnostic tool. Additionally, several states have enacted AI laws related to health data including imposing governance and transparency requirements that could apply to certain uses of our platform and may expand over time. Further, new federal and state laws and regulations may impose additional requirements on our AI platform that may increase compliance costs, restrict certain features or use cases, or require us to modify Researgency in ways that could affect its commercial appeal. We cannot predict the nature or scope of future AI-related regulation or litigation, and there can be no assurance that our Researgency business will be compliant with applicable regulations as they evolve.

Data security and privacy risks are heightened in our Researgency business given that our platform may process proprietary biological and clinical data of our customers.

Researgency is designed to be deployed within client environments to process proprietary biological data, clinical trial datasets, and other sensitive information of our biotechnology and pharmaceutical customers. As a result, our platform may be subject to heightened data security and privacy requirements, including obligations under HIPAA, GDPR, CCPA, and other applicable privacy laws that govern the handling of protected health information and other sensitive personal data. Legislative activity in the privacy area may result in new laws that are applicable to us and that may hinder our business, for example, by restricting use or sharing of customer data, limiting our ability to provide certain customer data, or otherwise regulating artificial intelligence or machine learning. These new laws could materially affect our business or lead to significant increases in the cost of compliance. Any actual or perceived breach of data security involving customer data processed by our platform could expose us to significant liability, regulatory penalties, and reputational harm. In addition, the on-premises deployment model that underlies our business creates specific cybersecurity risks related to integration with customer IT environments, and any security vulnerabilities in our platform software could expose our customers' proprietary data to unauthorized access. The costs and complexity of maintaining compliance with evolving data privacy and security requirements may be substantial.

Our plans to use our KPI-012 clinical development dataset as a proof-of-concept for Researgency may not generate the commercial benefits we expect, and may expose us to additional risks.

We intend to use our accumulated KPI-012 clinical development dataset, which includes data from 79 patients across 37 clinical trial sites, as an initial proof-of-concept validation environment for Researgency. We may not be able to successfully use this dataset in the manner we anticipate, and even if we do, the results of this self-validation effort may not be persuasive to potential commercial customers or may not generate the commercial benefits we expect. In addition, the use of clinical trial data for purposes beyond those originally described to trial participants may raise ethical, legal, or regulatory concerns, particularly with respect to patient consent and data governance requirements. If existing consents or notices are deemed insufficient for such uses, we may be required to suspend or cease processing some or all of the dataset; de-identify or segregate and delete records; obtain additional required consents, approvals, or permissions; or implement additional contractual and technical controls, any of which could delay or limit our AI platform development and commercialization. We could also face complaints or investigations by trial sites, IRBs, or regulators, contractual disputes with CROs or investigators, participant claims, and be forced to rely on smaller de-identified subsets or synthetic data that may reduce the AI model performance and diminish the value proposition of Researgency.

The information, research, and analytical outputs generated by Researgency are based on data sources and methodologies that we believe to be reliable; however, we make no representation or warranty, express or implied, as to the completeness, accuracy, or timeliness of such outputs. There may be errors, omissions, or inaccuracies in the underlying data or in the manner in which such data has been interpreted, compiled, or presented by our platform. Our customers and other users of our platform's outputs should not place undue reliance on such outputs without conducting their own independent review and verification. If our platform outputs are found to contain material errors, omissions, or inaccuracies, we could be subject to claims of liability from our customers, suffer reputational harm, and experience reduced demand for our platform services, any of which could have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Our Intellectual Property

We may be unable to obtain and maintain patent protection for our technology or product candidates, or the scope of the patent protection obtained may not be sufficiently broad or enforceable, such that our competitors could develop and commercialize technology, products and product candidates similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be impaired.

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 proprietary technology and product candidates, including KPI-012. We have sought to protect our proprietary position by filing in the United States and in certain foreign jurisdictions patent applications related to our proprietary technologies and product candidates.

The patent prosecution process is expensive and time-consuming, and we may not have filed, maintained, or prosecuted and may not be able to file, maintain and prosecute all necessary or desirable patents or patent applications at a reasonable cost or in a timely manner. We may also fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of pharmaceutical, biotechnology, and medical device companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. 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 fail to result in issued patents in the United States or in other foreign countries which protect our technology or product candidates, or which effectively prevent others from commercializing competitive technologies and products. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and the standards applied by the U.S. Patent and Trademark Office and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, unlike patent law in the United States, European patent law precludes the patentability of methods of treatment of the human body and imposes substantial restrictions on the scope of claims it will grant if broader than specifically disclosed embodiments. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. Databases for patents and publications, and methods for searching them, are inherently limited so we may not know the full scope of all issued and pending patent applications. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies, products and product candidates. In particular, during prosecution of any patent application, the issuance of any patents based on the application may depend upon our ability to generate additional preclinical or clinical data that support the patentability of our proposed claims. We may not be able to generate sufficient additional data on a timely basis, or at all. Moreover, changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection for our proprietary technology and product candidates, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies, products or product candidates in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity, or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology, products or product candidates, or limit the duration of the patent protection of our technology and product candidates. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs or methods.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we are not able to obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for our product candidates, our business may be materially harmed.

Depending upon the timing, duration, and specifics of FDA marketing approval of our product candidates, one of the U.S. patents covering each of such product candidates or the use thereof may be eligible for up to five years of patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product as compensation for the 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 and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Also, the regulatory review period of an FDA-approved product may not serve as a basis for a patent term extension if the active ingredient of such product was subject to regulatory review and approval in an earlier product approved by the FDA. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates. Nevertheless, we may not be able to seek or be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product may be shortened and our competitors may obtain approval of competing products following our patent expiration sooner, and our revenue could be reduced, possibly materially.

It is possible that we will not obtain patent term extension under the Hatch-Waxman Act for a U.S. patent covering our product candidates even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought. Further, for our licensed patents, we may not have the right to control prosecution, including filing with the U.S. Patent and Trademark Office, a petition for patent term extension under the Hatch-Waxman Act. Thus, if one of our licensed patents is eligible for patent term extension under the Hatch-Waxman Act, we may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the U.S. Patent and Trademark Office.

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

Competitors and other third parties may infringe, misappropriate or otherwise violate our owned and licensed patents, trade secrets, or other intellectual property rights. As a result, to counter infringement, misappropriation or unauthorized use, we may be required to file infringement or misappropriation claims or other intellectual property related proceedings, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or that our asserted patents are invalid. In addition, in a patent infringement or other intellectual property related proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly, and could put any of our patent applications at risk of not yielding an issued patent. 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 or trade secrets could be compromised by disclosure during this type of litigation.

We may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in other contested proceedings such as opposition, derivation, reexamination, inter partes review, post-grant review, or interference proceedings in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates 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. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

In the United States, the FDA does not prohibit clinicians from prescribing an approved product for uses that are not described in the product's labeling. Although use of a product directed by off-label prescriptions may infringe our method-of-treatment patents, the practice is common across medical specialties, particularly in the United States, and such infringement is difficult to detect, prevent, or prosecute and may have negative impacts on our business, operating results and financial condition.

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

Part of our commercial success depends upon our ability to use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and frequent litigation regarding patents and other intellectual property rights. We cannot assure you that our products, product candidates or any future product candidates, including methods of making or using these product candidates, will not infringe existing or future third-party patents. We may become party to, or threatened with, infringement litigation claims regarding our product candidates and technology, including claims from competitors or from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. Moreover, we may become party to future adversarial proceedings or litigation regarding our patent portfolio or the patents of third parties. Such proceedings could also include contested post-grant proceedings such as oppositions, inter partes review, reexamination, interference, or derivation proceedings before the U.S. Patent and Trademark Office or foreign patent offices.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. The risks of being involved in such litigation and proceedings may increase if our product candidates commence commercialization. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. We may not be aware of all such intellectual property rights potentially relating to our product candidates and their uses. Thus, we do not know with certainty that any of our product candidates or our development and commercialization thereof, do not and will not infringe or otherwise violate any third-party's intellectual property.

If we are found to infringe, misappropriate or otherwise violate a third-party's intellectual property rights, we could be required to obtain a license from such third-party to continue developing, manufacturing, marketing and selling any products, if and when approved, product candidates and technology. Under any such license, we would most likely be required to pay various types of fees, milestones, royalties or other amounts. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. Without such license, we could be forced, including by court order, to cease developing and commercializing the infringing technology, products or product candidates. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent and could be forced to indemnify our customers or collaborators. A finding of infringement could also result in an injunction that prevents us from commercializing our product candidates or forces us to cease some of our business operations, which could materially harm our business. In addition, we may be forced to redesign our product candidates, seek new regulatory approvals and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Even if we are successful in defending against such claims, litigation can be expensive and time consuming and would divert management's attention from our core business. Any of these events could harm our business significantly.

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

Periodic maintenance, renewal and annuity fees on any issued patent must be paid to the U.S. Patent and Trademark Office and foreign patent agencies in several stages or annually over the lifetime of our owned and licensed patents and patent applications. The U.S. Patent and Trademark Office and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we may rely on our licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, it would have a material adverse effect on our business.

KPI-012 is protected by patent rights exclusively licensed from other companies or institutions. If these third parties terminate their agreements with us or fail to maintain or enforce the underlying patents, or we otherwise lose our rights to these patents, our competitive position and our market share in the markets for any of our products, if any when approved, will be harmed.

A portion of our patent portfolio is in-licensed. As such, we are a party to license agreements and certain aspects of our business depend on patents and/or patent applications owned by other companies or institutions. In particular, we hold an exclusive license for a patent family relating to KPI-012. We rely on a license from Stanford University for certain patent rights related to KPI-012. The license agreement between Combangio and Stanford University, or Stanford University License Agreement, imposes specified diligence, milestone payment, royalty and other obligations on us and requires that we meet development timelines, or to exercise diligent or commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the license. Our rights with respect to in-licensed patents and patent applications may be lost if the applicable license agreement expires or is terminated or if we fail to satisfy the obligations under the Stanford University License Agreement. We are likely to enter into additional license agreements to in-license patents and patent applications as part of the development of our business in the future, under which we may not retain control of the preparation, filing, prosecution, maintenance, enforcement and defense of such patents. If we are unable to maintain these patent rights for any reason, our ability to develop and commercialize our product candidates could be materially harmed.

Our licensors may not successfully prosecute certain patent applications, the prosecution of which they control, under which we are licensed and on which our business depends. Even if patents issue from these applications, our licensors may fail to maintain these patents, may decide not to pursue litigation against third-party infringers, may fail to prove infringement, or may fail to defend against counterclaims of patent invalidity or unenforceability.

Risks with respect to parties from whom we have obtained intellectual property rights may also arise out of circumstances beyond our control. In spite of our best efforts, our licensors might conclude that we have materially breached our intellectual property agreements and might therefore terminate the intellectual property agreements, thereby removing our ability to market products covered by these intellectual property agreements. If our intellectual property agreements are terminated, or if the underlying patents fail to provide the intended market exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products similar or identical to ours. Moreover, if our intellectual property agreements are terminated, our former licensors and/or assignors may be able to prevent us from utilizing the technology covered by the licensed or assigned patents and patent applications. This could have a material adverse effect on our competitive business position and our financial condition, results of operations and our business prospects.

Our biologics product candidates, including KPI-012 and KPI-014, are protected by patent rights exclusively licensed from other companies or institutions. Our AI platform operates under an exclusive license. If any licensor terminates their agreement with us, fails to maintain or enforce the underlying patents, or if we otherwise lose our rights under these licenses, our ability to monetize our biologics assets or to operate our Researgency business could be materially harmed.

The value of our biologics asset portfolio, including KPI-012 and KPI-014, is substantially dependent on the continued validity and enforceability of the patent rights licensed to us from third parties. If any such patent rights are challenged, invalidated, or circumvented, the commercial value of our biologics intellectual property could be materially diminished. Our ability to attract licensing or collaboration partners for our biologics assets depends in part on the strength of the underlying patent portfolio, and any deterioration in the patent position for KPI-012 or KPI-014 could make it more difficult for us to enter into such arrangements on acceptable terms. Similarly, with respect to our Researgency business, if the intellectual property underlying the Researgency platform is found to be invalid, or if our exclusive license is terminated for any reason, we would lose our ability to operate our Researgency business as currently planned.

Some intellectual property which we own or have licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements, and a preference for United States industry. Compliance with such regulations may limit our exclusive rights, subject us to expenditure of resources with respect to reporting requirements, and limit our ability to contract with non-U.S. manufacturers.

Some of the intellectual property rights we own or have licensed have been generated through the use of United States government funding and may therefore be subject to certain federal regulations. For example, certain aspects of KPI-012 were developed using United States government funds. As a result, the United States government may have certain rights to intellectual property embodied in KPI-012 pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole. These United States government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the United States government has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third-party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The United States government also has the right to take title to these inventions if we fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. In addition, the United States government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the United States government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for United States manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. Further, to the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of Bayh-Dole may similarly apply. Accordingly, any exercise by the government of any of the foregoing rights could harm our competitive position, business, financial condition, results of operations and prospects.

Moreover, in December 2023, the National Institute of Standards and Technology, or NIST, released for public comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, or the Draft Framework. The Draft Framework sets forth the factors that an agency may consider when deciding whether to exercise march-in rights pursuant to Bayh-Dole, and includes a first-ever specification that price can be a factor in determining that a drug or other taxpayer-funded invention is not accessible to the public. NIST is currently seeking public comments on the proposed Draft Framework. The potential inclusion of price as a factor in a march-in determination and the exercise of "march-in" rights by the federal government could result in decreased demand for our future products, which could have a material adverse effect on our results of operations and financial condition. In addition, any failure to comply with applicable laws or regulations could harm our business and divert our management's attention.

If we fail to comply with our obligations under our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business.

Our Stanford Agreement, under which we license certain patent rights related to KPI-012, imposes royalty and other financial obligations on us and other substantial performance obligations. We also may enter into additional licensing and funding arrangements with third parties that may impose diligence, development and commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under current or future license and collaboration agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product or product candidate that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could diminish the value of any product or product candidate. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

In addition, it is possible that Stanford may conclude that we have materially breached the Stanford Agreement and might therefore terminate the agreement, thereby removing our ability to market products covered by our license agreement with Stanford. If the Stanford University License Agreement is terminated, or if the underlying patents fail to provide the intended market exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products similar or identical to ours. Moreover, if our Stanford University License Agreement is terminated, Stanford and/or its assignors may be able to prevent us from utilizing the technology covered by the licensed or assigned patents and patent applications. If we breach the agreement (including by failing to meet our payment obligations) and do not adequately cure such breach, the rights in the technology licensed to us under the Stanford University License Agreement will revert to Stanford at no cost to Stanford. This could have a material adverse effect on our competitive business position, our financial condition, our results of operations and our business prospects.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize any affected product or product candidate, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

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

Filing, prosecuting, and defending patents on our product candidates 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 the laws of the United States. 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 or licenses, 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 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.

Beginning June 1, 2023, European patent applications and patents may be subjected to the jurisdiction of the Unified Patent Court, or UPC. Under the unitary patent system, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the UPC. As the UPC is a new court system, there is minimal precedent for the court, increasing the uncertainty of any litigation. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

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 or any of our licensors is 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.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our and our licensors' employees and contractors were previously employed at other biotechnology, medical device or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We may also in the future be subject to claims that we have caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the 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 develops intellectual property that we regard as our own. Furthermore, we are unable to control whether our licensors have obtained similar assignment agreements from their own employees and contractors. Our and their assignment agreements may not be self-executing or may be breached, and we or our licensors may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we or our licensors fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel which could have a material adverse effect on our competitive business position and prospects. Such intellectual property rights could be awarded to a third-party, and we could be required to obtain a license from such third-party to commercialize our technology or products, which may not be available on commercially reasonable terms or at all. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property litigation or other legal proceedings relating to intellectual property could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our 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. 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 may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

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 technology and our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, 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, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed. Despite these 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 obtain adequate remedies for such breaches. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Detecting the disclosure or misappropriation of a trade secret and 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, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating such trade secrets.

Patent reform legislation under Leahy-Smith America Invents Act could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office has been developing new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. The first to file provisions limit the rights of an inventor to patent an invention if not the first to file an application for patenting that invention, even if such invention was the first invention. Although it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, which could have a material adverse effect on our business, financial condition, results of operations and prospects. For example, the Leahy-Smith Act provides a new administrative tribunal known as the Patent Trial and Appeals Board, or PTAB, that provides a venue for companies to challenge the validity of competitor patents at a cost that is much lower than district court litigation and on timelines that are much faster. Although it is not clear what, if any, long term impact the PTAB proceedings will have on the operation of our business, the initial results of patent challenge proceedings before the PTAB since its inception in 2013 have resulted in the invalidation of many U.S. patent claims. The availability of the PTAB as a lower-cost, faster and potentially more potent tribunal for challenging patents could therefore increase the likelihood that our own patents will be challenged, thereby increasing the uncertainties and costs of maintaining, defending and enforcing them.

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters

If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate significant revenue will be materially impaired. Although we have suspended active clinical development of KPI-012 following the results of the CHASE Phase 2b clinical trial, we continue to evaluate opportunities to resume preclinical and clinical development activities, subject to the availability of additional financing and the identification of a suitable development partner. If we were to resume development activities and seek marketing approval for KPI-012 or any other product candidate, the marketing approval process would be expensive, time-consuming and uncertain. As a result, we cannot predict when or if we, or any collaborators we may have in the future, will obtain marketing approval to commercialize KPI-012 or any product candidates we may develop in the future.

Although we have suspended active clinical development of KPI-012 following the results of the CHASE Phase 2b clinical trial, KPI-012 and any other future product candidate and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, potency, purity, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate.

Other than EYSUVIS and INVELTYS, which we sold to Alcon in July 2022, we have not received approval to market any product candidate from regulatory authorities in any jurisdiction. We may never generate the necessary data or results required to obtain regulatory approval of KPI-012 or any other product candidate we may develop with the market potential sufficient to enable us to achieve profitability. We have only limited experience in submitting and supporting the applications necessary to gain marketing approvals and have relied on, and expect to continue to rely on, third-party consultants and vendors to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish a biologic product candidate's purity, safety and potency. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA or other regulatory authorities may determine that KPI-012 or any other product candidate that we develop does not satisfy these standards or has undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or a comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of 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. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate.

In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted. For example, in December 2022, with the passage of Food and Drug Omnibus Reform Act, or FDORA, Congress required sponsors to develop and submit a diversity action plan for each phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical

trials of FDA-regulated products. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for diversity action plans. Unlike most guidance documents issued by the FDA, the diversity action plan guidance when finalized will have the force of law.

On January 27, 2025, in response to an Executive Order issued by President Trump on January 21, 2025, on Diversity, Equity and Inclusion programs, the FDA removed the draft DAP guidance from its website. That action, along with similar actions by the Trump Administration to remove many other healthcare webpages, is currently the subject of ongoing litigation. On July 3, 2025, the U.S. District Court for the District of Columbia ruled that the administration's actions to remove these webpages, including the draft DAP guidance, is unlawful under the Administrative Procedure Act, or the APA. The court ordered the restoration of many of these webpages. As of July 24, 2025, the draft DAP guidance had not been restored to the FDA's website. Accordingly, in light of these ongoing actions, there is considerable uncertainty surrounding the draft DAP guidance and how the FDA will consider diversity action plans in connection with its review of marketing applications.

In February 2026, the Commissioner of FDA and the Director of Center for Biologics Evaluation and Research published an editorial in the New England Journal of Medicine in which they declared that, in most cases, the new default requirement for FDA approval of a new product will be one adequate and well-controlled pivotal clinical trial plus confirmatory evidence, rather than two pivotal clinical trials. In determining whether to rely on one trial, the FDA will focus on the single trial's quality, including magnitude of effect, appropriateness of control arms, endpoint selection, statistical power, blinding, handling of missing data, biological plausibility and alignment with intermediate biomarkers. The FDA has long had authority to approve new products on the basis of one trial plus confirmatory evidence and, in recent years, the agency has exercised that authority with respect to certain types of products. The FDA now takes the position that this will be the new official default standard for most product candidates. At this point, it is unclear how this new policy will be implemented by the FDA and how, if at all, it will affect our clinical development programs.

Further, under the Pediatric Research Equity Act, or PREA, a Biologics License Application, or BLA or supplement to a BLA for certain biological products must contain data to assess the safety, potency and purity of the biological product in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe, potent and pure, unless the sponsor receives a deferral or waiver from the FDA. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety, potency and purity data need to be collected before the pediatric trials begin. The applicable legislation in the European Union also requires sponsors to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan approved by the Pediatric Committee of the European Medicines Agency, or EMA, or to obtain a waiver or deferral from the conduct of these studies by this Committee. For any of our product candidates for which we are seeking regulatory approval in the United States or the European Union, we cannot guarantee that we will be able to obtain a waiver or alternatively complete any required studies and other requirements in a timely manner, or at all, which could result in associated reputational harm and subject us to enforcement action.

In addition, we could be adversely affected by several significant administrative law cases decided by the U.S. Supreme Court in 2024. In *Loper Bright Enterprises v. Raimondo*, for example, the court overruled *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, which for 40 years required federal courts to defer to permissible agency interpretations of statutes that are silent or ambiguous on a particular topic. The U.S. Supreme Court stripped federal agencies of this presumptive deference and held that courts must exercise their independent judgment when deciding whether an agency such as the FDA acted within its statutory authority under the Administrative Procedure Act, or the APA. Additionally, in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, the court held that actions to challenge a federal regulation under the APA can be initiated within six years of the date of injury to the plaintiff, rather than the date the rule is finalized. The decision appears to give prospective plaintiffs a personal statute of limitations to challenge longstanding agency regulations. Another decision, *Securities and Exchange Commission v. Jarkesy*, overturned regulatory agencies' ability to impose civil penalties in administrative proceedings. These decisions could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies, including the FDA and CMS, that we rely on. In addition to potential changes to regulations as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays and other impacts, any of which could adversely impact our business and operations.

Further, our ability to develop and market new products may be impacted by litigation challenging the FDA's approval of mifepristone. In April 2023, the U.S. District Court for the Northern District of Texas stayed the approval by

the FDA of mifepristone, a drug product which was originally approved in 2000 and whose distribution is governed by various conditions adopted under a REMS. The Court of Appeals for the Fifth Circuit declined to order the removal of mifepristone from the market, but did hold that plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone that FDA authorized in 2016 and 2021 were arbitrary and capricious. In June 2024, the Supreme Court reversed and remanded that decision after unanimously finding that the plaintiffs did not have standing to bring this legal action against the FDA. On October 11, 2024, the Attorneys General of three states filed an amended complaint in the U.S. District Court for the Northern District of Texas challenging the FDA's actions. In January 2025, the district court agreed to allow these states to file an amended complaint and continue to pursue this challenge. Depending on the outcome of this litigation, if it continues, our ability to develop and market new drug products could be delayed, undermined or subject to protracted litigation.

Further, there is substantial uncertainty as to how measures being implemented by the new Trump Administration across the government will impact the FDA, CMS and other federal agencies with jurisdiction over our activities. For example, since taking office, President Trump has issued a number of executive orders, which could have a significant impact on the manner in which the FDA conducts its operations and engages in regulatory and oversight activities. If these or other orders or executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. In addition, the loss of FDA personnel could lead to further disruptions and delays in FDA review and oversight of our product candidates. Similarly, efforts by the new administration to substantially reduce or delay research funding by the National Institutes of Health of medical research could have substantial direct or indirect impacts on our research activities.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidate that we develop, the commercial prospects for such product candidate may be harmed and our ability to generate revenues will be materially impaired.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad. We may be subject to additional risks in commercializing any of our product candidates that receive marketing approval in foreign jurisdictions.

In order to market and sell KPI-012 or any other product candidate we may develop in the European Union and many other jurisdictions outside of the United States, we or our potential third-party collaborators, must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. Clinical trials of any product candidate in the United States may not be sufficient to support an application for marketing approval outside the United States.

The time required to obtain approval outside of the United States may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be sold in that country. We or our potential collaborators may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market, which could significantly and materially harm our business.

Additionally, we could face heightened risks with respect to obtaining marketing authorization in the United Kingdom as a result of the withdrawal of the United Kingdom from the European Union, commonly referred to as Brexit. The UK is no longer part of the European Single Market and EU Customs Union. As of January 1, 2025, the Medicines and Healthcare Products Regulatory Agency, or MHRA, is responsible for approving all medicinal products destined for the United Kingdom market (i.e., Great Britain and Northern Ireland). On April 28, 2025, the United Kingdom Parliament adopted amendments to improve and strengthen the United Kingdom's clinical trials regulatory regime; they will take effect on April 28, 2026. These changes were needed since the current United Kingdom requirements are based upon the now-repealed EU Clinical Trials Directive (2001/20/EC), which has been replaced by the European Clinical Trials Regulation (Regulation EU No 536/2014). Since the United Kingdom left the European

Union prior to the date on which the EU Clinical Trials Regulation took effect, the United Kingdom's legal framework did not benefit from the same revisions as occurred at European Union level.

At the same time, a new international recognition procedure, or IRP, will apply, which intends to facilitate approval of pharmaceutical products in the United Kingdom. The IRP is open to applicants that have already received an authorization for the same product from one of the MHRA's specified Reference Regulators, or RRs, The RRs notably include EMA and regulators in the European Union/European Economic Area member states for approvals in the EU centralized procedure and mutual recognition procedure as well as the FDA (for product approvals granted in the United States). However, the concrete functioning of the IRP is currently unclear. Any delay in obtaining, or an inability to obtain, any marketing approvals may force us or our collaborators to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business.

In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the European Union pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (including potentially reducing the duration of regulatory data protection and exclusivity periods for orphan drugs, and revising the eligibility for expedited pathways) was published in April 2023 and the European Parliament has requested several amendments. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may however have a significant impact on the pharmaceutical industry and our business in the long term. On June 4, 2025, after almost two years of negotiations among the European Union Member States, the Council of the European Union adopted its position on the proposed overhaul of the European Union general pharmaceutical legislative framework, which is known as the new Pharma Package. This proposal will now be the subject of additional negotiations and technical meetings, with the objective of reaching agreement on issues such as the regulatory data protection framework and the access and supply obligations.

Even if our product candidates receive regulatory approval, they will be subject to significant post-marketing regulatory requirements and oversight.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and ongoing surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements and regulatory inspection. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, EMA or foreign regulatory authorities approve our product candidates, the manufacturing processes, labelling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as ongoing compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA, EMA and other regulatory authorities for compliance with cGMP regulations and standards. The PREVENT Pandemics Act, which was enacted in December 2022, clarifies that foreign drug manufacturing establishments are subject to registration and listing requirements even if a drug or biologic undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the United States prior to being imported or offered for import into the United States. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA, EMA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;

- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements;
- revisions to the labelling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions; and
- requirements to conduct additional post-market clinical trials to assess the safety of the product.

The FDA, EMA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and if we are found to have improperly promoted such off-label uses, we may become subject to significant liability.

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability, which would materially adversely affect our business and financial condition. The FDA, EMA and other regulatory authorities strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted in the United States for uses that are not approved by the FDA as reflected in the product's approved labelling, or in other jurisdictions for uses that differ from the labelling or uses approved by the applicable regulatory authorities. While physicians may prescribe products for off-label uses, the FDA, EMA and other regulatory authorities actively enforce laws and regulations that prohibit the promotion of off-label uses by companies, including promotional communications made by companies' sales force with respect to off-label uses that are not consistent with the approved labelling. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

We will also need to carefully navigate the FDA's various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing promotion of products. In September 2021, the FDA published final regulations which describe the types of evidence that the FDA will consider in determining the intended use of a drug or biologic. Moreover, with passage of the Pre-Approval Information Exchange Act in December 2022, sponsors of products that have not been approved may proactively communicate to payors certain information about products in development to help expedite patient access upon product approval. In addition, in January 2025, the FDA published final guidance outlining its policies governing the distribution of scientific information to healthcare providers about unapproved uses of approved products. The final guidance calls for such communications to be truthful, non-misleading and scientifically sound and to include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use of the approved product. If a company engages in such communications consistent with the guidance's recommendations, the FDA indicated that it will not treat such communications as evidence of unlawful promotion of a new intended use for the approved product.

We will need to carefully navigate the FDA's various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing promotion of our products. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

We may not be able to obtain orphan drug exclusivity for one or more of our product candidates, and even if we do, that exclusivity may not prevent the FDA or the EMA from approving other competing products. Additionally, if another company with a competing product candidate were to obtain orphan drug exclusivity for its competing product candidate before we do, we may be barred from marketing our product candidate for the same indication as the competing product candidate during the exclusivity period. Although we have suspended active clinical development, KPI-012 retains its Orphan Drug designation from the FDA for PCED, and these risks would become relevant if we or a future licensee or development partner were to resume development and seek marketing approval.

Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. A similar regulatory scheme governs approval of orphan products by the EMA in the European Union. KPI-012 has received orphan drug designation from the FDA for the treatment of PCED.

Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same product for the same therapeutic indication for that time period. The applicable period is seven years in the United States and currently ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a product no longer meets the criteria for orphan drug designation, in particular if the product is sufficiently profitable so that market exclusivity is no longer justified. If a competing product candidate with an orphan designation for PCED were to obtain regulatory approval before we are able to obtain approval of KPI-012 for PCED, we could be barred from marketing KPI-012 for PCED in the United States during the seven-year orphan exclusivity period, which would have a severe adverse effect on our business.

In order for the FDA to grant orphan drug exclusivity to one of our products, the FDA must find that the product is indicated for the treatment of a condition or disease with a patient population of fewer than 200,000 individuals annually in the United States. The FDA may conclude that the condition or disease for which orphan drug exclusivity is sought does not meet this standard. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition.

In addition, even after an orphan drug is approved, the FDA can subsequently approve the same product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may also be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition.

The FDA Reauthorization Act of 2017, or FDARA, requires that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. FDARA reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term "same disease or condition" means the designated "rare disease or condition" and could not be interpreted by the FDA to mean the "indication or use." Thus, the Court of Appeals concluded that orphan drug exclusivity applies to the entire designated disease or condition rather than the "indication or use." Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, the FDA announced that, in matters beyond the scope of that court order, the FDA will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved. However, on February 14, 2025, a federal district court in Washington, D.C. fully embraced the reasoning of the court decision in another decision challenging the scope of orphan drug exclusivity. On April 17, 2025, the FDA appealed this decision to the U.S. Court of Appeals for the D.C. Circuit. The implications of this decision, and its impact on the FDA's implementation of the Orphan Drug Act, are unclear at this point. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

In addition, to obtain orphan drug designation in the European Union, we would need to demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the medicinal product will be of significant benefit to those affected by that condition. There is no assurance that we would be able to meet that standard for any of our product candidates. Further, if we do obtain orphan drug designation for a product candidate in the European Union, we will not be able to maintain that designation if we are not able to show, to the satisfaction of the European Union regulatory authorities, that the product candidate is of significant benefit to patients over available commercial products for the indication in the European Union and any additional products that are ahead of our product candidate in clinical development for the indication.

We may seek certain designations for our product candidates, including Breakthrough Therapy, Fast Track and Priority Review designations in the United States, and PRIME Designation in the European Union, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process.

We may seek certain designations for one or more of our product candidates that could expedite review and approval by the FDA. A Breakthrough Therapy product is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

The FDA may also designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track review products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track review product may be effective.

In April 2023, the FDA designated KPI-012 for the treatment of PCED for Fast Track review. Notably, in September 2025, we announced the discontinuation of the development of KPI-012 following the failure of the CHASE Phase 2b clinical trial to meet its primary endpoints. As a result, clinical development of KPI-012 has been suspended. The FDA may rescind the Fast Track designation previously granted to KPI-012 if it determines that the product candidate no longer meets the criteria for such designation, including because the CHASE Phase 2b clinical trial's

failure to meet primary endpoints may been viewed to undermine KPI-012's potential to address unmet medical needs. Under FDA regulations and guidance, Fast Track designation may be withdrawn if the criteria under which the designation was granted are no longer met, and the suspension of active clinical development and the lack of demonstrated efficacy in the CHASE trial could each independently support such a determination. The rescission of KPI-012's Fast Track designation could diminish the perceived value of our biologics portfolio, reduce the attractiveness of KPI-012 to potential licensing or collaboration partners, and adversely affect our ability to monetize our biologics assets, whether through out-licensing, partnership arrangements, or any future resumption of clinical development.

We may also seek a priority review designation for one or more of our product candidates. If the FDA determines that a product candidate is intended to treat a serious condition and, if approved, offers a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal is for the FDA to review an application for marketing approval in six months, rather than the standard review period of 10 months.

On June 17, 2025, the FDA announced the creation of a new voucher program to expedite the development and approval of new drug products. Vouchers issued under the new program, which is known as the Commissioner's National Priority Voucher, or CNPV, Program, may reportedly be redeemed by sponsors to shorten the review time of an NDA from approximately 10-12 months to 1-2 months. The FDA has indicated that the new CNPV process will convene experts from the FDA's offices for a team-based review rather than using the standard review system of a drug application being sent to numerous FDA offices. Clinical information will be reviewed by a multidisciplinary team of physicians and scientists who will pre-review the submitted information and convene for a 1-day meeting. Vouchers under this program will reportedly be given to companies aligned with U.S. national priorities.

These designations are within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. Further, even if we receive a designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to product candidates considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualifies for these designations, such as the Fast Track designation for KPI-012 for the treatment of PCED, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. The risk that FDA will decide KPI-012 no longer meets the conditions for qualification of Fast Track designation could be heightened by our termination of the CHASE Phase 2b clinical trial due to failure to meet its primary endpoints and our subsequent suspension of clinical development of KPI-012.

In the European Union, we may seek PRIME designation for some of our product candidates in the future. The PRIME program focuses on product candidates that target conditions for which there exists no satisfactory method of treatment in the European Union, or even if such a method exists, the product candidate may offer a major therapeutic advantage over existing treatments. To be accepted for PRIME designation, a product candidate must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that is capable of substantiating the claims. The benefits of a PRIME designation include the appointment of a rapporteur of the Committee for Medicinal Products for Human Use to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME designation enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA's grant of a marketing authorization.

If approved, our products regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biologic products that are biosimilar to or interchangeable with an FDA-licensed reference biologic 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 regulatory exclusivity, another company may still market a competing version of the reference product if the FDA approves a 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 the other company's product.

In December 2022, Congress clarified through the Food and Drug Omnibus Reform Act, that the FDA may approve multiple first interchangeable biosimilar biological products so long as the products are all approved on the same first day on which such a product is approved as interchangeable with the reference product and the exclusivity period may be shared amongst multiple first interchangeable products. More recently, in October 2023, the FDA issued its first interchangeable exclusivity determination under the BPCIA.

To date, we have not had a product candidate approved as a biologic product. We believe that any of our product candidates that may be approved as a biologic product under a BLA should qualify for the 12-year period of exclusivity. Nonetheless, the approval of biosimilar products referencing any of our product candidates would have a material adverse impact on our business due to increased competition and pricing pressures. Moreover, there is a risk that any exclusivity we do receive could be shortened due to congressional action or otherwise, or that the FDA will not consider our products 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. The extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. If competitors are able to obtain regulatory approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. The ultimate impact, implementation, and meaning of the BPCIA are subject to uncertainty, and any new regulations, guidance, policies or processes adopted by the FDA to implement the law could have a material adverse effect on the future commercial prospects for our biological product candidates.

Our relationships with customers and third-party payors may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, clinicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription and use of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. 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;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which imposes obligations, including mandatory contractual terms, on covered healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act requires 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 specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or transfers of value made to physicians, other healthcare providers and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state and foreign 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 or otherwise restrict payments that may be made to healthcare providers, state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to clinicians and other healthcare providers or marketing expenditures, 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 often are not preempted by HIPAA, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, individual imprisonment, integrity obligations, and the curtailment or restructuring of our operations. Any penalties, damages, fines, individual imprisonment, integrity obligations, exclusion from funded healthcare programs, or curtailment or restructuring of our operations could adversely affect our financial results. Our corporate compliance program is designed to ensure that we will develop, market and sell our products and product candidates in compliance with all applicable laws and regulations, but we cannot guarantee that this program will protect us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or 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 fines or other sanctions.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If

any of the clinicians or other healthcare providers or entities with whom we do or expect to do business is found to be not in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government funded healthcare programs.

Existing and future legislation may affect our ability to commercialize our products, if and when approved, and increase the difficulty and cost for us to obtain reimbursement for our products, if and when approved.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could affect our ability to profitably sell or commercialize any product candidate for which we obtain marketing approval. The pharmaceutical industry has been a particular focus of these efforts and have been significantly affected by legislative initiatives. Current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any FDA approved product.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the ACA. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2021, the Budget Control Act of 2011, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year which went into effect in 2013 and will remain in effect through the first half of 2032.

The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any product candidate is prescribed or used. Indeed, under current legislation, the actual reductions in Medicare payments may vary up to 4%. The Consolidated Appropriations Act, which was signed into law by President Biden in December 2022, made several changes to sequestration of the Medicare program. Section 1001 of the Consolidated Appropriations Act delays the 4% Statutory PAYGO sequester for two years, through the end of calendar year 2024. Triggered by enactment of the American Rescue Plan Act of 2021, the 4% cut to the Medicare program would have taken effect in January 2023. The Consolidated Appropriations Act's health care offset title includes Section 4163, which extends the 2% Budget Control Act of 2011 Medicare sequester for six months into fiscal year 2032 and lowers the payment reduction percentages in fiscal years 2030 and 2031.

We expect that additional healthcare reforms may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any product which receives regulatory approval and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Since enactment of the ACA, there have been and continue to be numerous legal challenges and Congressional actions to repeal and replace provisions of the law and litigation and legislation over the ACA is likely to continue with unpredictable and uncertain results. For example, with enactment of the Tax Cuts and Jobs Act of 2017, or the 2017 Tax Act, Congress repealed the "individual mandate." The repeal of this provision, which required most Americans to carry a minimal level of health insurance, became effective in 2019. In June 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Shortly after taking office in January 2025, President Trump revoked numerous executive orders issued by President Biden, including at least two executive orders which where were designed to further implement the ACA. We anticipate similar efforts to undermine the ACA, and the accompanying uncertainty, for the foreseeable future.

Further, the recent election of President Trump, coupled with a consolidation of party control of both chambers of the U.S. Congress, has led to new legislative and regulatory initiatives in the United States and the roll-back of many initiatives of the previous presidential administration, which may impact our business in unpredictable ways. Market uncertainty and volatility have been magnified and may intensify due to the statements and actions of the new U.S. presidential administration and resulting uncertainties regarding actual and potential shifts in U.S. and foreign, trade, economic and other policies, including with respect to treaties and tariffs.

Current and future legislation designed to reduce prescription drug costs may affect the prices we and any collaborators may obtain for our product candidates.

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid.

In October 2020, Health Insurance Portability and Accountability Act of 1996, or HHS, and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program to import certain prescription drugs from Canada into the United States. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America, or PhRMA, but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. A few states have passed legislation establishing workgroups to examine the impact of a state importation program. Several states have passed laws allowing for the importation of drugs from Canada. Certain states have submitted Section 804 Importation Program proposals and are awaiting FDA approval. On January 5, 2024, the FDA approved Florida's plan for Canadian drug importation. Florida now has authority to import certain drugs from Canada for a period of two years once certain conditions are met. Florida will first need to submit a pre-import request for each drug selected for importation, which must be approved by the FDA. Florida will also need to relabel the drugs and perform quality testing of the products to meet FDA standards. On May 21, 2025, the FDA announced that it would offer individual states the opportunity to submit a draft proposal for pre-review and meet with the agency to obtain initial feedback from FDA prior to formally submitting their section 804 importation program (SIP) proposal. The intent of these meetings is to assist states in developing their proposals by further clarifying requirements, enhancing the quality of proposals submitted to the agency and ultimately shortening the review timeline.

Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. The Inflation Reduction Act of 2022, or IRA, further delayed implementation of this rule to January 1, 2032.

The IRA has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. The IRA also, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. Further, 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 through a newly established manufacturer discount program. It is unclear how any additional challenges or future healthcare reform measures will impact the ACA.

Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare beginning in 2026, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation and replaces the Part D coverage gap discount program with a new discounting program beginning in 2025. The IRA permits the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028 and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. With passage of the One Big Beautiful Bill Act ("OBBBA") on July 3, 2025, which was signed into law by the President on July 4, 2025, Congress expanded the exemption from this provision to drugs and

biologics with multiple orphan drug designations. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would be at risk of government action if our products are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, these provisions of the IRA may also further heighten the risk that we would not be able to achieve the expected return on our products or full value of our patents protecting our products if prices are set after such products have been on the market for nine years. On August 15, 2024, HHS published the results of the first Medicare drug price negotiations for ten selected drugs that treat a range of conditions, including diabetes, chronic kidney disease, and rheumatoid arthritis. The prices of these ten drugs became effective January 1, 2026. On January 17, 2025, CMS announced its selection of 15 additional drugs covered by Part D for the second cycle of negotiations. CMS issued a public statement on January 29, 2025, declaring that lowering the cost of prescription drugs is a top priority of the new administration and CMS is committed to considering opportunities to bring greater transparency in the negotiation program. The second cycle of negotiations with participating drug companies were announced in March 2025, and any negotiated prices for this second set of drugs will be effective starting January 1, 2027.

Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The law also caps Medicare out-of-pocket drug costs at an estimated $2,000 a year beginning in 2025. In addition to the drug price negotiation program, the IRA established inflation rebate programs under Medicare Part B and Part D. These programs require manufacturers to pay rebates to Medicare if they raise their prices for certain Part B and Part D drugs faster than the rate of inflation. On December 9, 2024, with the issuance of its 2025 Physician Fee Schedule final regulation, CMS finalized its rules governing the IRA inflation rebate programs.

Accordingly, while it is currently unclear how the IRA will be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition. For example, based on current guidance from CMS concerning the application of the IRA's drug pricing provisions to orphan drugs, we may be eligible for reduced reimbursement if and when, if ever, KPI-012 is approved as an orphan drug for PCED and a different rare disease or condition.

On June 6, 2023, Merck & Co. filed a lawsuit against HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, other parties, including the U.S. Chamber of Commerce and certain pharmaceutical companies have also filed lawsuits in various courts with similar constitutional claims against HHS and CMS. There have been various decisions by the courts considering these cases since they were filed. HHS has generally won the substantive disputes in these cases or succeeded in getting claims dismissed for lack of standing. Most of these cases are now on appeal. On October 30, 2024, the U.S. Court of Appeals for the Third Circuit heard oral argument in three of these cases. In April 2025, the U.S. Court of Appeals for the Second Circuit and the U.S. Court of Appeals for the Third Circuit heard argument in an additional three cases. On May 8, 2025, the Third Circuit rejected AstraZeneca's challenge to the Medicare price negotiation program, finding that the program did not violate the company's due process rights under the constitution since there is no protected property interest in selling goods to Medicare beneficiaries at a price higher than what the government is willing to pay in reimbursement. We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results.

Further, in December 2023, NIST released for public comment the Draft Framework. The Draft Framework sets forth the factors that an agency may consider when deciding whether to exercise march-in rights pursuant to Bayh-Dole, and includes a first-ever specification that price can be a factor in determining that a drug or other taxpayer-funded invention is not accessible to the public. NIST is currently seeking public comments on the proposed Draft Framework. The potential inclusion of price as a factor in a march-in determination and the exercise of "march-in" rights by the federal government could result in decreased demand for our future products, which could have a material adverse effect on our results of operations and financial condition. In addition, any failure to comply with applicable laws or regulations could harm our business and divert our management's attention.

Trump's current administration has also taken several measures focusing on healthcare and drug pricing and access in particular. For example, President Trump has signed multiple executive orders addressing drug pricing including: on April 15, 2025, outlining several actions the Secretary of the Department of HHS must take to optimize healthcare regulations that will provide access to prescription drugs at lower costs; on May 5, 2025, aiming to promote domestic production of critical medicines; and on May 12, 2025, aiming to establish a most-favored-nation ("MFN") drug pricing policy that would tie U.S. drug prices to the prices paid for drugs in other countries. On November 6, 2025, CMS announced a new voluntary payment initiative called the GENEROUS Model (GENErating cost Reductions for U.S. Medicaid Model) where drug manufacturers may voluntarily offer supplemental rebates to participating state Medicaid programs that are intended to provide such Medicaid programs with a MFN price for participating manufacturers' products. On December 23, 2025, CMS published two proposed rules that would incorporate MFN pricing principles into federal reimbursement for prescription drugs. The first proposal, the GLOBE Model (Global Benchmark for Efficient Drug Pricing Model) for Medicare Part B, would require manufacturers of specified single source drugs and sole source biologics to pay incremental rebates based on international benchmark prices, with participation triggered for products meeting CMS's spending and eligibility criteria. The second proposal, the GUARD Model (Guarding U.S. Medicare Against Rising Drug Costs) for Medicare Part D, would similarly mandate manufacturer rebates for qualifying sole source drugs where the Medicare net price exceeds an MFN benchmark derived from international reference pricing methodologies. On January 15, President Trump called upon Congress to enact " The Great Healthcare Plan," to codify lower drug pricing, lower insurance premiums, and increase healthcare price transparency, among other things. On February 5, 2026, the Trump administration launched the TrumpRx platform designed to allow consumers to purchase certain drugs at reduced prices as negotiated between the drug manufacturers and the Trump administration. At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. This is increasingly true with respect to products approved pursuant to the accelerated approval pathway. State Medicaid programs and other payers are developing strategies and implementing significant coverage barriers, or refusing to cover these products outright, arguing that accelerated approval drugs have insufficient or limited evidence despite meeting the FDA's standards for accelerated approval. This may be especially true with respect to products approved pursuant to the accelerated approval pathway. State Medicaid programs and other payers are developing strategies and implementing significant coverage barriers, or refusing to cover these products outright, arguing that accelerated approval drugs have insufficient or limited evidence despite meeting the FDA's standards for accelerated approval.

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory, and policy changes and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Further, while the FDA's review of BLAs and other applications is funded through the user fee program established under PDUFA, the Trump Administration has indicated that it will be reviewing that program and its implementation.

Disruptions at the FDA, EMA and other agencies may also slow the time necessary for new drugs or biologics to be reviewed or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC had to furlough critical employees and stop critical activities.

In addition, disruptions may result from events similar to the COVID-19 pandemic. During the COVID-19 pandemic, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. In the event of a similar public health emergency in the future, the FDA may not be able to continue its current pace and review timelines could be extended. Regulatory authorities outside the United States facing similar circumstances may adopt similar restrictions or other policy measures in response to a similar public health emergency and may also experience delays in their regulatory activities.

Further, there is substantial uncertainty as to how measures being implemented by the new Trump Administration across the government will impact the FDA, CMS and other federal agencies with jurisdiction over our activities. For example, since taking office, President Trump has issued a number of executive orders, which could have a significant impact on the manner in which the FDA conducts its operations and engages in regulatory and oversight activities. If these or other orders or executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. For example, the potential loss of FDA personnel could lead to further disruptions and delays in FDA review of our product candidates. Similarly, efforts by the new administration to substantially reduce or delay research funding by the National Institutes of Health of medical research could have substantial direct or indirect impacts on our research activities.

If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

If we or any third-party manufacturers we engage or may engage in the future fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur significant costs.

We and any third-party manufacturers we engage or may engage in the future are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous materials, including chemicals and biological materials, and produce hazardous waste products. 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. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain general liability insurance as well as 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.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Further, with respect to the operations of any future third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates or products.

We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, be precluded from developing, manufacturing and selling certain products outside the United States or be required to develop and implement costly compliance programs, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act, or FCPA,

the U.K. Bribery Act 2010, or Bribery Act, and other anti-corruption laws that apply in countries where we do business and may do business in the future. The FCPA, Bribery Act and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Compliance with the FCPA, in particular, is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

We may in the future operate in jurisdictions that pose a high risk of potential FCPA or Bribery Act violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA, Bribery Act or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. If we expand our operations outside of the United States, we will need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA, the Bribery Act or other legal requirements, including Trade Control laws. If we are not in compliance with the FCPA, Bribery Act and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Any investigation of any potential violations of the FCPA, the Bribery Act, other anti-corruption laws or Trade Control laws by U.S., U.K. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

On February 10, 2025, President Trump issued an executive order directing the Attorney General to review the guidelines and policies governing FCPA investigations and enforcement actions. Per the executive order, this review will result in new DOJ FCPA guidelines intended to enhance American economic competitiveness and to safeguard national security interests. During the 180-day review period, any new FCPA investigations and enforcement actions are to be suspended absent authorization from the Attorney General, and all existing FCPA investigations and enforcement actions will be reviewed. Additionally, after the Attorney General issues revised guidelines, the executive order directs the Attorney General to assess whether "remedial measures" related to past FCPA actions are warranted. We will need to carefully monitor the implementation of this order.

We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies, contractual obligations and failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally-identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the U.S., EU and U.K. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. These obligations may be applicable to some or all of our business activities now or in the future. In recent months, the Office of Civil Rights at HHS, or OCR, has been especially active in enforcing the HIPAA rules. Additionally, OCR is looking to amend the HIPAA Security Rule, which (if and when finalized) could create additional compliance obligations and risk for our business.

If we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

In addition to potential enforcement by HHS, we are also potentially subject to privacy enforcement from the Federal Trade Commission, or the FTC. The FTC has been particularly focused on the unpermitted processing of health and genetic data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be "unfair" under Section 5 of the Federal Trade Commission Act, as well as the types of activities it views to trigger the Health Breach Notification Rule, which the FTC also has the authority to enforce. The FTC is also in the process of developing rules related to commercial surveillance and data security that may impact our business. We will need to account for the FTC's evolving rules and guidance for proper privacy and data security practices in order to mitigate our risk for a potential enforcement action, which may be costly. If we are subject to a potential FTC enforcement action, we may be subject to a settlement order that requires us to adhere to very specific privacy and data security practices, which may impact our business. We may also be required to pay fines as part of a settlement, depending on the nature of the alleged violations. If we violate any consent order that we reach with the FTC, we may be subject to additional fines and compliance requirements. Finally, both the FTC and HHS's enforcement priorities (as well as those of other federal regulators) may be impacted by the change in administration and new leadership. These shifts in enforcement priorities may also impact our business.

There are also increased restrictions at the federal level relating to transferring sensitive data outside of the United States to certain foreign countries. For example, in 2024, Congress passed H.B. 815, which included the Protecting Americans' Data from Foreign Adversaries Act of 2024. This law creates certain restrictions for entities that disclose sensitive data (including potential health data) to countries such as China. Failure to comply with these rules can lead to a potential FTC enforcement action. Additionally, the DOJ recently finalized a rule implementing Executive

Order 14117, which creates similar restrictions related to the transfer of sensitive U.S. data to countries such as China. These data transfer restrictions (and others that may pass in the future) may create operational challenges and legal risks for our business.

States are also active in creating specific rules relating to the processing of personal information. In 2018, California passed into law the California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020 and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA's requirements are similar to those found in the General Data Protection Regulation, or GDPR, described below, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of "sales" of their personal information. The CCPA contains significant penalties for companies that violate its requirements. The California Privacy Rights Act, or the CPRA, went into effect on January 1, 2023 and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created a new enforcement agency – the California Privacy Protection Agency – whose sole responsibility is to enforce the CPRA, and other California privacy laws, which will further increase compliance risk. The provisions in the CPRA may apply to some of our business activities.

In addition to California, a number of other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime over the next few years. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data, which includes health data in some cases. Some of the provisions of these laws may apply to our business activities. There are also states that are strongly considering or have already passed comprehensive privacy laws during the 2025 legislative sessions. Other states will be considering these laws in the future, and Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, Washington state passed a health privacy law in 2023 which regulates the collection and sharing of health information that is not otherwise regulated by HIPAA rules, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data, and more states are considering such legislation in 2025. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products, if approved.

Plaintiffs' lawyers in the United States are also increasingly using privacy-related statutes at both the state and federal level to bring lawsuits against companies for their data-related practices. In particular, there have been a significant number of cases filed against companies for their use of pixels and other web trackers. These cases often allege violations of the California Invasion of Privacy Act and other state laws regulating wiretapping, as well as the federal Video Privacy Protection Act. The rise in these types of lawsuits creates potential risk for our business.

Additionally, laws in all 50 states require businesses to provide notice to customers whose personal information has been disclosed as a result of a data breach. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. Moreover, states have been frequently amending existing laws, requiring attention to changing regulatory requirements. We also may be contractually required to notify affected individuals or other counterparties of a security breach, incident, or compromise. Although we may have contractual protections with our vendors, any actual or perceived security breach, incident, or compromise could harm our reputation and brand, expose us to potential liability or require us to expend significant resources on data security and in responding to any such actual or perceived breach, incident, or compromise. Any contractual protections we may have from our vendors may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections. In addition to government regulation, privacy advocates and industry groups have and may in the future propose self-regulatory standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply.

Similar to the laws in the United States, there are significant privacy and data security laws that apply in Europe, Latin America and other countries. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the European Economic Area, or EEA, and the

processing of personal data that takes place in the EEA, is regulated by the GDPR, which imposes obligations on companies that operate in our industry with respect to the processing of personal data and the cross-border transfer of such data. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If our or our service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill.

The GDPR places restrictions on the cross-border transfer of personal data from the European Union to countries that have not been found to offer adequate data protection legislation, such as the United States. There are ongoing concerns about the ability of companies to transfer personal data from the European Union to other countries. In July 2020, the Court of Justice of the European Union, or CJEU, invalidated the EU-U.S. Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEU decision has resulted in increased scrutiny on data transfers generally and may increase our costs of compliance with data privacy legislation as well as our costs of negotiating appropriate privacy and security agreements with our vendors and business partners.

Additionally, in October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which serves as a replacement to the EU-U.S. Privacy Shield. The European Commission adopted the adequacy decision in July 2023. The adequacy decision permits U.S. companies who self-certify to the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the European Union to the United States. However, some privacy advocacy groups have already suggested that they will be challenging the EU-U.S. Data Privacy Framework. If these challenges are successful, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and other data transfer mechanisms. The uncertainty around this issue has the potential to impact our business.

Beyond GDPR and similar laws in the United States, there are privacy and data security laws in a growing number of countries around the world, including countries in Latin America where we have initiated several clinical trial sites in the CHASE Phase 2b clinical trial. While many loosely follow GDPR as a model, other laws contain different or conflicting provisions. These laws may impact our ability to conduct our business activities.

While we continue to address the implications of the recent changes to data privacy regulations, data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the EEA and elsewhere and carries with it the potential for significant penalties if we are found to be non-compliant. Similarly, failure to comply with federal and state laws in the United States regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government-imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects.

We might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards.

As of December 31, 2025, we had federal net operating loss, or NOL, carryforwards of $405.5 million, which may be available to offset future federal tax liabilities and expire at various dates beginning in 2030. As of December 31, 2025, we also had state NOL carryforwards of $469.1 million, which may be available to offset future state income tax liabilities and expire at various dates beginning in 2025. As of December 31, 2025, we had $5.1 million federal and state research and development credit carryforwards. Our NOL carryforwards could expire unused and be unavailable to offset our future income tax liabilities.

In general, under Sections 382 and 383 of the Code, the amount of benefits from our NOL and research and development tax credit carryforwards, respectively, may be impaired or limited if we incur an "ownership change," generally defined as a greater than 50% change (by value) in our equity ownership by certain stockholders, over a three-year period. We previously completed an analysis and determined that an ownership change has materially limited our net operating loss carryforwards and research and development tax credits available to offset future tax liabilities. During December 2022, an additional ownership change occurred as a result of our entry into the securities purchase agreement for the private placement transaction. As a result of this ownership change, the utilization of our net operating loss carryforwards is subject to an annual limitation of $0.2 million. We may be further limited by any changes that may have occurred or may occur subsequent to December 31, 2022. Any such limitations may result in greater tax liabilities than we would incur in the absence of such limitations and increased liabilities could adversely affect our business, results of operations, financial position and cash flows. If our ability to use our historical NOL and research and development tax credit carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs and research and development tax credit carryforwards could expire or otherwise become unavailable to offset future income tax liabilities. As described below in "Changes in tax laws or in their implementation or interpretation could adversely affect our business and financial condition," the 2017 Tax Act, as amended by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, includes changes to U.S. federal tax rates and the rules governing NOL carryforwards that have significantly impacted our ability to utilize our NOLs to offset taxable income in the future. In addition, state NOLs generated in one state cannot be used to offset income generated in another state. For these reasons, even if we attain profitability, we will likely be unable to use a material portion of our NOLs and other tax attributes.

Risks Related to Employee Matters

We have recently undertaken a cost reduction plan and may do so again in the future. The assumptions underlying these activities may prove to be inaccurate, or we may fail to achieve the expected benefits therefrom.

As part of our strategic positioning to reduce costs, we have reduced our workforce such that as of the date of this Annual Report, we only have 3 full-time employees. This reduction in force, and any other future reductions, and the attrition that may occur following them, result in the loss of institutional knowledge and expertise and the reallocation and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations. These actions and other additional measures we might take to reduce costs could strain our workforce, divert management attention, yield attrition beyond our intended reduction in force, reduce employee morale, cause us to delay, limit, reduce or eliminate certain development plans or otherwise interfere with our ability to operate and grow our business effectively, each of which could have an adverse impact on our business, operating results and financial condition. We may not complete the current or any cost reduction plan and reorganization on the anticipated timetable, and even if successfully completed, we may not achieve the anticipated cost savings, operating efficiencies or other benefits of such activities.

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

We are highly dependent on the research and development, clinical, business development and commercialization expertise of Avi Minkowitz, our Chief Executive Officer and Chief Financial Officer, as well as the other principal members of our teams. We do not maintain "key person" insurance for any of our executives or other employees.

The success of our Researgency business depends in part on our ability to attract and retain personnel with expertise in artificial intelligence, machine learning, software engineering, and biotechnology. There can be no assurance that we will be able to build and sustain a sufficient engineering team at costs consistent with our current estimates or operational budget. The market for skilled software engineers and data scientists with expertise in artificial intelligence is highly competitive, and we expect such competition to intensify as the demand for AI talent continues to grow across industries. Such individuals are in high demand and may be difficult to attract given our early stage of development, limited financial resources, and the competitive market for AI talent. Engineers and other technical personnel hired or contracted by us may be recruited by competitors or other companies that are able to offer more competitive compensation, equity incentives, or other benefits. The loss of key engineering or technical staff could disrupt our ongoing development efforts, delay product enhancements and platform improvements, and result in increased expenses related to recruitment, onboarding, and training of replacement personnel. Our biologics asset monetization strategy also depends on our ability to retain personnel and consultants with deep expertise in clinical development, regulatory affairs, and pharmaceutical business development. If we are unable to attract and retain key individuals across both of our business lines, our ability to execute on our business strategy could be materially impaired.

Recruiting and retaining qualified scientific, clinical, manufacturing, accounting, legal and other personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Our decision to cease active clinical development of KPI-012 and our MSC-S platform, combined with the significant workforce reductions we implemented in September and October 2025, could harm our ability to attract and retain qualified personnel who are critical to our business. In addition, we rely on consultants and advisors, including scientific, clinical and regulatory advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to successfully develop our business and commercialize product candidate we may develop in the future will be harmed.

We implemented significant reductions in our workforce in September 2025 (approximately 51% reduction) and October 2025 (termination of substantially all remaining employees) following the failure of the CHASE trial and the default under our Loan Agreement with Oxford Finance. These workforce reductions have resulted in the loss of significant institutional knowledge and clinical expertise. Our ability to attract and retain new employees and consultants is also adversely affected by the uncertainty surrounding our business strategy and the stage of development of our AI platform business. Qualified personnel in the AI and biotechnology fields typically have multiple employment options available to them and may be reluctant to join a company with our level of development-stage uncertainty and limited financial resources. As of the date of this Annual Report, we only have 3 full-time employees.

A partially or fully remote workplace could negatively impact our business.

Although we have a nominal amount of office space on a short-term basis to conduct in-person meetings from time-to-time in Arlington, Massachusetts and lease office and laboratory space in Menlo Park, California, the vast majority of our employees no longer have individual offices. As a result, our management team and the vast majority of our employees will work remotely and without dedicated office space, until such time as we determine to obtain a new operating lease. Our employees are accessing our servers remotely through home or other networks to perform their job

responsibilities, which may be less secure. The risk of cyber incidents or other privacy or data security incidents may be heightened as a result of our remote work environment. Remote working arrangements could also impact employee productivity and morale, impede employee training, strain our technology resources and introduce operational risks, all of which could negatively impact our business. We have limited ability to control the amount or timing of resources that any such third party will devote to our research and development activities, and such third parties may terminate their engagements with us at any time. We also expect to have to negotiate budgets and contracts with such third parties, and we may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs.

We are substantially dependent on our remaining employees and consultants, along with any other advisors and consultants we may engage, to facilitate pursuit of strategic options and additional financing.

Our ability to successfully identify and consummate any licensing, collaboration, or other strategic arrangements with respect to our biologics asset portfolio, to develop and commercialize our AI platform, and to obtain additional financing, if any, depends in large part on our ability to retain our remaining employees and consultants along with any other advisors and consultants we may engage. One or more may terminate their engagement with us on short notice. The loss of the services of any of these individuals could potentially harm our ability to identify, evaluate and pursue our strategic objectives and to identify and obtain potential additional financing.

Risks Related to Evaluation of Strategic Options and Bankruptcy Proceedings

Our pursuit of strategic options with respect to our biologics asset portfolio and the development of our AI platform business may not be successful, and there can be no assurance that either strategy will generate value for our stockholders.

We are currently pursuing a dual-track business strategy consisting of (i) the preservation and monetization of our MSC-S biologics asset portfolio through licensing, collaboration, sale, or other strategic arrangements, and (ii) the development and commercialization of our AI platform business through our exclusive license for the Researgency agentic AI research platform. There can be no assurance that either of these strategies will be successful. With respect to our biologics assets, the market for licensing or acquiring assets based on a product candidate that failed in a Phase 2b clinical trial is challenging, and we may be unable to identify a willing purchaser or licensee on acceptable terms. With respect to our AI platform business, we are at an early stage of development and have not yet generated revenue or established a customer base. The simultaneous pursuit of both strategies requires management attention and financial resources that are both limited, and the failure of either strategy could materially harm our business and financial condition.

Our board of directors may elect to commence bankruptcy or insolvency proceedings.

Our board of directors may decide that it is in the best interests of our stockholders to commence bankruptcy proceedings. It may be necessary for us to pursue bankruptcy proceedings under Chapter 7 of the United States Bankruptcy Code. In such event, a Chapter 7 trustee would be appointed or elected to liquidate our assets for distribution in accordance with the priorities established by the United States Bankruptcy Code. It is unlikely that there will be cash available for distribution to stockholders in connection with a bankruptcy proceeding. Accordingly, holders of our Common Stock and other securities could lose all or a significant portion of their investment in the company.

We may become involved in securities class action litigation that could divert management's attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities class action litigation has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as clinical trial results. These events may also result in investigations by the SEC. We may be exposed to such litigation or investigation even if no wrongdoing occurred. Litigation and investigations are usually expensive and divert management's attention and resources, which could adversely affect any of our remaining cash resources and our ability to consummate a potential strategic option or identify additional funding.

Risks Related to Our Common Stock

If we fail to comply with the continued listing requirements of the Nasdaq Capital Market, our Common Stock may be delisted and the price of our Common Stock and our ability to access the capital markets could be negatively impacted.

Our Common Stock is currently listed on Nasdaq. We must satisfy Nasdaq's continued listing requirements, including, among other things, a minimum closing bid price of $1.00 per share and either a minimum stockholders' equity of $2,500,000, or a minimum market value of our Common Stock of at least $35,000,000, or risk delisting, which would have a material adverse effect on our business. On November 10, 2025, we received a letter from the Staff of the Nasdaq Stock Market LLC notifying us that we were not in compliance with Nasdaq Listing Rule 5550(b)(2), the Minimum Market Value of Listed Securities (MVLS) Requirement, for continued listing on Nasdaq, as the market value of our listed securities was less than $35,000,000 for the previous 30 consecutive business days. We have been provided a period of 180 calendar days, or until May 11, 2026, to regain compliance with the Minimum MVLS Requirement. We also do not currently meet the alternative standards for continued listing on Nasdaq, as we do not have stockholders' equity of at least $2.5 million or net income from continued operations of at least $500,000 in the most recently completed fiscal year or for two of the three most recently completed fiscal years. If we are unable to demonstrate compliance with the Minimum MVLS Requirement or an alternative listing standard by May 11, 2026, Nasdaq may initiate delisting proceedings. We cannot assure you that we will be able to regain or maintain compliance with Nasdaq's continued listing requirements. While we have not received a formal notice from Nasdaq, we believe that as of the date of this Form 10-K, we meet the Minimum MVLS Requirement and the requirement to have stockholders' equity of at least $2.5 million. We intend to inform Nasdaq prior to May 11, 2026, of such compliance.

We are currently taking steps to regain compliance with Nasdaq's continued listing requirements, including the pursuit of our AI platform business strategy and related financing activities, which we believe are designed in part to increase our market capitalization. However, there can be no assurance that these actions will result in our Common Stock meeting the Minimum MVLS Requirement or any alternative listing standard within the required cure period. A delisting of our Common Stock from Nasdaq could materially reduce the liquidity of our Common Stock , impair our ability to raise additional capital, and adversely affect the market price of our Common Stock. In addition, any delisting of our Common Stock from Nasdaq or a transfer of our listing to an exchange with less restrictive listing standards, in each case after a specified cure period, may constitute an event of default under certain of our existing indebtedness.

Additionally, on January 20, 2026, we received a letter from the Listing Qualifications Department of the Nasdaq Stock Market indicating that, based upon the closing bid price of our Common Stock for the 30 consecutive business days between December 3, 2025, to January 16, 2026, we did not meet the minimum bid price of $1.00 per share required for continued listing on Nasdaq pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). The letter also indicated that the Company will be provided with a compliance period of 180 calendar days, or until July 20, 2026 (the "Bid Price Compliance Period"), in which to regain compliance pursuant to Nasdaq Listing Rule 5810(c)(3)(A).

In order to regain compliance with the Minimum Bid Price Requirement, our Common Stock must maintain a minimum closing bid price of $1.00 for at least ten consecutive business days during the Bid Price Compliance Period. In the event the Company does not regain compliance by the end of the Bid Price Compliance Period, we may be eligible for additional time to regain compliance. To qualify, we will be required to meet the continued listing requirement for the market value of its publicly held shares and all other initial listing standards for Nasdaq, with the exception of the bid price requirement, and will need to provide written notice of its intention to cure the deficiency during the second compliance period, by effecting a reverse stock split if necessary. If we met these requirements, we may be granted an additional 180 calendar days to regain compliance. However, if it appears to Nasdaq that we will be unable to cure the deficiency, or if we are not otherwise eligible for the additional cure period, Nasdaq will provide notice that our Common Stock will be subject to delisting. There can be no assurance that we will be eligible for the additional 180 calendar day compliance period, if applicable, or that the Nasdaq staff would grant our request for continued listing subsequent to any delisting notification. In the event of such a notification, we may appeal the Nasdaq staff's determination to delist its securities.

A delisting of our Common Stock from Nasdaq could materially reduce the liquidity of our Common Stock and result in a corresponding material reduction in the price of our Common Stock. In addition, delisting could harm our ability to pursue a strategic option and raise capital through alternative financing sources on terms acceptable to us, or at

all. In addition, any potential delisting of our Common Stock from Nasdaq would also make it more difficult for our stockholders to sell their shares in the public market. Moreover, any delisting of our Common Stock from Nasdaq or a transfer of the listing of our Common Stock to another nationally recognized stock exchange having listing standards that are less restrictive than Nasdaq, in each case after a specified cure period, are additional events of default under certain of our indebtedness.

We intend to monitor the market value of our Common Stock and may, if appropriate, consider available options to regain compliance with the Minimum MVLS Requirement and the Minimum Bid Price Requirement. However, there can be no assurance that we will be able to regain compliance with Nasdaq's continued listing requirements or that we will maintain compliance with the other Nasdaq markets listing requirements.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our Restated Certificate of Incorporation, as amended ("Certificate of Incorporation"), and the Third Amended and Restated By-Laws, as amended ("Bylaws") may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock , thereby depressing the market price of our Common Stock. In addition, because our Board is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- provide for a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- provide for advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three-years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

An active trading market for our Common Stock may not be sustained.

From July 20, 2017 through January 10, 2023, our Common Stock traded on The Nasdaq Global Select Market. On January 11, 2023, our Common Stock began trading on The Nasdaq Capital Market. Given the limited trading history of our Common Stock , there is a risk that an active trading market for our shares will not be sustained, which could put downward pressure on the market price for our Common Stock and thereby affect your ability to sell your shares. An inactive trading market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

The price of our Common Stock is volatile and fluctuates substantially, which could result in substantial losses for purchasers of our Common Stock.

Our stock price is volatile and fluctuates substantially. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your Common Stock at or above the price you paid for such Common Stock. The market price for our Common Stock may be influenced by many factors, including:

- our ability to receive marketing approval for and to successfully commercialize any product candidate we may develop;
- results of clinical trials of product candidates of our competitors;
- whether we receive, and the amount of, any future milestone payments from Alcon in connection with the sale of our Commercial Business;
- changes in the structure of healthcare payment systems;
- the success of competitive products or technologies;
- 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 scientific, commercial or management personnel;
- the level of expenses related to any product candidate we may develop;
- the results of our efforts to discover, develop, acquire or in-license additional products, product candidates or technologies for the treatment of diseases or conditions, the costs of commercializing any such products and the costs of development of any such product candidates or technologies;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- sales of Common Stock by us, our executive officers, directors or principal stockholders, or others, or the anticipation of such sales;
- the concentration of our stock ownership;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions;
- political instability in the United States and Europe, including as a result of Congress failing to timely raise the U.S. debt ceiling; or
- the other factors described in this “Risk Factors” section.

In the past, following periods of volatility in the market price of a company’s securities, securities class-action litigation has often been instituted against that company. We also may face securities class-action litigation if we cannot obtain regulatory approval for or fail to successfully commercialize future product candidate we develop. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management’s attention and resources.

Sales of a substantial number of shares of our Common Stock could cause the market price of our Common Stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our Common Stock , or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our Common Stock. As of April 10, 2026, we had outstanding 929,491,578 shares of Common Stock.

Shares of our Common Stock may be freely sold in the public market at any time to the extent permitted by Rules 144 and 701 under the Securities Act of 1933, as amended, or the Securities Act, or to the extent such shares have already been registered under the Securities Act and are held by non-affiliates of ours. If our stockholders sell, or indicate an intention to sell, substantial amounts of our Common Stock in the public market, the trading price of our Common Stock could decline. In addition, we have filed or intend to file registration statements registering all shares of Common Stock that we may issue under our equity compensation plans or pursuant to equity awards made to newly hired employees outside of equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

In 2022, 2023, 2024, 2025 and 2026, we sold to certain investors shares of our Common Stock and/or shares of our preferred stock in private placements. We have filed registration statements on Form S-3 covering the resale of such shares of Common Stock and the Common Stock issuable upon conversion of the preferred stock issued in the private placements, and we have agreed to keep each such registration statement effective until the date the shares covered by it have been sold or can be resold without restriction under Rule 144 of the Securities Act. As of March 31, 2026, all of our shares of preferred stock were converted to Common Stock, except for our Series AA Preferred Stock, of which 681,818 shares are outstanding.

The sale or resale of these shares in the public market, or the market's expectation of such sales, may result in an immediate and substantial decline in our stock price. Such a decline would adversely affect our investors and also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

Certain existing stockholders will experience dilution upon any future conversion of the outstanding shares of our preferred stock into shares of our Common Stock.

Each outstanding share of Series AA Preferred Stock is convertible into 55 shares of our Common Stock. Certain existing stockholders will experience dilution upon any future conversion of the outstanding shares of our preferred stock into shares of our Common Stock.

We are a "smaller reporting company", and the reduced disclosure requirements applicable to smaller reporting companies may make our Common Stock less attractive to investors.

We are a "smaller reporting company," as defined in Rule 12b-2 under the Exchange Act. We would cease to be a smaller reporting company if we have a public float in excess of $250 million or have annual revenues in excess of $100 million and a public float in excess of $700 million, determined on an annual basis.

As a smaller reporting company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not smaller reporting companies. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- reduced disclosure obligations regarding executive compensation;
- being permitted to provide only two years of audited financial statements in our annual report on Form 10-K, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure; and
- not being required to furnish a stock performance graph in our annual report.

We cannot predict whether investors will find our Common Stock less attractive as a result of our reliance on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile.

We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives and corporate governance practices.

As a public company, and particularly since we ceased being an "emerging growth company", we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Capital Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and these costs are disproportionately burdensome for a company of our current size and stage of development and will make some activities more time-consuming and costly. For as long as we remain a smaller reporting company, we may take advantage of certain exemptions from various reporting requirements.

For as long as we remain a smaller reporting company, we may take advantage of certain exemptions from various reporting requirements as described in the preceding risk factor.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain a non-accelerated filer and a smaller reporting company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our Common Stock will be sole source of gain for our stockholders for the foreseeable future.

Our Certificate of Incorporation designates the state courts in the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against the company and our directors, officers and employees.

Our Certificate of Incorporation, provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or employees to our company or our stockholders, any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our Certificate of Incorporation or Bylaws or as to which the General Corporation Law of the State of Delaware confers jurisdiction on the Court of Chancery of the State of Delaware, or any action asserting a claim against us governed by the internal affairs doctrine. We do not expect this choice of forum provision will apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act, or any other claim for which federal courts have exclusive jurisdiction.

This exclusive forum provision may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur

additional costs associated with resolving such action in other jurisdictions, which could materially adversely affect our business, financial condition and operating results.

General Risk Factors

Our internal computer systems, or those of our vendors, contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Despite the implementation of security measures, our information technology systems and those of our current and any future vendors, contractors or consultants, including any collaborator, are vulnerable to damage from cyber-attacks, computer viruses, worms and other destructive or disruptive software, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Cyber incidents or attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, unauthorized access to or deletion of files, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Cyber incidents also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient. System failures, accidents, cyberattacks or security breaches could cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential, personal or proprietary information, we could incur liability, including civil fines and penalties under the GDPR, HIPAA and other relevant state and federal privacy laws in the United States and abroad, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. In addition, we may not have adequate insurance coverage to provide compensation for any losses associated with such events.

While we have not experienced any material losses relating to cyber-attacks, we have been the subject of a successful phishing attempt. We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company, including personal information of our employees. In addition, outside parties may attempt to penetrate our systems or those of our vendors, contractors or consultants or fraudulently induce our employees or employees of our vendors, contractors or consultants to disclose sensitive information in order to gain access to our data. Like other companies, we may experience threats to our data and systems, including malicious codes and viruses, and other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our security or that of our vendors, contractors or consultants occurs, the market perception of the effectiveness of our security measures could be harmed, we could lose business and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become more sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely.

Cybersecurity risks are heightened for our AI platform business, which is designed to be deployed within customer IT environments and may process sensitive biological and clinical data.

In addition to the general cybersecurity risks above, our AI platform business presents additional and more acute cybersecurity risks because the platform is specifically designed to be deployed within the IT environments of our biotechnology and pharmaceutical customers and to process their proprietary biological data and clinical trial datasets. Any vulnerability in our platform software, or any breach of security arising from our access to or integration with customer IT environments in connection with implementation, maintenance, or support services, could expose our customers' proprietary data to unauthorized access. Such a breach could result in significant liability to us, the termination of our customer agreements, reputational harm that could materially impair our ability to attract new customers, and regulatory investigations or penalties. The costs of investigating and remediating any such breach, as well as any resulting litigation, could be substantial. We cannot assure you that our cybersecurity measures will be

adequate to prevent breaches or unauthorized access, and the rapidly evolving nature of cybersecurity threats means that our defenses may become obsolete more quickly than we can adapt them.

Changes in tax laws or in their implementation or interpretation could adversely affect our business and financial condition.

Changes in tax law may adversely affect our business or financial condition. The 2017 Tax Act, subject to amendments made by the CARES Act, contained significant changes to corporate taxation, including a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21% and the limitation of the deduction for NOLs to 80% of current year taxable income for losses arising in taxable years beginning after December 31, 2017 (though any such NOLs may be carried forward indefinitely). In addition, applicable law currently and requires corporations to capitalize and amortize expenditures attributable to foreign research over 15 years.

In addition to the CARES Act, as part of Congress's response to the COVID-19 pandemic, economic relief legislation was enacted in 2020 and 2021 containing tax provisions. The IRA was also signed into law in August 2022. The IRA introduced new tax provisions, including a one percent excise tax imposed on certain stock repurchases by publicly traded companies. The one percent excise tax generally applies to any acquisition of stock by the publicly traded company (or certain of its affiliates) from a stockholder of the company in exchange for money or other property (other than stock of the company itself), subject to a de minimis exception. Thus, the excise tax could apply to certain transactions that are not traditional stock repurchases.

Regulatory guidance under the 2017 Tax Act, the IRA, and such additional legislation is and continues to be forthcoming, and such guidance could ultimately increase or lessen impact of these laws on our business and financial condition. In addition, various states may not conform entirely to the 2017 Tax Act, the IRA and such additional legislation.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

We have certain processes for assessing, identifying and managing cybersecurity risks, which are designed to help protect our information assets and operations from internal and external cyber threats, as well as secure our networks and systems. Such processes, which are implemented principally through an outside information technology management/cybersecurity consultant and a computer security firm that we have engaged, include procedural and technical safeguards, response plans, incident simulations and routine review of our policies and procedures to identify risks and refine our practices. Our computer security firm serves as our managed security services provider, and its services include managed detection and response, incident management, managed security awareness and a quarterly risk assessment. Our information technology management/cybersecurity consultant has responsibility for managing detection and incident response in consultation with our managed security services provider. We considered the internal risk oversight programs of our information technology management/cybersecurity consultant and our managed security services provider before engaging them. As part of our overall risk mitigation strategy, we also maintain cyber insurance coverage; however, such insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks and other related breaches.

While we have not experienced any material losses relating to cyber-attacks, in 2019 we were the subject of a successful phishing attempt. We do not believe that there are currently any known risks from cybersecurity threats that are reasonably likely to materially affect us or our business strategy, results of operations or financial condition.

The Audit Committee of our Board, provides direct oversight over cybersecurity risk. Our Audit Committee and Board of Directors receive periodic updates from our Chief Business Officer together with our outside information technology management/cybersecurity consultant, and the Audit Committee and Board of Directors is notified between such updates regarding significant new cybersecurity threats or incidents.

Our Chief Business Officer is responsible for the management oversight of company-wide cybersecurity strategy, policy, standards and processes and works across relevant departments to assess and help prepare us to address cybersecurity risks. Our Chief Business Officer has many years of experience overseeing company-wide legal and compliance risks. Our Chief Business Officer is supported by our outside information technology management/cybersecurity consultant and our managed security services provider.

We have also established a cross-functional Cybersecurity Committee led by our Chief Business Officer serving as the chair and consisting of senior leaders within our organization. The Cybersecurity Committee, with assistance from our outside information technology management/cybersecurity consultant, oversees our cybersecurity policy, which includes risk assessment, investments in cybersecurity technologies, cybersecurity insurance and review of relevant information technology policies.

In an effort to deter and detect cyber threats, we provide all employees, including part-time and temporary employees, with periodic cybersecurity training. This training program covers timely and relevant topics, including social engineering, phishing, password protection, confidential data protection, asset use and mobile security, and educates employees on the importance of reporting all cybersecurity incidents immediately. We also use technology-based tools to mitigate cybersecurity risks and to bolster our employee-based cybersecurity programs.

Avi Minkowitz, our Chief Executive Officer and Chief Financial Officer, is acting as our interim Chief Business Officer.

Item 2. Properties

We currently lease a limited amount of office space in Arlington, Massachusetts, which serves as our corporate headquarters since 2021. The lease is short term, with approximately $3,000 monthly rent, and is renewable every six months.

In April 2023, Combangio entered into a lease agreement with Menlo Prepi I, LLC, pursuant to which Combangio leased approximately 6,135 square feet of office, laboratory and research and development space in Menlo Park, California. The term of the lease commenced on July 1, 2023. The initial term of the lease was for 62 months, unless earlier terminated. The lease provided Combangio with an option to extend the lease for an additional five-year term. During the fourth quarter of 2025, the Company terminated the lease and signed, and paid, a settlement agreement to release the Company from all obligations.

Item 3. Legal Proceedings

We are not currently subject to any material legal proceedings.

Item 4. Mine Safety Disclosures

None.

Part II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer's Purchases of Equity Securities

Our Common Stock has been publicly traded on The Nasdaq Stock Market under the symbol "KALA" since July 20, 2017 in connection with our IPO. From July 20, 2017 through January 10, 2023 our Common Stock traded on The Nasdaq Global Select Market. Since January 11, 2023, our Common Stock has been trading on The Nasdaq Capital Market.

Holders

As of March 31, 2026, there were approximately 40 holders of record of our Common Stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividend Policy

We have not declared or paid any cash dividends on our Common Stock since our inception. We intend to retain all available funds and any future earnings to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination to declare and pay dividends will be made at the discretion of our board of directors and will depend on then-existing conditions, including our results of operations, financial condition, contractual restrictions, capital requirements, business prospects and other factors our Board may deem relevant.

Information About our Equity Compensation Plans

The information required by this item will be set forth in our Proxy Statement for our 2026 Annual Meeting of Stockholders (the "2026 Proxy Statement") under the caption "Equity Compensation Plans", and is incorporated herein by reference.

Recent Sales of Unregistered Securities

No unregistered securities were issued during the fiscal year ended December 31, 2025 that were not previously reported in a Quarterly Report on Form 10-Q or Current Report on Form 8-K

Repurchase of Equity Securities

We did not repurchase any of our equity securities during the fourth quarter of the fiscal year ended December 31, 2025.

Item 6. [Reserved]

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 financial statements and related notes thereto appearing at the end of this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements and Industry Data." Because of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biopharmaceutical company in transition, evaluating the development of a dedicated, on-premises artificial intelligence (AI) infrastructure platform for the biotechnology industry. Our current focus is leveraging our mesenchymal stem cell secretome platform to test development of a scalable AI platform-as-a-service business to deploy secure, purpose-built AI systems directly within biotech and pharmaceutical client environments. We have historically been engaged in the research, development and commercialization of innovative therapies for rare and severe diseases of the front and back of the eye. Our lead product candidate was KPI-012, a MSC-S, which we acquired from Combangio on November 15, 2021. KPI-012 was in clinical development for the treatment of PCED, a rare disease of impaired corneal healing. Based on the results of a Phase 1b clinical safety and efficacy trial of KPI-012 in patients with PCED, we submitted an investigational new drug application to the FDA, which was accepted in December 2022. In February 2023, we dosed our first patient in the United States in our CHASE trial. By September 2025, the CHASE trial did not meet its primary endpoints, and we determined to discontinue our development of KPI-012 and the MSC-S platform. We have since expanded upon our business to evaluate strategic alternatives for our legacy MSC-S assets and capitalize on the substantial intellectual property (IP), proprietary biological datasets, and research experience generated during the clinical trials by starting development of an AI platform.

We are in the process of evaluating and transitioning from historical biologics research and development (R&D) activities to an "AI platform-as-a-service" model intended to provide dedicated, on-premises artificial intelligence infrastructure solutions to biotechnology and pharmaceutical customers. Following the discontinuation of the CHASE Phase 2b clinical trial of KPI-012 in September 2025 and the subsequent resolution of our obligations to Oxford Finance, our current operating focus is (i) the monetization or out-licensing of remaining biologics-related assets and (ii) development and commercialization planning for our licensed Researgency AI platform. This transition is expected to impact our operating expenses, capital requirements, and sources and uses of cash as described further below.

We have refocused our business on two complementary strategic priorities. First, we are preserving and seeking to maximize the value of our MSC-S biologics asset portfolio, including the KPI-012 and KPI-014 product candidates and related intellectual property, through potential licensing, collaboration, and other strategic arrangements with third parties, as well as through evaluation of opportunities to resume preclinical development activities subject to the availability of additional capital. Second, we are building our Researgency business through our exclusive license for Researgency, which we intend to deploy as a dedicated, on-premises AI infrastructure solution for biotechnology and pharmaceutical companies. We believe this dual-track strategy preserves and creates optionality with respect to our biologics assets while simultaneously pursuing a potential business opportunity in the rapidly growing AI platform market for the biotechnology industry.

Since inception, we have incurred significant losses from operations and negative cash flows from operations. Our net losses were $27.0 million for the year ended December 31, 2025 and $38.5 million for the year ended December 31, 2024. As of December 31, 2025, we had an accumulated deficit of $694.9 million. We have historically financed our operations primarily through proceeds from the sale of our Commercial Business to Alcon, our IPO, follow-on public Common Stock offerings and sales of our Common Stock under our sales agreement with Jefferies, LLC in at-the-market offerings, private placements of Common Stock and/or preferred stock (including our most recent private placements resulting in gross proceeds of approximately $1.2 million in November 2025 and $4.2 million in January 2026).

Material Fourth Quarter 2025 Developments

Oxford Foreclosure and Workforce Terminations

On September 29, 2025, we received a written notice (the "Default Notice") of event of default from Oxford Finance LLC ("Oxford Finance"), with respect to the Loan and Security Agreement, dated as of May 4, 2021, by and among us, Combangio and Oxford Finance, as lender and collateral agent (as amended, the "Loan Agreement"). The Default Notice asserted that an event of default had occurred under the Loan Agreement and that the Company's obligations under the Loan Agreement were immediately due and payable. The total amount of our obligations under the Loan Agreement as of the date of the Default Notice that were accelerated and declared payable by Oxford Finance was $29.1 million, plus any additional interest due upon final payment and any expenses that become payable by us under the Loan Agreement.

On October 18, 2025, Oxford Finance informed us that it intended to foreclose on all of our remaining assets and that Oxford Finance would not consent to our use of cash for any reason other than for minimal payroll expenses pending Oxford Finance's foreclosure of our assets. In addition, Oxford swept substantially all of our cash resources from our bank accounts. As a result, on October 19, 2025, we terminated all remaining employees not deemed necessary by Oxford Finance to execute a foreclosure of our assets.

On November 3, 2025, Oxford Finance informed us that it intended to pause its foreclosure of our assets and permitted us to use $125,000 of cash it previously swept to fund the negotiation and execution of the Convertible Loan Agreement (as defined below).

On November 25, 2025, we entered into a Loan Settlement Agreement (the "Settlement Agreement") with Oxford Finance pursuant to which the Company owed Oxford Finance $2.0 million to be paid pursuant to the terms of the Settlement Agreement. The Settlement Agreement was entered into in connection with events of default by the Company, under the Loan Agreement. On December 26, 2025, the Company paid Oxford Finance $2.0 million, resulting in the Company's obligations under the Settlement Agreement and the Loan Agreement being satisfied and the aggregate liability due to Oxford Finance of approximately $10,600 being settled and released.

Convertible Loan Agreement

On November 9, 2025, we entered into a Convertible Loan Agreement (the "Convertible Loan Agreement") with David Lazar, an individual lender, pursuant to which David Lazar provided us a convertible loan in the aggregate amount of $375,000 (the "Loan Principal").

Pursuant to the terms of the Convertible Loan Agreement, the Loan Principal bore simple interest at a rate equal to 15% per annum, commencing on the date we receive the applicable portion of the Loan Principal and until full repayment thereof in accordance with the terms of the Convertible Loan Agreement. The Loan Principal was due and payable by us to David Lazar on the first anniversary of receiving the Loan Principal. Subject to compliance with the rules and regulations of The Nasdaq Stock Market, at any time prior to the full repayment of the Loan Amount to David Lazar, David Lazar had the right, upon prior written notice to us, to convert all or any of the then outstanding and unpaid portion of the Loan Amount into shares of our Common Stock at the conversion prices specified in the Convertible Loan Agreement. In addition, if we had entered into a definitive agreement to consummate an M&A Transaction (as defined in the Convertible Loan Agreement) or an underwritten public offering, and if the Loan Amount had not previously converted or been repaid pursuant to the Convertible Loan Agreement, David Lazar had the right to elect to (i) convert the entire Loan Amount into the most senior class of shares issued us immediately prior to such events or (ii) have the entire Loan Amount repaid in cash. We repaid the Loan Principal in full to David Lazar on December 18, 2025.

Private Placement of Series AA Preferred Stock

On November 23, 2025, the Company entered into a Securities Purchase Agreement (the "November 2025 Purchase Agreement") with David Lazar, pursuant to which the Company agreed to issue and sell, in a private placement, shares of our Series AA Preferred Convertible Preferred Stock, par value $0.001 per share (the "Series AA

Preferred Stock") and our Series AAA Preferred Stock, par value $0.001 per share (the "Series AAA Preferred Stock"), in two closings for aggregate gross proceeds of up to $6.0 million, subject to the terms and conditions set forth in the November 2025 Securities Purchase Agreement (the "Series AA Private Placement").

The closing of the Series AA Private Placement occurred on November 24, 2025, on which date we issued and sold to David Lazar an aggregate of 900,000 shares of Series AA Preferred Stock at a price per share equal to $2.00, for aggregate gross proceeds of $1.8 million. Each share of Series AA Preferred Stock was convertible into 55 shares of Common Stock for an aggregate total of 49,500,000 shares of Common Stock issuable upon conversion of the Series AA Preferred Stock. As of March 31, 2026, all of the shares of Series AA Preferred Stock have been converted to shares of Common Stock, and there are no Series AA Preferred Shares of the Company outstanding. As of March 31, 2026, there were 681,818 shares of Series AA Preferred Stock outstanding.

Pursuant to the November 2025 Purchase Agreement, the Company also agreed to issue and sell to David Lazar 2,100,000 Series AAA Preferred Shares, at a price per Series AAA Preferred Share equal to $2.00, for aggregate gross proceeds of $4.2 million. The closing of the Series AAA Preferred Stock was subject to (i) the approval by the Company's stockholders at a meeting of stockholders (the "Stockholder Meeting") of (A) an increase in the number of authorized shares of Common Stock to enable the Company to issue all of the shares of Common Stock that are issuable upon the conversion of the Series AA Preferred Stock and Series AAA Preferred Stock into Common Stock (the "Share Increase") and (B) the conversion of the Series AA Preferred Stock and Series AAA Preferred Stock into shares of Common Stock in accordance with the listing rules of Nasdaq (collectively, the "Stockholder Approvals"), (ii) the filing of an amendment to the Company's Restated Certificate of Incorporation, as amended (the "Restated Certificate of Incorporation), with the Secretary of State of the State of Delaware (the "Charter Amendment") effecting the Share Increase, (iii) the filing of a Certificate of Designations, Preferences and Rights of Series AAA Convertible Non-Redeemable Preferred Stock (the "Series AAA Certificate of Designations"), with the Secretary of State of the State of Delaware creating the Series AAA Preferred Stock, and (iv) the satisfaction of other customary closing conditions.

Pursuant to the Securities Purchase Agreement, if at any time during the six-month period following the date of the closing of the Series AAA Preferred Stock (the "Participation Period"), the Company proposes to offer and sell new equity securities in an offering that is conducted pursuant to an exemption from registration under the Securities Act, or in an offering that is registered under the Securities Act that is not conducted as a firm-commitment underwritten offering, then, subject to compliance with securities laws and regulations, the Company has agreed to offer David Lazar the right to purchase, on the same terms, including the price per security, and subject to the same conditions, as are applicable to the other investors in such offering, that amount of new equity securities equal to up to 25% of the total amount of new equity securities being offered for sale in such offering. In addition, if during the Participation Period, the Company proposes to offer and sell new equity securities in a firm-commitment underwritten offering registered under the Securities Act, then subject to compliance with securities laws and regulations, the Company has agreed to use its commercially reasonable efforts to cause the managing underwriters of such offering to contact the Investor about potentially participating in such offering and to provide to the Investor the opportunity to purchase up to 25% of the total new equity securities, subject to certain conditions and limitations.

Pursuant to the November 2025 Purchase Agreement, subject to obtaining Stockholder Approvals and the consummation of the Second Closing, David Lazar has the right to recommend to the Company up to eight individuals to be nominated for election at the Stockholder Meeting (the "Investor Nominees"), provided that such right shall at all times be subject to, and in compliance with, Nasdaq Listing Rule 5640.

On December 11, 2025, David Lazar transferred his rights and obligations under the November 2025 Purchase Agreement solely with respect to the shares of Series AAA Preferred Stock and the director nomination rights, to AK Holdings Group Inc., a Panamanian company ("AK Holdings").

December 2025 Registered Direct Offering

On December 4, 2025, we entered into a securities purchase agreement (the "December 2025 Purchase Agreement") with a certain institutional investor (the "RD Investor"), pursuant to which the Company agreed to issue and sell in a registered direct offering (the "RD Offering") (i) 900,000 shares of the Company's Common Stock and (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to an aggregate of 9,100,000 shares of Common Stock

(the "Pre-Funded Warrant Shares"), at a purchase price of $1.00 per Pre-Funded Warrant Share (less $0.0001 per Pre-Funded Warrant). The gross proceeds to the Company from the RD Offering was approximately $10.0 million before deducting placement agent fees and other offering expenses payable by the Company.

The shares of Common Stock, Pre-Funded Warrants and Pre-Funded Warrant Shares were offered by the Company pursuant to an effective shelf registration statement on Form S-3 (File No. 333-270263) which was filed with the Securities and Exchange Commission (the "SEC") on March 3, 2023, as amended, and declared effective by the SEC on May 11, 2023, and related base prospectus and a prospectus supplement dated December 4, 2025, thereunder.

The Pre-Funded Warrants have an initial exercise price per share of $0.0001, subject to certain adjustments. The Pre-Funded Warrants may be exercised at any time until exercised in full, except that a holder (together with its affiliates) will not be entitled to exercise any portion of any Pre-Funded Warrant, which, upon giving effect to such exercise would cause the aggregate number of shares of the Company's Common Stock beneficially owned by the holder (together with its affiliates) to exceed 4.99% (or, upon election of the holder, 9.99%) of the number of shares of Common Stock outstanding immediately prior to or after giving effect to the exercise, subject to such holder's rights under the Pre-Funded Warrants to increase or decrease such percentage to another percentage not in excess of 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Funded warrants, provided that any increase shall only be effective upon at least 61 days' prior notice from such holder to the Company. The Offering closed on December 5, 2025.

Pursuant to the terms of the Purchase Agreement, the Company has agreed to certain restrictions on the issuance and sale of its Common Stock or Common Stock Equivalents (as defined in the December 2025 Purchase Agreement) until 30 days following the closing date, and not to issue any Common Stock or Common Stock Equivalents in a Variable Rate Transaction (as defined in the December 2025 Purchase Agreement) for one year from the closing date, subject to an exception as contained therein.

Recent Developments

ATM Facility

On January 8, 2026, the Company entered into an At The Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC ("Wainwright") providing for the sale and issuance by the Company of shares of its Common Stock from time to time, through or to Wainwright as the Company's sales agent or principal in an "at the market offering" program and as set forth in the ATM Agreement (the "ATM Offering").

The Company filed a prospectus supplement, dated January 8, 2026, including an accompanying base prospectus, dated May 11, 2023, contained therein (the "ATM Prospectus Supplement"), which together form a part of the Company's shelf registration statement on Form S-3, as amended (File No. 333-270263), initially filed by the Company with the SEC on March 3, 2023 and declared effective by the SEC on May 11, 2023 in connection with the offer and sale of shares of Common Stock pursuant to the ATM Agreement. The aggregate market value of the shares of Common Stock eligible for sale under the prospectus supplement is currently $15.0 million.

Pursuant to the terms of the ATM Agreement, Wainwright agreed to use its commercially reasonable efforts, consistent with applicable state and federal law, rules and regulations, and the rules of the Nasdaq Capital Market, to sell the shares of Common Stock from time to time. Under the ATM Agreement, the Company may designate the parameters for the sale of shares of Common Stock, including the number of shares to be issued, the time period during which sales are requested to be made, limitations on the number of shares that may be sold on any trading day and any minimum price below which sales may not be made. Subject to the terms and conditions of the ATM Agreement, Wainwright may sell the shares by methods deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act, including without limitation, sales made directly on Nasdaq or on any other existing trading market for the Common Stock or to or through a market maker. In addition, with the Company's prior written approval, Wainwright may also sell shares in privately negotiated transactions or block transactions. The gross sales price of the shares of

Common Stock sold by Wainwright under the ATM Agreement as sales agent is the market price for the shares of Common Stock on Nasdaq at the time of sale.

Private Placement of Series AAA Preferred Stock

On January 29, 2026, pursuant to the terms of a certain Rights Purchase Agreement, by and among AK Holdings and each signatory thereto (the "Series AAA Investors"), AK Holdings sold its rights to purchase the Series AAA Preferred Stock (but not its director nomination rights under the November 2025 Purchase Agreement) to the Series AAA Investors.

On January 30, 2026, the Company entered into a Securities Purchase Agreement (the "January 2026 Purchase Agreement"), pursuant to which we issued and sold to the "Series AAA Investors" in a private placement (the "January 2026 Private Placement"), an aggregate of 2,100,000 shares of Series AAA Preferred Stock at a price per share equal to $2.00, for aggregate gross proceeds of $4.2 million. The closing of the January 2026 Private Placement occurred on January 30, 2026. Each share of Series AAA Preferred Stock was convertible into 420 shares of Common Stock for an aggregate total of 882,000,000 shares of Common Stock issuable upon conversion of the Series AAA Preferred Stock. As of the date of this Annual Report on Form 10-K, all of the shares of Series AAA Preferred Stock have been converted into shares of Common Stock and there are no Series AAA Preferred Shares of the Company outstanding.

Loan and Security Agreement

On February 9, 2026, the Company made a loan (the "Loan") in the principal amount of $7.0 million evidenced by a secured promissory note (the "Note") to Minglemint Solutions LLC ("Borrower"). The Loan bears interest at a rate of 8.0% per annum, and is due and payable on February 9, 2027.

The Note includes customary event of default provisions, including, but not limited to, for a breach of any representations and warranties or covenants, any bankruptcy or insolvency proceedings of the Borrower, and the failure of the Borrower to pay, upon 15 days' written notice of default, any principal amount of the Loan or interest due. The Note provides for a default interest rate of 13.0%. As described in the Note, upon the occurrence of certain events of default, the Company may, among other remedies, declare the outstanding balance of the Note including all accrued interest thereon immediately due and payable.

Additionally, the Note is secured by a continuing first priority lien and security interest in all fixtures and personal property of the Borrower (the "Collateral"), pursuant to the security agreement with the Borrower dated February 9, 2026 (the "Security Agreement"). The Collateral includes, but is not limited to, all accounts, goods, documents, instruments, securities and investment properties, money, accounts and rights to payment of the Borrower, and any proceeds, records and obligations relating to the foregoing, as more fully detailed in the Security Agreement.

Platform Development and Exclusive License Agreement

On March 3, 2026, the Company entered into a Platform Development and Exclusive License Agreement (the "Younet License Agreement") pursuant to which the Company obtained a worldwide exclusive license of Younet's Researgency Platform, together with associated trademarks and intellectual property. The term of the Younet License Agreement is for 12 months following the Effective Date (the "Initial Term"), with the option by the Company to renew the agreement for successive 12 months terms (each, a "Renewal Term"), in each case by providing notice to Younet pursuant to the terms of the Agreement (the "Extension Notice"). Pursuant to the Agreement, Younet agreed to provide to the Company certain deliverables and services related to the Researgency Platform, with certain additional deliverables to be provided by Younet in the event of a Renewal Term, in each case with all operating costs relating to the Researgency Platform to be paid by the Company.

In consideration of the services to be performed by Younet under the Agreement, the Company paid to Younet for the Initial Term a cash fee of up to $530,000 consisting of (i) $80,000 in cash, which was paid by the Company on the Effective Date, and (ii) in the event the Company delivers to Younet a written notice electing to engage Younet for the continued development of Researgency, $450,000 in cash, payable in 9 monthly installments of $50,000, pursuant to

the terms of the Agreement. Such notice may be provided at any time on or after the first business day of the third month following the Effective Date and such continued development may be terminated upon 30 days notice by the Company. In addition, the Company has to issued to Younet 5,000,000 shares of Common Stock, within 10 business days of the Effective Date. In addition, each time the Agreement is extended for a Renewal Term, the Company shall (i) pay to Younet $250,000 in cash and (ii) issue to Younet 5,000,000 shares of Common Stock within 10 business days of the Extension Notice. Any shares of Common Stock issuable to Younet pursuant to the Agreement shall herein be referred to as the "Younet Shares." Except for certain block trades, during the Term (as defined in the Agreement) and for the twelve months thereafter, Younet shall not sell any Younet Shares on any Trading Day (as defined in the Agreement) in an amount that exceeds 3% of the Daily Trading Volume (as defined in the Agreement) for such Trading Day.

In addition, Younet has granted to the Company an irrevocable option, exercisable at any time during the Initial Term or any Renewal Terms, to acquire all of the issued and outstanding equity interests of Younet, or, at the Company's election, substantially all of the assets of Younet, for a total purchase price of $55,000,000, subject to the terms of the Agreement.

If the Company does not deliver an Extension Notice prior to the expiration of the Initial Term or any Renewal Term, the Agreement shall expire automatically at the end of the applicable term. In addition, the Agreement may be terminated by either party (i) for uncured material breach or (ii) due to the insolvency of the other party. Upon termination or expiration, (a) the Exclusive License will terminated, (b) all licenses granted to Younet with respect to KALA Data (as defined in the Agreement) will immediately terminate, (c) all licenses granted to the Company with respect to Younet Background IP (as defined in the Agreement) will survive in accordance with their terms, and (d) all Work Product (as defined in the Agreement) completed as of the date of termination shall be delivered to and owned by the Company.

Nasdaq Deficiencies

On November 10, 2025, we received a deficiency letter (the "MVLS Letter") from the Listing Qualifications Department (the "Staff") of the Nasdaq Stock Market notifying us that the listing of our Common Stock was not in compliance with Nasdaq Listing Rule 5550(b)(2) (the "Minimum MVLS Requirement") for continued listing on Nasdaq, as the market value of our listed securities was less than $35 million for the previous 30 consecutive business days.

In accordance with Nasdaq Listing Rule 5810(c)(3)(C), we have been provided a period of 180 calendar days, or until May 11, 2026 (the "MVLS Compliance Date"), to regain compliance with the Minimum MVLS Requirement. If, at any time before the MVLS Compliance Date, the market value of our listed securities closes at $35 million or more for a minimum of 10 consecutive business days, the Staff will provide written notification to us that we have regained compliance with the Minimum MVLS Requirement.

If we do not regain compliance with the Minimum MVLS Requirement by the MVLS Compliance Date, we will receive written notification that our securities are subject to delisting. At that time, we may appeal the Staff's delisting determination to a Nasdaq Listing Qualifications Panel (the "Panel") pursuant to the procedures set forth in the applicable Nasdaq Listing Rules. However, there can be no assurance that, if we receive a delisting notice and appeal the delisting determination by the Staff to the Panel, such appeal would be successful.

In addition, on January 20, 2026, we received a letter from the Staff indicating that, based upon the closing bid price of the Company's Common Stock for the 30 consecutive business days between December 3, 2025, to January 16, 2026, the Company did not meet the minimum bid price of $1.00 per share required for continued listing on Nasdaq pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Rule"). The letter also indicated that we will be provided with a compliance period of 180 calendar days, or until July 20, 2026 (the "Minimum Bid Price Compliance Period"), in which to regain compliance pursuant to Nasdaq Listing Rule 5810(c)(3)(A).

In order to regain compliance with the Minimum Bid Price Rule, our Common Stock must maintain a minimum closing bid price of $1.00 for at least ten consecutive business days during the Minimum Bid Price Compliance Period. In the event we do not regain compliance by the end of the Minimum Bid Price Compliance Period, we may be eligible for additional time to regain compliance. To qualify, we will be required to meet the continued listing requirement for

the market value of its publicly held shares and all other initial listing standards for Nasdaq, with the exception of the bid price requirement, and will need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split if necessary. If we meet these requirements, we may be granted an additional 180 calendar days to regain compliance. However, if it appears to Nasdaq that we will be unable to cure the deficiency, or if we are not otherwise eligible for the additional cure period, Nasdaq will provide notice that our Common Stock will be subject to delisting. There can be no assurance that we will be eligible for the additional 180 calendar day compliance period, if applicable, or that the Nasdaq staff would grant our request for continued listing subsequent to any delisting notification. In the event of such a notification, we may appeal the Staff's determination to delist its securities.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as critical because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates—which also would have been reasonable—could have been used. On an ongoing basis, we evaluate our estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to be 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.

While our significant accounting policies are described in more detail in the notes to our financial statements appearing at the end of this Annual Report on Form 10-K, we believe that the following critical accounting estimates are those most critical to the judgments and estimates used in the preparation of our financial statements and that involve a significant level of estimation uncertainty.

Grant Income

We account for grants received to perform research and development activities in accordance with Accounting Standards Codification Topic 730-20, *Research and Development Arrangements*, which requires an assessment, at the inception of the grant, of whether the grant is a liability or a contract to perform research and development activities. If we are obligated to repay the grant funds to the grantor regardless of the outcome of the research and development activities, then we are required to estimate and recognize that liability. Alternatively, if we are not required to repay, or if we were required to repay the grant funds only if the research and development activities are successful, then the grant agreement is accounted for as a contract to perform research and development activities, in which case, grant income is recognized as the related research and development expenses are incurred. Grant income recognized is based on a calculation derived from the eligible research and development expenses incurred which is, in part, based on estimates, specifically related to costs incurred for services performed by our vendors in connection with research and development activities for which we have not been invoiced. We base our estimates on the best information available at the time. Costs of grant income are recorded as a component of research and development expenses in our consolidated statements of operations and comprehensive loss.

Acquisition Accounting

We are required to make significant judgments and estimates to determine whether an acquisition constitutes an acquisition of a business or assets. For asset acquisitions, this includes whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets. We are also required to make several significant judgments and estimates in order to determine the total consideration transferred for the asset acquisition and then allocate it to the assets that we have acquired and the liabilities that we have assumed on a relative fair value basis. If the asset related to acquired in-process research and development expenses has no alternative future use, it is expensed immediately upon the completion of the transaction.

In addition to upfront consideration, our asset acquisitions may also include contingent consideration payments to be made for future milestone events or royalties on net sales of future products. We assess whether such contingent

consideration is required to be recorded at fair value on the date of the acquisition and subsequently remeasured to fair value at each reporting date. Contingent consideration payments in an asset acquisition not required to be recorded at fair value are recognized when the contingency is resolved, and the consideration is paid or becomes payable. Changes in the fair value of the contingent milestone payments can result from changes to one or more inputs, including adjustments to the probability of achievement, timing of the contingent milestone payments and changes to the applicable discount rates. Significant judgment is used in determining these assumptions and estimates during each reporting period. Reasonable changes in these assumptions can cause material changes to the fair value of our contingent consideration liability. Any changes in the fair value of these contingent consideration liabilities are included in loss from operations in the consolidated statements of operations and comprehensive loss. For information related to the unobservable inputs related to the contingent consideration, see Note 3, "Fair Value of Financial Instruments", of our consolidated financial statements.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

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

	Year Ended December 31,		
	2025	2024	Change
	(in thousands)		
Costs and expenses:			
General and administrative	$ 23,629	$ 18,340	$ 5,289
Research and development	18,780	22,094	(3,314)
(Gain) Loss on fair value remeasurement of contingent consideration	(4,659)	549	(5,208)
Impairment of right-of-use assets	1,411	—	1,411
Total operating expenses	39,161	40,983	(1,822)
Loss from operations	(39,161)	(40,983)	1,822
Other income (expense)			
Interest income	1,140	2,056	(916)
Interest expense	(3,276)	(5,783)	2,507
Grant income	3,377	6,199	(2,822)
Gain on extinguishment of debt	5,793	—	5,793
Other income (expense), net	5,147	—	5,147
Net loss	$ (26,980)	$ (38,511)	$ 11,531

General and administrative expenses

General and administrative expenses consist primarily of salaries, benefits, stock-based compensation and travel expenses related to our executive, finance, human resources, legal, compliance, information technology and business development functions. General and administrative expenses also include professional fees for auditing, tax, information technology, consultants, legal services and allocated facility related costs not otherwise included in research and development expenses.

General and administrative expenses were $23.6 million for the year ended December 31, 2025, compared to $18.3 million for the year ended December 31, 2024, which was an increase of $5.3 million, or 29.0%. The increase in general and administrative expenses for the year ended December 31, 2025 was primarily due to a $2.7 million increase in administrative and professional service fees and $2.6 million increase in employee-related costs, primarily a result of our decision to cease development of KPI-012 and our MSC-S platform, including costs related to restructuring and wind-down activities, increased legal and professional services support, and higher employee-related costs in connection with those activities.

Research and development expenses

The following table summarizes the research and development expenses incurred during the years ended December 31, 2025 and 2024:

	Year Ended December 31,		
	2025	2024	Change
	(in thousands)		
KPI-012 development costs	$ 8,156	$ 10,170	$ (2,014)
Employee-related costs for research and development personnel	8,928	10,757	(1,829)
Other research and development costs	1,696	1,167	529
Total research and development	$ 18,780	$ 22,094	$ (3,314)

Research and development expenses consist of costs associated with our research activities, including compensation and benefits for full time research and development employees, an allocation of facilities expenses, overhead expenses and certain outside expenses. Our research and development expenses generally include: employee related expenses, including salaries and stock based compensation; expenses incurred for the preclinical and clinical development of our product candidates and under agreements with contract research organizations, including costs of manufacturing product candidates prior to the determination that FDA approval of a drug candidate is probable and before the future economic benefit of the drug is expected to be realized; and facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and supplies.

We expense research and development costs as they are incurred. We expense costs relating to the production of inventory for our product candidates, as research and development expenses within our consolidated statements of operations and comprehensive loss in the period incurred, unless we believe regulatory approval and subsequent commercialization of the product candidate is probable and we expect the future economic benefit from sales of the drug to be realized. Research and development costs that are paid in advance of performance are capitalized as a prepaid expense until incurred. We track outsourced development costs by development program but do not allocate personnel costs, payments made under license agreements or other costs to specific product candidates or development programs. These costs are included in employee related costs and other research and development costs in the line items in the above table.

Research and development expenses were $18.8 million for the year ended December 31, 2025, compared to $22.1 million for the year ended December 31, 2024, a decrease of $3.3 million driven by a $2.0 million decrease in KPI-012 clinical development costs following our discontinuation of our MSC-S platform and a $1.8 million decrease in personnel and facilities expenses after workforce reductions.

(Gain) loss on fair value remeasurement of contingent consideration

We recorded an obligation for such contingent consideration at fair value on the acquisition date. We then revalue our contingent consideration obligations each reporting period. Changes in the fair value of our contingent consideration obligations, other than changes due to issuance, are recognized as a gain or loss on fair value remeasurement of contingent consideration in our consolidated statements of operations and comprehensive loss.

Gain on fair value remeasurement of Contingent Consideration for the year ended December 31, 2025 was $4.7 million as compared to a loss of $0.5 million for the year ended December 31, 2024, primarily due to our decision to cease development of KPI-012 and our MSC-S platform.

Impairment of right-of-use assets

Impairment of right-of-use assets for the year ended December 31, 2025 was $1.4 million of expense, compared to $0 for the year ended December 31, 2024, due to the impairment of the right-of-use asset related to our Menlo Park lease.

Interest income

Interest income consists of interest earned on our cash, cash equivalents and short-term investments, if any.

Interest income was $1.1 million for the year ended December 31, 2025, compared to $2.1 million for the year ended December 31, 2024, a decrease of $1.0 million. Interest income consists of interest earned on our cash, cash equivalents and short-term investments, if any. The decrease was attributable to a lower cash balance during the year ended December 31, 2025 as compared to the year ended December 31, 2024.

Interest expense

Interest expense primarily consists of contractual coupon interest, amortization of debt discounts and debt issuance costs and accretion of the final payment fee recognized on our debt arrangements

Interest expense was $3.3 million and $5.8 million for the years ended December 31, 2025 and 2024, respectively. Interest expense for the years ended December 31, 2025 and 2024 was comprised of the contractual coupon interest expense, the amortization of the debt discount and the accretion of the final payment fee associated with our Loan Agreement with Oxford Finance. The decrease in 2025 was primarily a result of the Settlement Agreement during the fourth quarter of 2025. As of December 31, 2025, $0 million of indebtedness was outstanding under our Loan Agreement. During the year ended December 31, 2024, $34.0 million of indebtedness was outstanding under our Loan Agreement until $4.7 million was repaid on December 26, 2024 resulting in an outstanding indebtedness of $29.3 million as of December 31, 2024.

Grant income

Grant income for the years ended December 31, 2025 and 2024 was $3.4 million and $6.2 million, respectively, related to the CIRM Award. The decrease in grant income was due to the early achievement of specified milestones under the CIRM Award and the timing of the associated costs related to the CHASE Phase 2b clinical trial. The CIRM Award is not in the scope of the contracts with customers accounting guidance as the government entity is not a customer under the agreement. Rather, the CIRM Award is accounted for as a contract to perform research and development activities. As a result, grant income is recognized as the related research and development expenses are incurred. Additionally, on September 29, 2025, the Company announced that the CHASE trial of KPI-012 for the treatment of PCED did not meet the primary endpoint of complete healing of PCED as measured by corneal fluorescein staining. The CHASE trial also failed to achieve statistical significance for key secondary efficacy endpoints and did not show any meaningful difference between either KPI-012 treatment arm and the placebo arm. Based on the CHASE trial results, we determined to cease development of KPI-012 and our MSC-S platform, and as such, we do not expect to receive grant income relating to the CIRM Award in the near future.

Gain on extinguishment of debt

We recognized a gain on extinguishment of debt of $5.8 million for the year ended December 31, 2025, compared to $0 for the year ended December 31, 2024, an increase of $5.8 million. This gain was recorded in connection with the resolution of our obligations under our debt arrangements during 2025. Because this item relates to a discrete financing and settlement event, the amount may not be indicative of our ongoing results of operations.

Other income (expense), net

Other income, net for the year ended December 31, 2025 was $5.1 million, compared to $0 for the year ended December 31, 2024, an increase of $5.1 million, primarily related to gains associated with settlements, including a $3.4 million gain on executive compensation settlements, $1.4 million gain on other liabilities' settlements and $0.9 million gain on Menlo Park lease settlement, partially offset by $0.5 million loss on disposal of fixed assets. There was no other expense, net for the year ended December 31, 2024. Because these items reflect discrete settlement activity, they may not be indicative of future period results.

Known trends, events and uncertainties affecting results of operations

We expect our results of operations to continue to be materially affected by the fact that we do not have revenue-generating commercial products and are dependent on external financing, asset monetization transactions, and/or partnering activity to fund operations. In addition, our future operating results are expected to be influenced by the timing, structure, and probability of any potential out-licensing or collaboration arrangements relating to KPI-012, KPI-014, and related intellectual property, as well as execution and commercialization risks associated with our Researgency initiative, including the time and cost required to develop and deploy on-premises AI systems, the pace of customer evaluation and adoption, and the evolution of the regulatory and data-governance environment applicable to AI-enabled platforms. Our operating results may also be affected by the impacts of prior workforce reductions and broader capital markets conditions, which may constrain our access to financing and increase volatility in our operating plans.

Liquidity and Capital Resources

As described in Note 2 to the consolidated financial statements, we have incurred recurring losses from operations and negative cash flows from operations since inception, had an accumulated deficit of $694.9 million as of December 31, 2025, and disclosed going concern uncertainty during the first, second and third quarters of 2025. During the fourth quarter of 2025, we also experienced significant liquidity constraints in connection with our debt arrangement with Oxford Finance. Management concluded that, after considering its plans and recent developments, substantial doubt about our ability to continue as a going concern was alleviated for the twelve months following the date the consolidated financial statements were issued.

Since our inception, we have incurred significant operating losses. We only generated limited revenues from product sales of EYSUVIS and INVELTYS prior to the sale of our Commercial Business to Alcon in July 2022. We have financed our operations primarily through proceeds from the sale of our Commercial Business to Alcon in July 2022, our IPO, follow-on public Common Stock offerings and sales of our Common Stock under our at-the-market equity offerings, private placements of Common Stock and/or preferred stock, borrowings under credit facilities, our Loan Agreement with Oxford Finance, disbursements under a grant from CIRM, and convertible promissory notes and warrants. As of December 31, 2025 and 2024, we had $7.6 million and $51.2 million, respectively, in cash and cash equivalents. As of December 31, 2025 and 2024, we had $0 and $29.3 million, respectively, of indebtedness outstanding under our Loan Agreement with Oxford Finance.

Based on our current operating plan, including anticipated expenses related to our Researgency initiative and routine corporate costs, we believe our existing cash and cash equivalents will fund operations into the first quarter of 2027. We are evaluating additional financing alternatives, including potential sales under our ATM program and private placements, and pursuing asset monetization opportunities. If these actions are not successful or timely, we will need to further reduce or defer planned expenditures, which could materially affect our strategy. Our ability to raise additional capital may be constrained by market conditions, our Nasdaq continued listing compliance efforts, and investor perceptions regarding our liquidity position and historical operating losses.

Combangio Merger Agreement

Pursuant to the Agreement and Plan of Merger (the “Merger Agreement”), we entered into with Combangio in connection with the acquisition of Combangio in November 2021, the former Combangio stockholders or other equityholders (the “Combangio Equityholders”), are entitled to receive from us up to $105.0 million in payments that are contingent upon the achievement of specified development, regulatory and commercialization milestones (the “Contingent Consideration”).

Upon dosing of the first patient in our CHASE trial for PCED in the United States in February 2023, we paid the former Combangio Equityholders an aggregate of $2.5 million in cash and $2.4 million in shares of our Common Stock (representing an aggregate of 105,038 shares of our Common Stock) in March 2023. The remaining amount of $0.1 million was paid in cash in January 2024. Any Contingent Consideration payable under the Merger Agreement in the future would be paid only in cash as follows: (i) $5.0 million payable upon the first patient dosed with any product candidate whose active ingredient comprises one or more biological factors secreted by MSC-S or their progenitors, including KPI-012, or the Product Candidate, in a pivotal clinical trial, (ii) $12.5 million payable upon regulatory

approval by the FDA of marketing and sale of a Product Candidate in the United States, subject to certain specified reductions; (iii) $17.5 million payable upon the first commercial sale of a Product Candidate in the United States, subject to certain specified reductions and (iv) an aggregate of up to $65.0 million payable upon the achievement of specified sales milestones; tiered cash royalties at percentage rates in the mid-to-high single digits payable on annual net sales of all Product Candidates; and a cash payment at a percentage rate in the high single digits of all income, including earnout payments, received by us or any of our affiliates from a product license granted by us to a third party to sell or otherwise commercialize the Product Candidate in countries where neither we nor our affiliates conduct sales of such Product Candidate, subject to certain exceptions set forth in the Merger Agreement.

If the aggregate amount of Contingent Consideration payable in any calendar year exceeds $2.5 million (the "Excess Cash Cap"), such excess portion, or the Carry Forward Contingent Cash Consideration, will be carried forward and, subject to application of the Excess Cash Cap in the following calendar year, become payable on the first business day of the following calendar year. Any Carry Forward Contingent Cash Consideration outstanding on June 1, 2026 is payable in full on June 1, 2026. While our CHASE trial is currently on hold, if we were to continue development of KPI-012 or certain other product candidates, the Contingent Consideration payable under the Merger Agreement.

Sale of Commercial Business

In July 2022, we sold our Commercial Business to Alcon. In addition to the upfront cash payment of $60.0 million we received from Alcon, we are also eligible to receive from Alcon up to four commercial-based sales milestone payments as follows: (1) $25.0 million upon the achievement of $50.0 million or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2028, (2) $65.0 million upon the achievement of $100.0 million or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2028, (3) $75.0 million upon the achievement of $175.0 million or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2029 and (4) $160.0 million upon the achievement of $250.0 million or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2029. Each milestone payment is only payable once, if at all, upon the first time such milestone is achieved, and only one milestone payment is paid with respect to a calendar year. In the event that more than one milestone is achieved in a calendar year, the higher milestone payment is payable and the lower milestone payment becomes payable only if the corresponding milestone is achieved again in a subsequent calendar year. To date, we have not received any such milestone payments. We now have no revenue-generating commercial products, and although we are eligible to receive up to $325.0 million in milestone-based payments from Alcon, there can be no assurance as to when we may receive such milestone payments or the amount of milestone payments we may receive, if any.

CIRM Award

Our development of KPI-012 was funded, in part, by an award from the California Institute for Regenerative Medicine ("CIRM"). On April 28, 2023, CIRM awarded Combangio a $15.0 million grant, or the CIRM Award, subject to entering into a final award agreement, to support Combangio's ongoing KPI-012 program for the treatment of PCED as well as product and process characterization and analytical development for the program. On August 2, 2023, Combangio entered into the CIRM Award and received an initial $5.9 million disbursement from CIRM. In 2025 and 2024, Combangio received an aggregate of $3.4 million and $5.8 million, respectively, in disbursements from CIRM upon the achievement of specified milestones. The CIRM Award is subject to a co-funding requirement under which Combangio is obligated to spend a specified minimum amount on the development of KPI-012 to obtain the full award amount and a significant portion of the award is payable to Combangio upon the achievement of specified milestones that are primarily related to Combangio's progress in conducting the CHASE clinical trial. Under the terms of the CIRM Award, Combangio is obligated to pay a royalty on net sales of any product, service or approved drug resulting in whole or in part from the CIRM Award in the amount of 0.1% per $1.0 million of funds utilized by us until the earlier of 10 years from the date of first commercial sale of such product, service or approved drug and such time as nine times the amount of funds awarded by CIRM has been paid in royalties, or the Base Royalty. In addition, following the satisfaction of the Base Royalty, Combangio is obligated to pay a 1.0% royalty on net sales of any CIRM-funded invention in excess of $500 million per year until the last to expire patent covering such invention expires.

Under the CIRM Award, if we were to fail to satisfy the co-funding requirement under the CIRM Award or fail to achieve the milestones within the timeframe required by the CIRM Award, we may not receive full funding under the CIRM Award. CIRM may permanently cease disbursements under the CIRM Award if the milestones are not met within

four months of their scheduled completion dates or if the delay is not addressed to CIRM's satisfaction, as determined by CIRM in its sole discretion. Additionally, if CIRM determines, in its sole discretion, that Combangio has not complied with the terms and conditions of the CIRM Award, CIRM may suspend or permanently cease disbursements. Moreover, disbursements under the CIRM Award are contingent upon the availability of funds in the state of California's Stem Cell Research and Cures Fund, which is outside of our control. On September 29, 2025, we announced that based on the CHASE trial results, we determined to cease development of KPI-012 and our MSC-S platform. As of December 31, 2025, no more funding is expected under the CIRM Award.

Offerings under Registration Statements

On March 3, 2023, we filed a shelf registration statement on Form S-3 with the SEC (the "2023 Shelf Registration"), which was declared effective on May 11, 2023. Under the 2023 Shelf Registration, we may offer and sell up to $350.0 million of a variety of securities including Common Stock, preferred stock, warrants, depositary shares, debt securities, subscription rights or units. In accordance with the terms of the Open Market Sale Agreement, we may issue and sell, from time to time, up to an aggregate of $40.0 million of our Common Stock in an at-the-market equity offering through Jefferies.

From entry into the Open Market Sale Agreement and as of December 31, 2025, we sold an aggregate of 784,196 shares of our Common Stock under the 2023 Shelf Registration for total net proceeds of approximately $7.0 million, none of which were sold during the year ended December 31, 2025. During the year ended December 31, 2024, we sold an aggregate of 527,940 shares of our Common Stock under the Open Market Sale Agreement under the 2023 Shelf Registration for total net proceeds of approximately $3.4 million.

On January 8, 2026, we entered into the ATM Agreement with Wainwright pursuant to which we filed the ATM Prospectus Supplement to the 2023 Shelf Registration. The aggregate market value of the shares of Common Stock eligible for sale under the ATM Prospectus Supplement is currently $15.0 million.

Loan Agreement

On May 4, 2021, we entered into the Loan Agreement with Oxford Finance, in its capacity as lender and as collateral agent, pursuant to which a term loan of up to an aggregate principal amount of $125.0 million became available to us, consisting of a tranche A term loan that was disbursed on the closing date of the Loan Agreement in the aggregate principal amount of $80.0 million and additional tranches that are no longer available to us. Through June 30, 2023, the term loan bore interest at a floating rate equal to the greater of 30-day LIBOR and 0.11%, plus 7.89%. Effective July 1, 2023, the term loan bears interest at a floating rate equal to the greater of (a) 8.00% and (b) the sum of (i) the 1-Month CME Term Secured Overnight Financing Rate ("SOFR"), (ii) 0.10% and (iii) 7.89%. Certain of the customary negative covenants limit our and certain of our subsidiaries' ability, among other things, to incur future debt, grant liens, make investments, make acquisitions, distribute dividends, make certain restricted payments and sell assets, subject in each case to certain exceptions. In connection with our entry into the purchase agreement for the sale of our Commercial Business to Alcon on May 21, 2022, we entered into an amendment to the Loan Agreement ("Second Loan Amendment"), pursuant to which Oxford Finance consented to the entry by us into the asset purchase agreement and the sale of the Commercial Business to Alcon and agreed to release its liens on the Commercial Business in consideration for the payment by us at the closing of the Alcon Transaction of an aggregate amount of $40.0 million (the "Second Amendment Prepayment"), to Oxford Finance. The Second Amendment Prepayment, which represented a partial prepayment of principal in the amount of $36.7 million of the $80.0 million principal amount outstanding under the term loan advanced by Oxford Finance, as lender, under the Loan Agreement, plus a prepayment fee of $0.7 million and a final payment fee of $2.6 million, was paid on July 8, 2022 in connection with the closing of the Alcon Transaction.

On December 27, 2022, we entered into an amendment to the Loan Agreement with Combangio and Oxford Finance (the "Third Loan Amendment"), pursuant to which Oxford Finance agreed to amend certain provisions of the Loan Agreement to permit the transfer of the listing of our Common Stock from The Nasdaq Global Select Market to The Nasdaq Capital Market. Pursuant to the Third Loan Amendment, we agreed (A) to make partial prepayments of the principal amount of the term loan outstanding under the Loan Agreement (the "Third Amendment Prepayments") as follows: (1) a payment of $5.0 million on or before June 30, 2023, representing a partial prepayment of principal in the amount of $4.7 million, plus a final payment fee of $0.3 million and (2) a payment of $5.0 million on or before January 31, 2024, representing a partial prepayment of principal in the amount of $4.7 million, plus a final payment fee of $0.3

million and (B) the start date for us to make amortization payments under the Loan Agreement was changed from January 1, 2026 to January 1, 2025 (the "Amortization Date"). On January 25, 2023, we paid the Third Amendment Prepayments and the principal loan balance under the Loan Agreement following such prepayments was $34.0 million.

Pursuant to the Third Loan Amendment, if we made an additional prepayment under the Loan Agreement equal to $5.0 million (inclusive of the final payment fee) on or prior to December 31, 2024(the "First Extension Prepayment"), the Amortization Date would be automatically changed to July 1, 2025, and the maturity date of the Loan Agreement would be automatically changed from May 1, 2026 to November 1, 2026. On December 26, 2024, we paid the First Extension Prepayment, and as a result, the Amortization Date was changed to July 1, 2025 and the maturity date of the Loan Agreement automatically changed to November 1, 2026.

If we made an additional prepayment under the Loan Agreement equal to $2.5 million (inclusive of the final payment fee) on or prior to June 30, 2025, or the Second Extension Prepayment, the Amortization Date would be automatically changed to January 1, 2026, and the maturity date of the Loan Agreement would be automatically changed to May 1, 2027. On June 26, 2025, we paid the Second Extension Prepayment, and as a result, the Amortization Date was automatically changed to January 1, 2026 and the maturity date of the Loan Agreement was automatically changed to May 1, 2027.

Under the Third Loan Amendment, Oxford Finance also agreed to waive the prepayment fees for the Third Amendment Prepayments, the First Extension Prepayment, the Second Extension Prepayment and any other prepayments under the Loan Agreement. Pursuant to the Loan Agreement, we also will be required to pay all accrued and unpaid interest on the principal amounts of the term loan being repaid at the time of repayment.

On August 1, 2023, we entered into a fourth amendment to the Loan Agreement pursuant to which certain provisions of the Loan Agreement were amended in connection with the change in our corporate name and the cessation of the U.S. Dollar LIBOR rate. On August 2, 2023, we entered into a fifth amendment to the Loan Agreement pursuant to which Oxford Finance consented to our entry into the CIRM Award and certain provisions of the Loan Agreement were amended in connection therewith.

On September 29, 2025, we received the Default Notice from Oxford Finance, with respect to the Loan Agreement. The Default Notice asserted that an Event of Default had occurred and was continuing under the Loan Agreement and alleged that other events of default under the Loan Agreement may exist. In the Default Notice, Oxford Finance declared by reason of the Event of Default, that all of our obligations under the Loan Agreement were immediately due and payable. In addition, the Default Notice indicated that our obligations under the Loan Agreement began accruing interest at the Default Rate (as defined in the Loan Agreement) effective immediately upon occurrence of the Event of Default. The total amount of our obligations under the Loan Agreement as of the date of the Default Notice that were accelerated and declared payable by Oxford Finance was $29.1 million, plus any additional interest due upon final payment and any expenses that become payable by us under the Loan Agreement.

On October 19, 2025, pursuant to the terms of the Loan Agreement, Oxford Finance informed us that it intended to foreclose on all of our remaining assets and that Oxford Finance would not consent to the Company's use of cash for any reason other than for minimal payroll and related expenses pending Oxford Finance's foreclosure of the Company's assets. Oxford then swept substantially all of our cash resources from our bank accounts. On November 3, 2025, Oxford Finance informed us that it intended to pause its foreclosure of the Company's assets and permitted us to use $125,000 of cash it previously swept to fund the negotiation and execution of the Convertible Loan Agreement and to fund preliminary preparation work on the Quarterly Report on Form 10-Q for the quarter ended September 30, 2025.

On November 25, 2025, the Company entered into the Settlement Agreement with Oxford Finance pursuant to which the Company owed Oxford Finance $2.0 million to be paid pursuant to the terms of the Settlement Agreement. On December 26, 2025, the Company paid Oxford Finance the settlement agreement amount of $2.0 million. As a result of such payment, all of its obligations under the Settlement Agreement and the Loan Agreement have been satisfied and the aggregate liability due to Oxford Finance of approximately $10,600 has been settled and released.

Convertible Loan Agreement

On November 9, 2025, the Company entered into the Convertible Loan Agreement with David Lazar, pursuant to which the David Lazar agreed to provide the Company a convertible loan in the aggregate amount of up to $375,000, which was received in November 2025 and repaid in December 2025.

Settlement Agreements

On December 30, 2025, the Company entered into a settlement agreement with Baker Bros. Advisors LP ("Baker Bros") under which the Company agreed to issue 900,000 shares of Common Stock to resolve certain claims relating to participation rights under prior financing arrangements (the "Baker Settlement"). In connection with the Baker Settlement, the Company and Baker Bros also entered into a voting agreement under which Baker Bros granted an irrevocable proxy in favor of the Company to vote the settlement shares and other specified shares in line with the Board's recommendations for a period of 6 months.

On December 30, 2025, the Company entered into a settlement agreement with LifeSci Capital LLC under which the Company agreed to issue 2,200,000 shares of Common Stock to settle certain payment obligations for financial advisory services.

On December 30, 2025, the Company entered into a consulting agreement and a settlement agreement with Delaware IR LLC ("Delaware IR"). Under the consulting agreement, Delaware IR agreed to provide marketing and advertising services for a six-month term for $600,000. Under the settlement agreement, the Company agreed to issue 1,100,000 shares of Common Stock to settle the outstanding $600,000 amount owed under the consulting agreement, with a make-whole mechanic tied to ultimate net sale proceeds from the future sales of the 1,100,000 shares of Common Stock.

December 2025 Registered Direct Offering

On December 4, 2025, we entered into a securities purchase agreement (the "December 2025 Purchase Agreement") with a certain institutional investor (the "RD Investor"), pursuant to which the Company agreed to issue and sell in a registered direct offering (the "RD Offering") (i) 900,000 shares of the Company's Common Stock and (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to an aggregate of 9,100,000 shares of Common Stock (the "Pre-Funded Warrant Shares"), at a purchase price of $1.00 per Pre-Funded Warrant Share (less $0.0001 per Pre-Funded Warrant). The gross proceeds to the Company from the RD Offering was approximately $10.0 million before deducting placement agent fees and other offering expenses payable by the Company.

The shares of Common Stock, Pre-Funded Warrants and Pre-Funded Warrant Shares were offered by the Company pursuant to an effective shelf registration statement on Form S-3 (File No. 333-270263) which was filed with the Securities and Exchange Commission (the "SEC") on March 3, 2023, as amended, and declared effective by the SEC on May 11, 2023, and related base prospectus and a prospectus supplement dated December 4, 2025, thereunder.

The Pre-Funded Warrants have an initial exercise price per share of $0.0001, subject to certain adjustments. The Pre-Funded Warrants may be exercised at any time until exercised in full, except that a holder (together with its affiliates) will not be entitled to exercise any portion of any Pre-Funded Warrant, which, upon giving effect to such exercise would cause the aggregate number of shares of the Company's Common Stock beneficially owned by the holder (together with its affiliates) to exceed 4.99% (or, upon election of the holder, 9.99%) of the number of shares of Common Stock outstanding immediately prior to or after giving effect to the exercise, subject to such holder's rights under the Pre-Funded Warrants to increase or decrease such percentage to another percentage not in excess of 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Funded warrants, provided that any increase shall only be effective upon at least 61 days' prior notice from such holder to the Company. The Offering closed on December 5, 2025.

Pursuant to the terms of the Purchase Agreement, the Company has agreed to certain restrictions on the issuance and sale of its Common Stock or Common Stock Equivalents (as defined in the December 2025 Purchase Agreement) until 30 days following the closing date, and not to issue any Common Stock or Common Stock Equivalents

in a Variable Rate Transaction (as defined in the December 2025 Purchase Agreement) for one year from the closing date, subject to an exception as contained therein.

Private Placements

On November 23, 2025, we entered into a Securities Purchase Agreement (the "November 2025 Purchase Agreement"), with David Lazar, an investor, pursuant to which we agreed to issue and sell, in a private placement, shares of our Series AA Convertible Non-Redeemable Preferred Stock (the "Series AA Preferred Stock"), and our Series AAA Convertible Non-Redeemable Preferred Stock (the "Series AAA Preferred Stock"), in two closings for aggregate gross proceeds of up to approximately $6.0 million.

The closing of the private placement of the Series AA Preferred Stock (the "Series AA Private Placement") occurred on November 24, 2025, pursuant to which we issued and sold to David Lazar an aggregate of 900,000 shares of Series AA Preferred Stock at a price per share equal to $2.00, for aggregate gross proceeds of approximately $1.8 million. Each share of Series AA Preferred Stock is convertible into 55 shares of Common Stock for an aggregate total of 49,500,000 shares of Common Stock issuable upon conversion of the Series AA Preferred Stock.

On January 30, 2026, the Company entered into a Securities Purchase Agreement (the "January 2026 Purchase Agreement"), pursuant to which we issued and sold to the "Series AAA Investors" in a private placement (the "January 2026 Private Placement"), an aggregate of 2,100,000 shares of Series AAA Preferred Stock at a price per share equal to $2.00, for aggregate gross proceeds of $4.2 million. The closing of the January 2026 Private Placement occurred on January 30, 2026. Each share of Series AAA Preferred Stock was convertible into 420 shares of Common Stock for an aggregate total of 882,000,000 shares of Common Stock issuable upon conversion of the Series AAA Preferred Stock. As of the date of this Annual Report on Form 10-K, all of the shares of Series AAA Preferred Stock have been converted into shares of Common Stock and there are no Series AAA Preferred Shares of the Company outstanding.

Series AA Preferred Stock

We filed the Certificate of Designations for the Series AA Preferred Stock (the "Series AA Preferred Stock") with the Secretary of State of the State of Delaware on November 24, 2025. Pursuant to the Series Certificate of Designations, in the event of a Dissolution (as defined in the Series AA Certificate of Designations), holders of the Series AA Preferred Stock will be entitled to receive, before any distributions to the holders of the Common Stock, an amount per share of Series AA Preferred Stock equal to the greater of (i) $2.00 (subject to adjustment in the event of any stock split, combination or reclassification), plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Series AA Preferred Stock been converted into Common Stock (without regard to any restrictions on conversion) immediately prior to such Dissolution. Shares of Series AA Preferred Stock will be entitled to receive dividends equal to (on an as-if-converted-to-Common Stock basis), and in the same form and manner as, dividends actually paid on shares of Common Stock. For the avoidance of any doubt, neither a change in control of the Company, the merger or consolidation of the Company with or into any other entity, nor the sale, lease, exchange or other disposition of all or substantially all of the Company's assets shall, in and of itself, be deemed to constitute a Dissolution.

Shares of Series AA Preferred Stock generally have no voting rights, except to the extent provided by applicable law, and except that the consent of the holders of a majority of the outstanding shares of Series AA Preferred Stock is be required to (i) alter, repeal or change the powers, preferences or rights of the Series AA Preferred Stock or alter or amend the Series AA Certificate of Designations so as to adversely affect the Series AA Preferred Stock, (ii) supplement, amend, restate, repeal, or waive any provision of the Company's Restated Certificate of Incorporation or Bylaws, or file any certificate of amendment, certificate of designation, preferences, limitations and relative rights of any series of preferred stock, if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the Series AA Preferred Stock, regardless of whether any of the foregoing actions shall be by means of amendment to the Company's Restated Certificate of Incorporation or by merger, consolidation, recapitalization, reclassification, conversion or otherwise, (iii) increase or decrease (other than by conversion) the number of authorized shares of Series AA Preferred Stock; or (iv) enter into any agreement with respect to any of the foregoing.

Off-Balance Sheet Arrangements

We have no material off-balance sheet arrangements that are reasonably likely to have a material effect on our liquidity, capital resources, or results of operations.

Contractual Obligations and Commitments

We previously entered into an operating lease for office, laboratory and research and development space in Menlo Park, California. In November 2025, we terminated the lease and entered into a settlement with the landlord, and the settlement was paid prior to December 31, 2025. As a result, we did not have any material remaining operating lease payment obligations as of December 31, 2025.

We currently lease a limited amount of office space in Arlington, Massachusetts, which serves as our corporate headquarters. The lease is currently for six months, starting 2025 with approximately $3,000 monthly rent.

We have ongoing obligations under our Stanford Agreement, including annual license maintenance fees in the low-to-mid five figures, which are creditable against earned royalties for the same year, potential development and regulatory milestone payments of up to approximately $1.1 million in the aggregate, potential sales milestone payments up to approximately $1.1 million in the aggregate and tiered royalties on net sales of licensed products and a sublicense revenue-sharing payment. The annual maintenance fees represent recurring obligations. The milestone payments and royalties are contingent on future development, regulatory and commercialization outcomes (and, for royalties, future sales), and therefore the amounts and timing of any such payments are not determinable at this time.

We may be required to make future milestone-based payments under the Combangio Merger Agreement, including contingent consideration related to the Combangio acquisition, as well as under the CIRM Award.

For information related to our future commitments, see Note 14, “Commitments and Contingencies” of our consolidated financial statements.

Cash Flows

As of December 31, 2025 and 2024, we had $7.6 million and $51.2 million in cash and cash equivalents, respectively. As of December 31, 2025 and 2024, we had $0 million and $29.3 million in indebtedness, respectively, which represented the aggregate principal amount that was outstanding under the Loan Agreement with Oxford Finance.

The following table summarizes our sources and uses of cash for each of the periods presented:

	Year Ended December 31,		
	2025	2024	Change
	(in thousands)		
Net cash used in operating activities	$ (31,991)	$ (29,382)	$ (2,609)
Net cash used in investing activities	(15)	(208)	193
Net cash (used in) provided by financing activities	(11,618)	29,876	(41,494)
Net decrease in cash and cash equivalents	$ (43,624)	$ 286	$ (43,910)

Operating Activities

Net cash used in operating activities for the year ended December 31, 2025 was $32.0 million, compared to $29.4 million for the year ended December 31, 2024, an increase of $2.6 million, primarily due to a $4.3 million increase due to the timing of working capital fluctuations, partially offset by the decrease in the net loss adjusted for non-cash charges of $1.7 million. Notable working capital fluctuations included a $3.8 million decrease in accounts payable, accrued expenses and other current liabilities during the year ended December 31, 2025, compared to a decrease of $1.8 million during the year ended December 31, 2024.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2025 was less than $0.1 million compared to $0.2 million for the year ended December 31, 2024, a decrease of $0.1 million. Net cash used in investing activities for the year ended December 31, 2025 and 2024 were related to purchases of property and equipment and other assets.

Financing Activities

Net cash used in financing activities for the year ended December 31, 2025 was $11.6 million compared to net cash provided by financing activities for the year ended December 31, 2024 of $29.9 million. Net cash used in financing activities for the year ended December 31, 2025 largely consisted of $22.4 million repayment of principal and payment fee on our Oxford Loan Agreement, partially offset by $9.1 million of net proceeds from our Common Stock offering and $1.8 million of proceeds from the issuance of our Series AA Preferred Stock.

Net cash provided by financing activities for the year ended December 31, 2024 was $29.9 million. Net cash provided by financing activities for the year ended December 31, 2024 largely consisted of $10.8 million of gross proceeds from the sale of Common Stock and shares of our Series I Preferred Stock in our December 2024 private placement, $12.3 million of net proceeds from the sale of Common Stock and shares of our Series H Preferred Stock in our June 2024 private placement, $8.5 million of net proceeds from the sale of shares of our Series G Preferred Stock in our March 2024 private placement and $3.4 million of net proceeds from the sale of shares of our Common Stock through Jefferies under our at-the-market equity offering, partially offset by a $5.0 million repayment of principal and payment fee on our Loan Agreement and a $0.1 million payment for the First Dosing Milestone reflected in financing activities.

Capital Requirements

We anticipate that our research and development expenses will increase substantially in the future as compared to prior periods as we strategically align our business to the development of the Researgency platform. Our research and development expenses will also increase in the future as we conduct any necessary evaluations and development activities for our the AI business. While the clinical trials relating to our product candidates are currently on hold, if we decide to relaunch the studies and if we obtain marketing approval for KPI-012 or any product candidates we may develop, we expect that our general and administrative expenses will increase substantially if and as we incur commercialization expenses related to product marketing, sales and distribution.

Our expenses will also increase if and as we:

- continue the clinical development of KPI-012 for PCED;
- initiate and continue the research and development of KPI-012 for additional indications, such as Limbal Stem Cell Deficiency, including initiating and conducting preclinical studies and clinical trials;
- scale up our manufacturing processes and capabilities to manufacture the clinical supply of KPI-012;
- seek regulatory approval for KPI-012 for PCED in the United States and other jurisdictions;
- seek regulatory approval for KPI-012 for additional indications;
- grow our sales, marketing and distribution capabilities in connection with the commercialization of any product candidates for which we may submit for and obtain marketing approval;
- initiate and progress any preclinical development programs under our MSC-S platform, including from our KPI-014 program;
- conduct clinical trials and other development activities and/or seek marketing approval for any product candidates we may develop in the future;

- in-license or acquire the rights to other products, product candidates or technologies;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control, scientific, manufacturing, commercial and management personnel to support our operations;
- expand our operational, financial and management systems; and
- increase our product liability insurance coverage if we initiate commercialization efforts for our product candidates.

We expect to continue to incur significant expenses and operating losses. Net losses may fluctuate significantly from quarter-to-quarter and year-to-year. We anticipate that our cash and cash equivalents as of December 31, 2025 will enable us to fund our operations, lease and debt service obligations, and capital expenditure requirements into the first quarter of 2027.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses will increase from what we anticipate if:

- we elect or are required by the FDA or non-U.S. regulatory agencies to perform clinical trials or studies in addition to those expected;
- there are any delays in enrollment of patients in or completing our clinical trials or the development of our product candidates;
- we in-license or acquire rights to other products, product candidates or technologies; or
- there are any third-party challenges to our intellectual property portfolio, or the need arises to defend against intellectual property-related claims or enforce our intellectual property rights.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate revenue from Researgency, KPI-012 or any other product candidate we may develop for the foreseeable future, if at all. Achieving and maintaining profitability will require us to be successful in a range of challenging activities, including:

- completing the clinical development of KPI-012 for PCED and any other indications we determine to pursue, including Limbal Stem Cell Deficiency;
- subject to obtaining favorable results from our ongoing and planned clinical trials of KPI-012, applying for and obtaining marketing approval of KPI-012;
- successfully commercializing KPI-012, if approved;
- discovering, developing and successfully seeking marketing approval and commercialization of any additional product candidates we may develop in the future, including under our KPI-014 program;
- hiring and building a full commercial organization required for marketing, selling and distributing those products for which we obtain marketing approval;
- manufacturing at commercial scale, marketing, selling and distributing those products for which we obtain marketing approval;

- achieving an adequate level of market acceptance, and obtaining and maintaining coverage and adequate reimbursement from third-party payors for any products we commercialize; and

- obtaining, maintaining and protecting our intellectual property rights.

As a company, we have limited experience commercializing products, and we may not be able to commercialize a product successfully in the future. There are numerous examples of unsuccessful product launches and failures to meet expectations of market potential, including by pharmaceutical companies with more experience and resources than us. We may never succeed in the foregoing activities and we may never generate revenue that is sufficient to achieve profitability. 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 would 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 product offerings or even continue our operations.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, royalty agreements, and marketing and distribution arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include pledging of assets as collateral, covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

We will need to raise additional capital in the future to advance our business. Additional private or public financings may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a material adverse effect on our financial condition and our ability to pursue our business strategy. If we raise additional funds through collaborations, strategic alliances, licensing arrangements, royalty agreements, or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or current or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves or cease operations and, potentially, wind down the company under the bankruptcy laws or otherwise. If we were to cease operations and wind down the company under the bankruptcy laws or otherwise, we cannot assure our stockholders or other stakeholders of any specific level of recovery, or any recovery at all on their specific claims or interest.

Known Trends, Events and Uncertainties

The following known trends and uncertainties are reasonably likely to have a material effect on our liquidity, financial condition and results of operations over the next 12 months: the absence of revenue-generating commercial products and our reliance on external financing, asset monetization and/or partnering to fund operations; the timing, structure and probability of any out-licensing or collaboration for KPI-012/KPI-014 and related IP; the execution and commercialization risks for our Researgency initiative, including regulatory roadblocks, customer adoption cycles, pricing and deployment costs; the effects of prior workforce reductions; and conditions in the capital markets, including our ability to utilize our shelf and ATM programs within applicable limits. These factors are reasonably likely to affect our results of operations, financial condition and liquidity over the next 12 months. In addition, the consequences of the ongoing geopolitical conflicts, such as the ongoing conflict between Russia and Ukraine and the ongoing conflicts in the Middle East, including related sanctions and countermeasures, and the effects of rising global inflation, are difficult to predict, and could adversely impact geopolitical and macroeconomic conditions, the global economy, and contribute to increased market volatility, which may in turn adversely affect our business and operations. In the past, U.S. federal government shutdowns, such as the shutdown that began on October 1, 2025 and ended on November 12, 2025, have curtailed operations of key agencies such as the FDA. Although we cannot predict the impact, if any, of these changes to our business, they could have an adverse impact. For a further discussion of factors that may affect future operating results see the sections entitled “Risk Factors” in this Annual Report on Form 10-K.

Recently Issued Accounting Pronouncements

From time to time the Financial Accounting Standards Board or other standard-setting bodies, issue new accounting pronouncements. Where applicable, we adopt these new standards according to the specified effective dates. Unless otherwise disclosed in Note 2, "Summary of Significant Accounting Policies" to the consolidated financial statements appearing at the end of this Annual Report on Form 10-K, we believe that the impact of any recently issued accounting pronouncements that are not yet effective will not have a material impact on our financial position or results of operation upon adoption.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Our financial instruments as of December 31, 2025 consisted primarily of cash. Due to the short-term maturities of our cash, an immediate 10% change in interest rates would not have an effect on the fair market value of our cash.

As of December 31, 2025 and 2024, the aggregate principal amount outstanding under the Loan Agreement was $0 million and $29.3 million, respectively. The aggregate principal amount outstanding under the Loan Agreement bore interest through June 30, 2023 at a floating rate equal to the greater of (i) 30-day LIBOR and (ii) 0.11%, plus 7.89%. Effective July 1, 2023, the aggregate principal amount outstanding under the Loan Agreement bears interest at a floating rate equal to the greater of (i) 8.00% and (ii) the sum of (a) the 1-Month CME Term SOFR, (b) 0.10% and (c) 7.89% per annum. An immediate 10% change in the 1-Month CME Term SOFR rate would not have a material impact on our operating results or cash flows. In December 2025, pursuant to the terms of the Settlement Agreement with Oxford, we made a payment of $2 million and effective immediately upon such payment, settled all Oxford debt obligations.

Item 8. Financial Statements and Supplementary Data

Our financial statements, together with the report of our independent registered public accounting firm, appear on pages F-1 through F-35 of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

On December 15, 2025, the Audit Committee of the Board approved the dismissal of Deloitte & Touche LLP ("Deloitte") as the Company's independent registered public accounting firm, effective as of December 15, 2025.

The audit reports of Deloitte on the Company's consolidated financial statements as of and for the fiscal years ended December 31, 2024 and 2023 did not contain an adverse opinion or a disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principles.

During the Company's fiscal years ended December 31, 2024 and 2023, and the subsequent interim periods through December 15, 2025, (i) there were no disagreements (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) with Deloitte on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to Deloitte's satisfaction, would have caused Deloitte to make reference to the subject matter of the disagreement in connection with its reports on the Company's financial statements, and (ii) there were no "reportable events" (as defined in Item 304(a)(1)(v) of Regulation S-K).

On December 19, 2025, the Audit Committee approved the engagement of HTL International, LLC ("HTL") as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2025. During the Company's fiscal years ended December 31, 2024 and 2023, and the subsequent interim period through December 19, 2025, neither the Company, nor anyone on its behalf, consulted HTL regarding (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's financial statements, and neither a written report nor oral advice was provided to the Company that HTL concluded was an important factor considered by the Company in reaching a decision as to any accounting, auditing, or financial reporting issue, (ii) any matter that was the subject of a disagreement within the meaning of Item 304(a)(1)(iv) of Regulation S-K, or (iii) any matter that was either the subject of a disagreement (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions to Item 304 of Regulation S-K) or a reportable event of the type described in Item 304(a)(1)(v) of Regulation S-K.

Item 9A. Controls and Procedures

Evaluation of disclosure controls and procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2025, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were not effective.

Management's annual report on internal control over financial reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for the company. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. 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.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated Framework (2013).

Based on that assessment and the most recent change in business strategy, our management noted the following deficiency that was believed to be material weakness.

- Insufficient personnel following the Company's restructuring has resulted in key controls over the financial reporting process not being fully implemented or operating effectively to support financial reporting in accordance with U.S. GAAP and SEC reporting requirements.

Our management is planning to implement the following to remediate the above mentioned deficiency:

(i) hiring additional accounting and financial personnel to address the staffing shortage following the Company's restructuring and to support the proper design and operation of key controls over financial reporting; and

(ii) organizing regular training for accounting staff to enhance their understanding of U.S. GAAP and SEC reporting requirements and to strengthen the execution of key controls; and

(iii) developing and implementing a U.S. GAAP accounting policies and procedures manual, which will be maintained, reviewed, and updated on a regular basis to support consistent application of accounting standards and improve the effectiveness of financial reporting controls.

As a non-accelerated filer and a "smaller reporting company", as defined in Rule 12-b-2 under the Exchange Act, our independent registered public accounting firm is not required to issue an attestation report on the internal control over financial reporting.

Changes in internal control over financial reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fourth quarter ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

(a) Loan and Security Agreement

On February 9, 2026, the Company made the Loan in the principal amount of $7,000,000 evidenced by a secured promissory note to the Borrower, Minglemint Solutions LLC in connection with the Company's determination that a portion of its cash on hand was in excess of its near-term working capital requirements and operational needs. In order to optimize the return on such excess cash, rather than holding the full balance in a bank deposit account, which offered a materially lower yield, the Company elected to deploy that portion into the Loan, which bears interest at a rate of 8.0% per annum. The Company believes that the interest rate obtained under the Loan, together with the security interest granted to the Company over all fixtures and personal property of the Borrower, provides a more favorable risk-adjusted return on idle cash than the return available through conventional bank deposit arrangements, while preserving the Company's ability to meet its anticipated working capital and operational obligations. The Loan bears interest at a rate of 8.0% per annum, and is due and payable on February 9, 2027.

The Note includes customary event of default provisions, including, but not limited to, for a breach of any representations and warranties or covenants, any bankruptcy or insolvency proceedings of the Borrower, and the failure of the Borrower to pay, upon 15 days' written notice of default, any principal amount of the Loan or interest due. The Note provides for a default interest rate of 13.0%. As described in the Note, upon the occurrence of certain events of default, the Company may, among other remedies, declare the outstanding balance of the Note including all accrued interest thereon immediately due and payable.

Additionally, the Note is secured by the Collateral, a continuing first priority lien and security interest in all fixtures and personal property of the Borrower, pursuant to the Security Agreement with the Borrower dated February 9, 2026. The Collateral includes, but is not limited to, all accounts, goods, documents, instruments, securities and investment properties, money, accounts and rights to payment of the Borrower, and any proceeds, records and obligations relating to the foregoing, as more fully detailed in the Security Agreement.

(b) 10b-1 Insider Trading Arrangements

None of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) during the three months ended December 31, 2025.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

Part III

Item 10. Directors, Executive Officers and Corporate Governance

Executive Officers and Directors

Set forth below are the names, ages as of March 31, 2026 and positions of each of the current directors and executive officers of the Company. Each director has served on the Board since January 2026.

Name	Age	Position
Executive Officers		
Avi Minkowitz	38	Chief Executive Officer, Chief Financial Officer and Director
Directors		
Avi Minkowitz	38	Chief Executive Officer, Chief Financial Officer and Director
Chaim (Dovi) Berger (1) (3)	45	Director
Yonatan Colman (1) (2)	41	Director
Brendan Purdy (2) (3)	39	Director
Hillel Posen (1) (2) (3)	36	Director

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

(3) Member of the Nominating and Corporate Governance Committee.

Composition of the Board of Directors

The number of directors of the Company is established by the Board, subject to the rights of holders of any of series of preferred stock of the Company to elect directors. The Board consists of three classes: Class I, Class II and Class III. Each class consists of one-third of the total number of directors constituting the entire Board. The allocation of directors among classes is determined by resolution of the Board.

Our Board currently consists of 5 members divided into 3 classes, with members of each class holding office for staggered 3-year terms. There are currently 2 Class I directors, Hillel Posen and Chaim (Dovi) Berger, whose terms expire at the 2027 annual meeting of stockholders; 1 Class II director, Avi Minkowitz, whose term expires at the 2028 annual meeting of stockholders; and 2 Class III directors, Yonatan Colman and Brendan Purdy, whose terms expire at the 2026 annual meeting of stockholders (in all cases subject to the election and qualification of their successors or to their earlier death, resignation or removal).

Executive Officer and Directors Biographies

Avi Minkowitz has served as a director of the Company since January 2026 and as Chief Executive Officer and Chief Financial Officer of the Company since February 2026. He has been a director at NuRAN Wireless (CSE-listed) since November 2025 and at International Star Inc. (OTC-listed) since October 2022, reflecting his broad involvement in public company governance. From January 2021 to October 2024, Mr. Minkowitz was a member of the team at Leonite Capital, where he contributed to deal structuring and strategic growth, with direct responsibilities spanning underwriting and portfolio management. Earlier in his career, he founded and successfully exited two businesses. Mr. Minkowitz has extensive experience with both public and private companies across real estate financing, management, and capital markets, including work with NorthLink Properties Ltd., a private real estate family office based in Toronto; Smart Parking Solutions Canada Inc., a company he co-founded and sold to Parkit Enterprise Inc. in 2018; and Parkit

Enterprise Inc., a TSX-listed public company (symbol: PKT), where he subsequently served as VP of Acquisitions. He has advised startups and finance firms and has been involved in community-based entrepreneurship initiatives, including teaching real estate. Mr. Minkowitz holds a Specialized Honours bachelor's in psychology and a Master's in Disaster and Emergency Management from York University (Toronto). We believe that Mr. Minkowitz's experience as an entrepreneur and finance professional spanning real estate, private equity, and business development makes him a highly qualified member of our Board.

Chaim (Dovi) Berger serves as Managing Attorney at Berger Law Firm LLC, a New York-based law firm where he has provided lead transactional counsel to a multi-strategy family office, overseeing deal structuring, negotiation, and execution across private equity, real estate, and specialty finance transactions since July 2019. Mr. Berger has also served as an Assistant Professor at Touro College since September 2007, teaching courses in accounting, finance, and law. He previously worked at Deloitte Tax from 2007 to 2009 and is a licensed CPA in New York State. Mr. Berger has held executive positions in finance roles at Edison Home Health Care and Reliance Global Holdings. He currently serves as a director of Nova Minerals Ltd., an Australian public company, where he is a member of the Audit Committee. We believe Mr. Berger's legal expertise and experience with negotiating and executing financing transactions qualifies him to serve as a member of our board of directors.

Hillel Posen has served on the board of directors of Rio Verde Industries Inc. since December 2020, where he also serves on the Audit Committee. He has served as Regional Operations Manager for High Tide Inc., a publicly traded national retail chain with over 200 stores across Canada since October 2018, where he oversees store openings, staffing and scheduling, procurement initiatives, and coordination among construction, compliance, marketing, sales, HR, and IT functions. Prior to his current role, Mr. Posen held a series of positions with this national retail chain, including business development and customer service roles supporting retail store purchasing, vendor relationships, and process efficiencies. Mr. Posen holds a Bachelor of Judaic Studies from Talpiot College. We believe Mr. Posen has expertise in business development and operations which qualifies him to serve as a director.

Yonatan Colman has served as Director of Leadership Development at NCSY since 2008, where he oversees organizational growth through talent development with a focus on people, strategy, and transformation. Mr. Colman regularly consults internationally, helping executives and their organizations transform, lead change, and build thriving, people-focused cultures. He holds a B.A. in Psychology from York University and an M.S. in Organizational Leadership from Colorado State University Global. Mr. Colman has served as a director of Rio Verde Industries Inc. since December 2020 and as a director of Newfoundland Goldbar Resources Inc. since May 2021, serving on the Audit Committee of each. He has also served as a board member of Yeshivas Limudei Hashem Society, a registered charity, since November 2021. He previously served as a director and Audit Committee member of Global Tactical Metals Corp. from November 2021 to December 2022 and of Green Scientific Labs Holdings Inc. from July 2021 to November 2021. Mr. Colman's qualifications to serve on the Board include his expertise in organizational leadership and strategy, his international consulting experience, and his service on the boards and audit committees of multiple public companies.

Brendan Purdy is a practicing securities lawyer and has served as a Partner at Fish Purdy LLP since June 2022. Prior to that, he served as President and Director of Purdy Law Professional Corporation from February 2018 to June 2022. Mr. Purdy's private practice is focused on the resource, life sciences, and technology sectors, where he has developed extensive experience with respect to public companies, capital markets, mergers and acquisitions, and other transactions fundamental to the junior equity markets. He also served as CEO and Director of Canadian GoldCamps Corp. from November 2020 to April 2024, and as CEO and Director of Musk Ventures Ltd. from November 2020 to September 2025. Mr. Purdy holds a J.D. from the University of Ottawa and a Bachelor of Management and Organizational Studies degree from the University of Western Ontario, where he majored in finance and administration. Mr. Purdy has served as a director and Audit Committee member of Red White & Bloom Brands Inc., a CSE-listed company, since July 2017, of NuRan Wireless Inc., a CSE-listed company, since October 2020, of i3 Interactive Inc. since March 2021, and of Slam Exploration Ltd., a CSE-listed company, since July 2021. He previously served as a director of Canadian GoldCamps Corp., a CSE-listed company, from December 2016 to April 2024, of DGTL Holdings Inc., a TSXV-listed company, from April 2022 to October 2024, of Musk Ventures Ltd., a CSE-listed company, from November 2020 to September 2025, of Wellbeing Digital Sciences Inc. from January 2021 to January 2024, of Powertap Hydrogen Capital Corp., a CSE-listed company, from March 2019 to February 2023, and of Talent Infinity Resource Developments Inc., a CSE-listed company, from December 2016 to April 2024. Mr. Purdy's qualifications to serve on the Board include his legal expertise in securities law and capital markets, his experience as a CEO of public companies, and his extensive public company board service.

Director Selection; Arrangements and Understandings

As required by Item 401(a) of Regulation S-K, we note the following arrangements or understandings with other persons pursuant to which certain individuals on our Board were selected as directors.

Mr. Minkowitz, Mr. Posen, Mr. Berger, Mr. Colman and Mr. Purdy were each selected to serve on our Board pursuant to an arrangement or understanding with AK Holdings in connection with the transactions described in the "Certain Relationships and Related Transactions, and Director Independence" of this Annual Report on Form 10-K.

Family Relationships

There are no family relationships among our directors or executive officers.

Involvement in Certain Legal Proceedings

Except as described below, none of our directors or executive officers has been involved in any of the legal proceedings required to be disclosed pursuant to Item 401(f) of Regulation S-K during the past ten years.

On May 3, 2019, Mr. Purdy was the subject of a hearing by the Law Society of Ontario relating to a failure to provide a timely response to a client complaint and to meet certain related deadlines; the matter was disposed of in May 2019 and resulted in a reprimand, and Mr. Purdy remains a member of the Law Society of Ontario.

In addition, Mr. Minkowitz, in his capacity as a director of International Star Inc., is among the directors named in litigation in Ontario arising from a dispute relating to the termination of a former officer of International Star Inc. International Star Inc. previously initiated litigation in Delaware against that former officer alleging material breach of contract.

Audit Committee and Audit Committee Financial Expert

The members of our Audit Committee of the Board are Mr. Posen, Mr. Colman and Mr. Berger. Mr. Berger is the chair of the Audit Committee. Our Board has determined that Mr. Berger is an "audit committee financial expert" as defined in applicable SEC rules. Our Board has determined that each member of our Audit Committee is "independent" as defined under applicable Nasdaq rules and satisfies the independence criteria set forth in Rule 10A-3 under the Exchange Act.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics (the "Code") that applies to our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer. A copy of the Code is available on the "Investors-Corporate Governance" section of our website, which is located at www.kalarx.com. Our Board is responsible for overseeing the Code and must approve any waivers of the Code. If we make any substantive amendments to, or grant any waivers from, the Code for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a Current Report on Form 8-K.

The information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K or in any other report or document we file with the SEC, and any reference to our website address is intended to be an inactive textual reference only.

Insider Trading Policy

We have adopted an Insider Trading Policy governing the purchase, sale and/or other dispositions of our securities by our directors, officers, employees and other covered persons. We believe the Insider Trading Policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, and Nasdaq listing standards. A copy of our Insider Trading Policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K. It is also our policy that we do not engage in transactions in our securities while in possession of material nonpublic information concerning the company or our securities.

Item 11. Executive Compensation

Executive and Director Compensation Processes

Our executive compensation program is administered by the compensation committee of our board of directors, subject to the oversight and approval of our board of directors. Our compensation committee reviews our executive compensation practices on an annual basis and based on this review approves, or, as appropriate, makes recommendations to our board of directors for approval of our executive compensation program. In designing our executive compensation program, our compensation committee considers publicly available compensation data for national and regional companies in the biotechnology/pharmaceutical industry to help guide its executive compensation decisions at the time of hiring and for subsequent adjustments in compensation. Our director compensation program is administered by our board of directors with the assistance of the compensation committee. The compensation committee conducts an annual review of director compensation and makes recommendations to the board of directors with respect thereto.

Since January 2023, our compensation committee has retained Pearl Meyer & Partners, LLC, or Pearl Meyer, as our independent compensation consultant for compensation matters. During the year ended December 31, 2024, our compensation committee directly engaged Pearl Meyer to provide comparative data on executive compensation practices in our industry and to advise on our executive and director compensation programs generally. Although our compensation committee considers the advice and guidelines of Pearl Meyer, our compensation committee ultimately makes its own decisions about these matters and recommendations to our board about these matters.

In the future, we expect that our compensation committee will continue to engage independent compensation consultants to provide additional guidance on our executive compensation programs, our director compensation programs and to conduct further competitive industry benchmarking against a peer group of publicly traded companies.

The compensation committee reviewed information regarding the independence and potential conflicts of interest of Pearl Meyer, taking into account, among other things, the factors set forth in the Nasdaq listing standards. Based on such review, the compensation committee concluded that the engagement of Pearl Meyer did not raise any conflict of interest.

Under its charter, the compensation committee may form, and delegate authority to, subcommittees, consisting of independent directors, as it deems appropriate. During fiscal year 2024, the compensation committee did not form or delegate authority to such subcommittees. In addition, under its charter, the compensation committee may delegate to one or more executive officers the power to grant options, restricted stock units, or RSUs, or other stock awards pursuant to our Amended and Restated 2017 Equity Incentive Plan to employees who are not directors or executive officers. During fiscal year 2024, the compensation committee delegated authority to our Chief Executive Officer to grant certain options and RSUs to non-executive employees with respect to annual equity awards and high performance awards throughout the year.

Executive Compensation

The following discussion relates to the compensation of: Mark Iwicki, former CEO and principal executive officer (who served until February 2025); Todd Bazemore, former CEO and principal executive officer (who served from February 2025 until November 2025); Kim Brazzell, Ph.D., former Head of Research and Development and Chief Medical Officer; and Mary Reumuth, former Chief Financial Officer.

David Lazar, who served as CEO of the Company from November 2025 until February 2, 2026 (subsequent to the reporting period) did not receive any compensation in connection with his role as CEO.

Summary Compensation Table

The following table sets forth information regarding the compensation awarded to or earned by the current and former executive officers listed below during the years ended December 31, 2025, and 2024. We have opted to comply with the reduced executive compensation disclosure rules applicable to “smaller reporting companies,” as such term is defined in the rules promulgated under the Securities Act, which require compensation disclosure for only (i) principal executive

officer, (ii) two most highly compensated executive officers other than our principal executive officer and (iii) if applicable, up to two individuals who would have qualified as our two most highly compensated executive officers other than the principal executive officer but for the fact that the individual was not serving as an executive officer of the Company at the end of the last completed fiscal year. Throughout this document, the officers below are referred to as our "named executive officers" or "NEOs".

Name and Principal Position	Year	Salary ($)	Bonus ($)(1)	Stock Awards ($)(2)	Option Awards ($)(3)	All other Compensation ($)(4)	Total ($)
Mark Iwicki	2025	111,866	—	166,413	627,467	896	906,642
Former Chief Executive Officer	2024	709,394	297,945	100,100	377,628	6,120	1,491,187
Todd Bazemore	2025	489,112	585,450	76,053	2,262,211	64,146	3,476,972
Former Interim Chief Executive Officer, President and Chief Operating Officer	2024	535,600	187,460	45,500	171,543	9,447	949,550
Kim Brazzell, Ph.D.	2025	420,000	522,000	76,053	285,040	55,081	1,358,174
Former Head of Research and Development and Chief Medical Officer	2024	520,000	163,800	45,500	171,543	19,844	920,687
Mary Reumuth	2025	438,962	475,550	76,053	285,040	47,002	1,322,608
Former Chief Financial Officer	2024	468,000	147,420	32,200	120,021	10,627	778,269

(1) The amounts reported in the "Bonus" column reflect discretionary annual cash bonuses and retention bonuses earned by our named executive officers for their performance in the years ended December 31, 2025 and 2024.

(2) The amounts reported in the "Stock Awards" column reflect the aggregate grant date fair value of RSUs granted during the periods presented, computed in accordance with the provisions of Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 718. For the assumptions underlying the valuation of such RSUs, see Note 2, "Summary of Significant Accounting Policies" to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K.

(3) The amounts reported in the "Option Awards" column reflect the aggregate grant date fair value of stock options awarded during the periods presented, computed in accordance with the provisions of FASB ASC Topic 718 using a Black-Scholes option pricing model. For the assumptions underlying the valuation of the stock option grants, see Note 11, "Stock-based Compensation" to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K.

(4) The following table describes the elements that are represented in the "All Other Compensation" column above:

Name	Year	401(k) Savings Plan Company Match	Severance, Company-Paid Life and Disability Insurance Premiums (1)
Mark Iwicki	2025	$ —	$ 896
	2024	$ —	$ 6,120
Todd Bazemore	2025	$ 7,000	$ 57,146
	2024	$ 5,007	$ 4,440
Kim Brazzell, Ph.D.	2025	$ 7,000	$ 48,081
	2024	$ 6,748	$ 13,096
Mary Reumuth	2025	$ 7,000	$ 40,002
	2024	$ 6,859	$ 3,768

(1) Other compensation for the year ended December 31, 2025 included a settlement of severance amount of $52,400, $37,700 and $36,613 to Mr. Bazemore, Dr. Brazzell and Ms. Reumuth, respectively.

Narrative Disclosure to Summary Compensation Table

Base Salary. We use base salaries to recognize the experience, skills, knowledge and responsibilities required of all our employees, including our named executive officers. None of our named executive officers is currently party to an employment agreement or other agreement or arrangement that provides for automatic or scheduled increases in base salary.

Annual Bonus. Performance-based bonuses, which are calculated as a percentage of base salary, are designed to motivate our employees to achieve annual goals based on our strategic, financial and operating performance objectives. Historically, our board of directors or our compensation committee has approved discretionary annual cash bonuses to our named executive officers with respect to their prior year performance.

With respect to 2024 performance, our compensation committee awarded bonuses of $297,945, $187,460, $163,800 and $147,420 to Mr. Iwicki, Mr. Bazemore, Dr. Brazzell, and Ms. Reumuth, respectively, which represented payments at 70% of each individual's target bonus opportunity (which target bonus opportunities, expressed as a percentage of 2024 annual base salary, were 60%, 50% and 45%, respectively). Mr. Bazemore's individual performance-based target bonus amount for 2025, expressed as a percentage of his 2025 base salary, was 50%. Dr. Brazzell's individual performance-based target bonus amount for 2025, expressed as a percentage of his 2025 base salary, was 45%.

Retention Bonus. In addition to the performance-based annual bonuses described above, in April 2025, our Compensation Committee awarded one-time cash retention bonuses of $281,190 and $260,000 to Mr. Bazemore and Dr. Brazzell, respectively, in recognition of their critical roles during leadership transitions. Such retention bonuses were conditioned upon each officer's continued service subject to certain conditions.

Equity Incentives. Although we do not have a formal policy with respect to the grant of equity incentive awards to our executive officers, or any formal equity ownership guidelines applicable to them, we believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. In addition, we believe that equity grants with time-based or performance-based vesting features promote executive retention because this feature incentivizes our executive officers to remain in our employment during the vesting period. Accordingly, our compensation committee annually reviews the equity incentive compensation of our named executive officers and from time to time may grant equity incentive awards to them in the form of stock options and/or RSUs with time-based and/or performance-based vesting conditions.

In January 2024, we granted options to purchase 64,500, 29,300, 29,300 and 20,500 shares of our Common Stock to Mr. Iwicki, Mr. Bazemore, Dr. Brazzell and Ms. Reumuth, respectively. Such options vest as to 1/48th of the shares underlying the option at the end of each successive one-month period over a four-year period following January 4, 2024, subject to continued service. In January 2024, we granted RSUs with respect to 14,300, 6,500, 6,500 and 4,600 shares of our Common Stock to Mr. Iwicki, Mr. Bazemore, Dr. Brazzell and Ms. Reumuth, respectively. Such awards vested as to 1/3 of the shares on each of January 4, 2025 and January 4, 2026. Mr. Iwicki, Mr. Bazemore, Dr. Brazzell and Ms. Reumuth each left the Company prior to the vesting of their remaining shares.

In January 2025, we granted options to purchase 99,500, 45,200, 45,200 and 45,200 shares of our Common Stock to Mr. Iwicki, Mr. Bazemore, Dr. Brazzell and Ms. Reumuth, respectively. Such options vest as to 1/48th of the shares underlying the option at the end of each successive one-month period over a four-year period following January 6, 2025, subject to continued service. In January 2025, we granted RSUs with respect to 22,100, 10,100. 10,100 and 10,100 shares of our Common Stock to Mr. Iwicki, Mr. Bazemore, Dr. Brazzell and Ms. Reumuth, respectively. Such awards vested as to 1/3 of the shares on January 6, 2026. Mr. Iwicki, Mr. Bazemore, Dr. Brazzell and Ms. Reumuth each left the Company prior to the vesting of their remaining shares.

In March 2025, in connection with Mr. Bazemore's appointment as our interim Chief Executive Officer, we granted to Mr. Bazemore options to purchase 45,200 shares of our Common Stock. Such options vest as to 1/12th of the shares underlying the option at the end of each successive one-month period over a one-year period following February 11, 2025, subject to continued service.

Prior to our IPO, our executives were eligible to participate in our 2009 Employee, Director and Consultant Equity Incentive Plan, as amended to date, or the 2009 Plan. Following the closing of our IPO, our employees and executives are eligible to receive stock options, RSUs and other stock-based awards pursuant to the Amended and Restated 2017 Equity Incentive Plan. For a description of our 2009 Plan and our Amended and Restated 2017 Equity Incentive Plan, see "— Stock Option and Other Compensation Plans".

Historically, we have used stock options to compensate our executive officers in the form of initial grants in connection with the commencement of employment and also at various times, often but not necessarily annually. The award of stock options to our executive officers, including our Chief Executive Officer, generally have been and going forward are expected to be made by our board of directors. Such options have been granted with time-based and/or performance-based vesting conditions. Vesting and exercise rights cease shortly after termination of employment except in the case of death or disability and, in certain circumstances, including, upon a change in control. Prior to the exercise of an option, the holder has no rights as a stockholder with respect to the shares subject to such option, including no voting rights and no right to receive dividends or dividend equivalents. In addition, prior to our IPO, we have granted stock options with exercise prices equal to the fair market value of our Common Stock on the date of grant as determined by our board of directors or compensation committee, based on a number of objective and subjective factors. The exercise price of all stock options granted after our IPO has been and will be equal to the fair market value of shares of our Common Stock on the date of grant, which will be determined by reference to the closing market price of our Common Stock on The Nasdaq Capital Market on the date of grant.

Outstanding Equity Awards at December 31, 2025

The following table sets forth information regarding all outstanding equity awards held by each of our named executive officers as of December 31, 2025.

	Option Awards					Stock Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($) (1)
Mark Iwicki	—	—	—	—	—	13,903 (2)	$ 7,730
	—	—	—	—	—	2,584 (3)	$ 1,437
	—	—	—	—	—	52,969 (4)	$ 29,451
	—	—	—	—	—	9,534 (5)	$ 5,301
	—	—	—	—	—	22,100 (6)	$ 12,288
	—	—	—	—	—	2,450 (7)	$ 1,362
	132,394	79,437 (9)	—	14.56	6/21/2033	—	—
	30,906	33,594 (10)	—	7.00	1/3/2034	—	—
	22,802	76,698 (11)	—	7.53	1/5/2035	—	—
	—	5,450 (12)	—	4.30	6/14/2035	—	—
Todd Bazemore	—	—	—	—	—	4,268 (2)	$ 2,373
	—	—	—	—	—	794 (8)	$ 441
	—	—	—	—	—	16,236 (4)	$ 9,027
	—	—	—	—	—	4,334 (5)	$ 2,410
	—	—	—	—	—	10,100 (6)	$ 5,616
	40,582	24,349 (9)	—	14.56	6/21/2033	—	—
	14,040	15,260 (10)	—	7	1/3/2034	—	—
	10,358	34,842 (11)	—	7.53	1/5/2035	—	—
	37,667	7,533 (13)	—	7.05	3/6/2035	—	—
	15,000	165,000 (14)	—	11.22	8/28/2035	—	—
Kim Brazzell, Ph.D.	—	—	—	—	—	—	—
	—	—	—	—	—	—	—
	—	—	—	—	—	—	—
	—	—	—	—	—	—	—
	—	—	—	—	—	—	—
	38,388	—	—	14.56	6/21/2033	—	—
	12,819	—	—	7.00	1/3/2034	—	—
	8,475	—	—	7.53	1/5/2035	—	—
Mary Reumuth	—	—	—	—	—	3,176 (2)	$ 1,766
	—	—	—	—	—	512 (8)	$ 285
	—	—	—	—	—	12,051 (4)	$ 6,700
	—	—	—	—	—	3,067 (5)	$ 1,705
	—	—	—	—	—	10,100 (6)	$ 5,616
	30,120	18,072 (9)	—	14.56	6/21/2033	—	—
	9,823	10,677 (10)	—	7.00	1/3/2034	—	—
	10,358	34,842 (11)	—	7.53	1/5/2035	—	—

(1) Amounts shown are based on a price of $0.56 per share, which was the closing price of our Common Stock as reported on the Nasdaq Capital Market on December 31, 2025, the last trading day of the year.

(2) The RSUs vest over three years, with 1/3 of such RSUs having vested on each of January 4, 2024, January 4, 2025 and January 4, 2026 and 1/3 of such RSUs vested on January 4, 2026.

(3) Represents replacement RSUs granted pursuant to the Option Exchange Program, which vest over three years, with 83% of such RSUs vested on May 31, 2025. Mr. Iwicki left the Company prior to the vesting of the remaining 17% of such RSUs.

(4) The RSUs vest over three years, with 1/3 of such RSUs having vested on June 22, 2024 and 1/3 of such RSUs vested on each of June 22, 2025 and June 22, 2026. Mr. Iwicki and Mr. Bazemore each left the Company prior to the vesting of their remaining RSUs.

(5) The RSUs vest over three years, with 1/3 of such RSUs having vested on January 4, 2025 and 1/3 of such RSUs vested on each of January 4, 2026. Mr. Iwicki and Mr. Bazemore each left the Company prior to the vesting of their remaining RSUs.

(6) The RSUs vest over three years, with 1/3 of such RSUs having vested on January 6, 2026. Mr. Iwicki and Mr. Bazemore each left the Company prior to the vesting of their remaining RSUs.

(7) The RSUs vest over one year on June 15, 2026. Mr. Iwicki left the Company prior to the vesting of the remaining RSUs.

(8) Represents replacement RSUs granted pursuant to the 2023 Option Exchange Program, which vest over three years, with 85% of such RSUs vested on May 31, 2025. Mr. Bazemore left the Company prior to the vesting of his remaining RSUs.

(9) The option vests over four years, with 25% of the shares underlying the option vested on June 22, 2024 and 2.0833% of the shares vesting monthly thereafter. Mr. Iwicki and Mr. Bazemore each left the Company prior to the vesting of their remaining shares.

(10) The option vests over four years, with 2.0833% of the shares vested on February 4, 2024 and 2.0833% of the shares vesting monthly thereafter. Mr. Iwicki and Mr. Bazemore each left the Company prior to the vesting of their remaining shares.

(11) The option vests over four years, with 2.0833% of the shares vested on February 6, 2025 and 2.0833% of the shares vesting monthly thereafter. Mr. Iwicki and Mr. Bazemore each left the Company prior to the vesting of their remaining shares.

(12) The option vest over one year on June 15, 2026. Mr. Iwicki left the Company prior to the vesting of his remaining shares.

(13) The option vests over one year, with 8.33% of the shares vested on March 11, 2025 and 8.33% of the shares vesting monthly thereafter. Mr. Bazemore left the Company prior to the vesting of his remaining shares.

(14) The option vests over four years, with 2.0833% of the shares vested on September 29, 2025 and 2.0833% of the shares vesting monthly thereafter, subject to continued service. Mr. Bazemore each left the Company prior to the vesting of his remaining shares.

Policies and Practices Related to the Grant of Certain Equity Awards

We generally grant stock options and restricted stock units to our employees and directors on an annual basis. We also grant stock options and/or restricted stock units to individuals upon hire or promotion or for retention purposes. We currently do not grant stock appreciation rights or similar option-like instruments. During the last fiscal year, neither the board of directors nor the compensation committee took material nonpublic information into account when determining the timing or terms of stock options. Stock options are not granted in anticipation of the release of material nonpublic information, and the release of material nonpublic information is not timed on the grant dates of such stock options. We have not timed the disclosure of material nonpublic information for the purpose of affecting the value of executive compensation.

Annual stock option grants to executive officers are typically approved by our board of directors or our compensation committee in December of each year and are effective on a specified date in the first or second week of January of the next year. In December of each year, our compensation committee has generally delegated authority to our Chief Executive Officer under our stock incentive plan to grant annual stock options to non-executive employees on a specified date in the first or second week of January of each year. Stock option grants to new hires are generally approved by our board of directors or compensation committee mid-month. Under our non-employee director compensation policy, the grants of our annual stock options to directors are effective on the date of the first board meeting held after each annual meeting of stockholders.

During fiscal year ended December 31, 2025, we did not grant stock options to any named executive officer during any period beginning four business days before and ending one business day after the filing of any Form 10-Q or 10-K, or the filing or furnishing of a Form 8-K that discloses material nonpublic information.

Employment Agreements with Named Executive Officers

Letter Agreement with Mr. Iwicki

Mr. Iwicki was appointed as our Chief Executive Officer and Chair of our board of directors pursuant to a letter agreement with us dated September 10, 2015, which amended and restated a prior letter agreement. Mr. Iwicki resigned as our Chief Executive Officer, effective February 11, 2025.

Letter Agreement with Mr. Bazemore

Mr. Bazemore was appointed as our Chief Operating Officer pursuant to a letter agreement with us dated November 6, 2017, and was appointed as our President commencing December 16, 2021 and our interim Chief Executive Officer commencing February 11, 2025. Mr. Bazemore resigned as our Chief Operating Officer on December 19, 2025.

Mr. Bazemore's base salary was subject to annual review and adjustment by our compensation committee. Mr. Bazemore's annual base salary was $535,600, effective January 1, 2025. In addition, Mr. Bazemore was eligible to receive a discretionary bonus in a target amount of 50% of his annual base salary, as determined by our board of directors in its sole discretion.

On March 11, 2019, Mr. Bazemore's employment letter agreement was amended to revise the severance benefits he is entitled to receive upon termination in connection with certain events. Subject to his execution and non-revocation of a release of claims in our favor, in the event of the termination of Mr. Bazemore's employment by us without cause or by him for good reason, each as defined in his employment letter agreement, and such termination is not within the twenty-four month period following a change of control, as defined in his employment letter agreement, Mr. Bazemore was entitled to a lump sum payment in an amount equal to (i) twelve months of his then-current annual base salary, (ii) any bonus earned for the year prior to the year of termination that has not yet been paid, (iii) a pro-rated portion of any bonus attributable to the year of termination based upon performance against company but not individual objectives and (iv) an amount equal to 100% of his target bonus for the year of termination. In addition, Mr. Bazemore was entitled to twelve months of COBRA premiums for continued health benefit coverage on the same terms as were applicable to him prior to his termination and outplacement services for the twelve-month period.

Further, in the event of the termination of Mr. Bazemore's employment by us without cause or by him for good reason within the twenty-four month period following a change of control, Mr. Bazemore was entitled to a lump sum payment in an amount equal to (i) eighteen months of his then-current annual base salary, (ii) any bonus earned for the year prior to the year of termination that has not yet been paid, (iii) a pro-rated portion of any bonus attributable to the year of termination based upon performance against company but not individual objectives and (iv) 150% of the greater of (A) the average bonus Mr. Bazemore received during the two years prior to termination or resignation, or (B) the target bonus for the year of termination or resignation. In addition, Mr. Bazemore was entitled to eighteen months of COBRA premiums for continued health benefit coverage on the same terms as were applicable to him prior to his termination and outplacement services for the eighteen-month period.

In addition, in the event we terminate his employment without cause or he terminates his employment for good reason, Mr. Bazemore was entitled to the automatic vesting and exercisability of any options and other equity awards granted to him that vest solely based on his continued employment that would have vested if his employment had continued for twelve months following such termination, and any performance-based grants with the performance period ending within one year after the termination shall be treated as having satisfied any service requirement with respect thereto and shall vest subject to, and only to the extent of, the satisfaction of the applicable performance goals at the end of the applicable performance period.

In the event we terminate his employment without cause or he terminates his employment for good reason in contemplation of a change of control, as defined in the letter agreement, or within the twenty-four-month period

following a change of control, Mr. Bazemore was entitled to the automatic vesting and exercisability of 100% of any options and other equity awards granted to him that vest solely based on his continued employment, and any performance based grants with a performance period ending within one year after the termination was treated as having satisfied any service requirement with respect such grant, and will vest subject to, and only to the extent of, the satisfaction of the applicable performance goals at the end of the applicable performance period.

Letter Agreement with Dr. Brazzell

Dr. Brazzell was appointed to serve on a full-time basis as our Chief Medical Officer pursuant to a letter agreement with us dated May 10, 2016, which amended and restated a prior letter agreement. Dr. Brazzell was an at-will employee, and his employment with us could be terminated by him or us at any time and for any reason. Dr. Brazzell resigned as our Chief Medical Officer on October 27, 2025

Brazzell's base salary was subject to annual review and adjustment by our compensation committee. Dr. Brazzell's annual base salary was $520,000, effective January 1, 2025. In addition, Dr. Brazzell is eligible to receive a discretionary bonus in a target amount of 45% of his annual base salary, as determined by our compensation committee in its sole discretion.

On March 11, 2019, Dr. Brazzell's employment letter agreement was amended to revise the severance benefits he was entitled to receive upon termination in connection with the following events. Subject to his execution and nonrevocation of a release of claims in our favor, in the event of the termination of Dr. Brazzell's employment by us without cause or by him for good reason, each as defined in his employment letter agreement, and such termination is not within the twenty-four month period following a change of control, as defined in his employment letter agreement, Dr. Brazzell will be entitled to a lump sum payment in an amount equal to (i) twelve months of his then-current annual base salary, (ii) any bonus earned for the year prior to the year of termination that has not yet been paid, (iii) a pro-rated portion of any bonus attributable to the year of termination based upon performance against company but not individual objectives and (iv) an amount equal to 100% of his target bonus for the year of termination. In addition, Dr. Brazzell is entitled to twelve months of COBRA premiums for continued health benefit coverage on the same terms as were applicable to him prior to his termination and outplacement services for the twelve-month period.

Further, in the event of the termination of Dr. Brazzell's employment by us without cause or by him for good reason within the twenty-four month period following a change of control, Dr. Brazzell was entitled to a lump sum payment in an amount equal to (i) eighteen months of his then-current annual base salary, (ii) any bonus earned for the year prior to the year of termination that has not yet been paid, (iii) a pro-rated portion of any bonus attributable to the year of termination based upon performance against company but not individual objectives and (iv) 150% of the greater of (A) the average bonus Dr. Brazzell received during the two years prior to termination or resignation, or (B) the target bonus for the year of termination or resignation. In addition, Dr. Brazzell is entitled to eighteen months of COBRA premiums for continued health benefit coverage on the same terms as were applicable to him prior to his termination and outplacement services for the eighteen-month period.

In addition, in the event we terminate his employment without cause or he terminates his employment for good reason, Dr. Brazzell was entitled to the automatic vesting and exercisability of any options and shares granted to him that vest solely based on his continued employment that would have vested if his employment had continued for twelve months following such termination. In the event of a change of control, as defined in his employment letter agreement, during his employment, Dr. Brazzell was entitled to the automatic vesting and exercisability of 100% of any options and restricted shares granted to him that vest solely based on his continued employment, and certain options are exercisable for a period of up to six months following his termination date.

In addition, in the event we terminate his employment without cause or he terminates his employment for good reason within the twenty-four-month period following a change of control, Dr. Brazzell was entitled to the automatic vesting and exercisability of any options and shares granted to him following a change of control that vest solely based on his continued employment and have not vested.

Letter Agreement with Ms. Reumuth

Ms. Reumuth was appointed to serve on a full-time basis as our Senior Director, Finance and Corporate Controller pursuant to a letter agreement with us dated August 18, 2014. Ms. Reumuth was appointed as Chief Financial Officer in July 2017. Ms. Reumuth was an at-will employee, and her employment with us could be terminated by him or us at any time and for any reason. Ms. Reumuth left the Company on November 21, 2025.

Ms. Reumuth base salary was subject to annual review and adjustment by our compensation committee. Ms. Reumuth annual base salary was $510,000, effective January 1, 2025. In addition, Ms. Reumuth was eligible to receive a discretionary bonus in a target amount of 25% of her annual base salary, as determined by our compensation committee in its sole discretion.

On March 11, 2019, Ms. Reumuth's employment letter agreement was amended to revise the severance benefits she was entitled to receive upon termination in connection with the following events. Subject to her execution and nonrevocation of a release of claims in our favor, in the event of the termination of Ms. Reumuth's employment by us without cause or by her for good reason, each as defined in her employment letter agreement, and such termination is not within the twenty-four month period following a change of control, as defined in her employment letter agreement, Ms. Reumuth would be entitled to a lump sum payment in an amount equal to (i) twelve months of her then-current annual base salary, (ii) any bonus earned for the year prior to the year of termination that has not yet been paid, (iii) a pro-rated portion of any bonus attributable to the year of termination based upon performance against company but not individual objectives and (iv) an amount equal to 100% of her target bonus for the year of termination. In addition, Ms. Reumuth is entitled to twelve months of COBRA premiums for continued health benefit coverage on the same terms as were applicable to her prior to her termination and outplacement services for the twelve-month period. Further, if Ms. Reumuth's employment was terminated by the Company without Cause or by her for Good Reason within twelve (12) months following a Change of Control, she was entitled to receive: (i) 18 months of her then-current base salary; (ii) any earned but unpaid bonus for the year prior to the year of termination; (iii) an amount equal to 1.5 times the greater of (A) her target bonus for the year of termination or (B) the average of the bonuses she received during the two years prior to the year of termination; (iv) a pro-rated portion of any bonus attributable to the year of termination, payable when active employees are paid for that year (and in any event by March 15 of the following year) based on Company (but not individual) milestones; (v) COBRA continuation medical benefits for the 18-month severance period subsidized by the Company at active employee rates on the same terms as before termination; and (vi) Company-paid outplacement services for the 18-month severance period. All payments other than the pro-rated bonus and the COBRA/outplacement benefits were payable in a lump sum on the Payment Date.

Retention Agreements

On April 10, 2025, we entered into a retention agreements with each of Mr. Bazemore, Ms. Reumuth, and Dr. Brazzell pursuant to which each was eligible to receive a 30% increase in their 2024 base salary plus retention bonuses of $281,190, $234,000 and $260,000, respectively. Under the retention agreement, the retention bonus was subject to repayment if, prior to the earlier of September 30, 2025 or the date of our public announcement of topline results from our Phase 2a clinical trial, (i) each of Mr. Bazemore, Ms. Reumuth, and Dr. Brazzell's employment is terminated by us for cause, or (ii) each of Mr. Bazemore, Ms. Reumuth, and Dr. Brazzell voluntarily resigns other than for good reason.

On October 2, 2025, the Company entered into additional retention agreements with Mr. Bazemore, Ms. Reumuth, and Dr. Brazzell. The second retention agreements entitled each of Mr. Bazemore, Ms. Reumuth and Dr. Brazzell to receive retention payment of $183,750, $136,250, and $145,000, respectively. Each of the retention agreements provided that if, prior to December 31, 2025, such executive's employment is terminated voluntarily by such executive or by the Company for cause (as defined in the applicable executive's employment agreement), then, pursuant to the terms of the Retention Agreement, such executive shall, upon request, repay the gross amount of the Retention Payment to the Company. Each of Mr. Bazemore, Ms. Reumuth and Dr. Brazzell entered into Settlement Agreement and General and Mutual Release agreements in the fourth quarter of 2025 upon their departure from the Company.

Employee Non-Competition, Non-Solicitation, Confidentiality, and Assignment of Inventions Agreements

Each of our named executive officers has entered into a standard form agreement with respect to non-competition, non-solicitation, confidential information and assignment of inventions. Under this agreement, each

executive officer has agreed not to compete with us during his or her employment and for a period of one year after the termination of his or her employment and to protect our confidential and proprietary information indefinitely. Under this agreement, each of Mr. Iwicki, Dr. Brazzell and Ms. Reumuth has agreed not to solicit our employees or consultants during his employment and for a period of twelve months after the termination of his employment, and Mr. Bazemore has agreed not to solicit our employees or consultants during his employment and for a period of eighteen months after the termination of his employment, and each executive officer has agreed to protect our confidential and proprietary information indefinitely. In addition, under this agreement, each executive officer has agreed that we own all inventions, as defined in the agreement, that are developed during such executive officer's employment and for a period of one year after the termination of his or her employment, to the extent such invention is our field of interest, as defined in the agreement. Each executive officer also agreed to assign to us any inventions which were not prepared or originated in the performance of employment but that were provided to us or incorporated into any of our products or systems.

Stock Option and Other Compensation Plans

In this section we describe our 2009 Plan, our Amended and Restated 2017 Equity Incentive Plan and our Amended and Restated 2017 Employee Stock Purchase Plan, or 2017 ESPP. Prior to our IPO, which closed on July 25, 2017, we granted awards to eligible participants under the 2009 Plan. Following the closing of our IPO, we ceased granting awards under the 2009 Plan and started granting awards to eligible participants under the 2017 Plan.

2009 Plan

Our 2009 Plan was adopted by our board of directors and approved by our stockholders on December 11, 2009 and subsequently amended by our board in 2012, 2013, 2014 and 2015. The 2009 Plan provided for the grant of incentive stock options, non-qualified options, shares, restricted or otherwise, of our Common Stock , and other stock-based awards. We refer to awards granted under our 2009 Plan as stock rights. Our employees, directors and consultants were eligible to receive stock rights under our 2009 Plan; however incentive stock options could only be granted to our employees who are deemed to be residents of the United States.

The type of stock right granted under our 2009 Plan and the terms of such stock right are set forth in the applicable stock right award agreement. Our board of directors (or a committee to which our board delegates its authority) administers the 2009 Plan. Subject to the provisions of the 2009 Plan, our board of directors is authorized to:

- interpret the provisions of the 2009 Plan and all stock rights and make all rules and determinations that it deems necessary or advisable for the administration of the 2009 Plan;

- amend any term or condition of an outstanding stock right, including, without limitation, to reduce or increase the exercise price or purchase price, accelerate the vesting or extend the expiration date, provided that no such change will impair a participant's rights under any prior grant unless we obtain the participant's consent;

- purchase and/or cancel a stock right previously granted and grant other stock rights in substitution, which may cover the same or a different number of shares and which may have a lower or higher exercise or purchase price per share, based on such terms and conditions as the board of directors establishes and the participant accepts; and

- adopt any sub-plans applicable to residents of any specified jurisdiction as it deems necessary or appropriate to facilitate the 2009 Plan or to comply with or take advantage of any tax or other laws applicable to us, any of our affiliates, or to participants, which sub-plans may include additional restrictions or conditions applicable to stock rights or shares issuable pursuant to a stock right.

Effect of certain changes in capitalization

If our shares of common stock are subdivided or combined into a greater or smaller number of shares, if we issue shares of common stock as a stock dividend, or if we make any distribution of additional, new or different shares or

securities of ours or any distribution of non-cash assets with respect to our shares of common stock, then, subject to the terms of the 2009 Plan, our board of directors shall proportionately and appropriately adjust:

- the number of shares of our Common Stock deliverable upon the exercise of an option or acceptance of a stock grant;
- the exercise or purchase price per share; and
- any other term or condition of a stock right.

Effect of certain corporate transactions

In the event that we are consolidated with or acquired by another entity in a merger, consolidation, or sale of all or substantially all of our assets (other than a transaction to merely change the state of incorporation), which we refer to as corporate transactions, our board of directors, or the board of directors of any entity assuming our obligations under the 2009 Plan, must take one of the following actions pursuant to the 2009 Plan as to outstanding options, subject to the terms of the 2009 Plan:

- provide for the continuation of the outstanding options by equitably substituting for the shares of our Common Stock then underlying such options either with securities of any successor or acquiring entity or the consideration payable with respect to the outstanding shares of our Common Stock in connection with the corporate transaction;
- provide by written notice to the participants that the outstanding options will terminate unless exercised (to the extent then exercisable or made partially or fully exercisable by our board of directors for purposes of the corporate transaction) within a specified period following the date of the notice; or
- terminate each outstanding option in exchange for a payment equal to the consideration payable upon consummation of the corporate transaction to a holder of the number of shares of our Common Stock into which such option would have been exercisable (to the extent then exercisable or made partially or fully exercisable by our board of directors for purposes of the corporate transaction), minus the aggregate exercise price of such option.

If there is a corporate transaction, our board of directors, or the board of directors of any entity assuming our obligations under the 2009 Plan, must take one of the following actions pursuant to the 2009 Plan as to outstanding stock grants, restricted or otherwise, subject to the terms of the 2009 plan:

- provide for the continuation of the outstanding stock grants on the same terms and conditions by equitably substituting for the shares of our Common Stock then subject to such stock grants either with securities of any successor or acquiring entity or the consideration payable with respect to the outstanding shares of our Common Stock in connection with the corporate transaction; or
- provide that each outstanding stock grant will terminate in exchange for a payment equal to the consideration payable upon consummation of the corporate transaction to a holder of the number of shares of our Common Stock comprising such stock grant (to the extent such stock grant is no longer subject to any forfeiture or repurchase rights or our board of directors waives all forfeiture and repurchase rights upon the corporate transaction).

In taking any of the above actions with respect to stock rights, our board of directors will not be obligated to treat all stock rights, all stock rights held by a participant, or all stock rights of the same type, identically.

As of March 31, 2026, options to purchase 26 shares of common stock were outstanding under the 2009 Plan at a weighted average exercise price of $193.00 per share.

We no longer grant awards under our 2009 Plan; however, awards outstanding under our 2009 Plan continue to be governed by their existing terms.

Amended and Restated 2017 Equity Incentive Plan

Our 2017 Equity Incentive Plan, which became effective on July 19, 2017, was adopted by our board of directors and approved by our stockholders in July 2017, and an amendment to our 2017 Equity Incentive Plan was adopted by our board of directors in April 2020 and approved by our stockholders at the 2020 annual meeting of stockholders. Our Amended and Restated 2017 Equity Incentive Plan, or the 2017 Plan, which became effective on June 22, 2023, was adopted by our board of directors in May 2023 and by our stockholders in June 2023, and amends and restates our 2017 Equity Incentive Plan, as amended.

The 2017 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock awards, RSUs and other stock-based awards. The number of shares of our Common Stock reserved for issuance under the 2017 Plan is the sum of: (1) 1,569,136; plus (2) such additional number of shares (up to 70,675) that remained available for grant under the 2009 Plan at the time of our IPO and the number of shares of our Common Stock subject to outstanding awards under the 2009 Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right; plus (3) an annual increase, to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2024 and continuing until, and including, the fiscal year ending December 31, 2033, equal to the lower of (i) 4% of the sum of (I) the number of shares of our Common Stock outstanding on the first day of such fiscal year and (II) the number of shares of Common Stock issuable upon any conversion of any outstanding shares of our convertible preferred stock (without giving effect to any restrictions or limitations on conversion) on such date and (ii) an amount determined by our board of directors. The number of shares authorized for issuance under the 2017 Plan further increased, pursuant to the terms of the 2017 Plan, by an additional 554,663 shares, effective as of January 1, 2025.

Our employees, officers, directors, consultants and advisors are eligible to receive awards under the 2017 Plan. Incentive stock options, however, may only be granted to our employees. Subject to certain adjustments, awards with respect to no more than 7,738,761 shares of Common Stock may be granted in the form of incentive stock options during the term of the 2017 Plan. For a description of the limitations on non-employee director compensation under our 2017 Plan, see “Director Compensation” below.

Pursuant to the terms of the 2017 Plan, our board of directors (or a committee delegated by our board of directors or, subject to certain limitations, officers delegated by our board of directors) administers the plan and, subject to any limitations in the plan, selects the recipients of awards and determines:

- the number of shares of our Common Stock covered by options and the dates upon which the options become exercisable;
- the type of options to be granted;
- the duration of options, which may not be in excess of ten years;
- the exercise price of options, which must be at least equal to the fair market value of our Common Stock on the date of grant; and
- the number of shares of our Common Stock subject to and the terms of any stock appreciation rights, restricted stock awards, RSUs or other stock-based awards and the terms and conditions of such awards, including conditions for repurchase, issue price and repurchase price (though the measurement price of stock appreciation rights must be at least equal to the fair market value of our Common Stock on the date of grant and the duration of such awards may not be in excess of ten years).

If our board of directors delegates authority to an executive officer to grant awards under the 2017 Plan, the executive officer will have the power to make awards to all of our employees, except executive officers. Our board of directors will fix the terms of the awards to be granted by such executive officer, including the exercise price of such awards (which may include a formula by which the exercise price will be determined), and the maximum number of shares subject to awards that such executive officer may make.

Effect of certain changes in capitalization

Upon the occurrence of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of our Common Stock other than an ordinary cash dividend, our board of directors shall equitably adjust:

- the number and class of securities available under the 2017 Plan and the number of awards that may be granted as incentive stock options;
- the share counting rules under the 2017 Plan;
- the number and class of securities and exercise price per share of each outstanding option;
- the share and per-share provisions and the measurement price of each outstanding stock appreciation right;
- the number of shares subject to, and the repurchase price per share subject to, each outstanding restricted stock award; and
- the share and per-share related provisions and the purchase price, if any, of each other stock-based award.

Effect of certain corporate transactions

Upon a merger or other reorganization event (as defined in our 2017 Plan), our board of directors may, on such terms as our board determines (except to the extent specifically provided otherwise in an applicable award agreement or other agreement between the participant and us), take any one or more of, or a combination of, the following actions pursuant to the 2017 Plan as to some or all outstanding awards, other than restricted stock awards:

- provide that all outstanding awards shall be assumed, or substantially equivalent awards shall be substituted, by the acquiring or successor corporation (or an affiliate thereof);
- upon written notice to a participant, provide that all of the participant's unvested awards will be forfeited, and/or vested but unexercised awards will terminate, immediately prior to the consummation of such reorganization event unless exercised by the participant (to the extent then exercisable) within a specified period following the date of the notice;
- provide that outstanding awards shall become exercisable, realizable or deliverable, or restrictions applicable to an award shall lapse, in whole or in part, prior to or upon such reorganization event;
- in the event of a reorganization event pursuant to which holders of shares of our Common Stock will receive a cash payment for each share surrendered in the reorganization event, make or provide for a cash payment to participants with respect to each award held by a participant equal to (1) the number of shares of our Common Stock subject to the vested portion of the award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such reorganization event) multiplied by (2) the excess, if any, of the cash payment for each share surrendered in the reorganization event over the exercise, measurement or purchase price of such award and any applicable tax withholdings, in exchange for the termination of such award; and/or
- provide that, in connection with a liquidation or dissolution, awards shall convert into the right to receive liquidation proceeds (if applicable, net of the exercise, measurement or purchase price thereof and any applicable tax withholdings).

Our board of directors does not need to take the same action with respect to all awards, all awards held by a participant or all awards of the same type.

In the case of certain RSUs, no assumption or substitution is permitted, and the restricted stock units will instead be settled in accordance with the terms of the applicable RSU agreement.

Upon the occurrence of a reorganization event other than a liquidation or dissolution, the repurchase and other rights with respect to outstanding restricted stock awards will continue for the benefit of the successor company and will, unless our board of directors may otherwise determine, apply to the cash, securities or other property into which shares of our Common Stock are converted or exchanged pursuant to the reorganization event. Upon the occurrence of a reorganization event involving a liquidation or dissolution, all restrictions and conditions on each outstanding restricted stock award will automatically be deemed terminated or satisfied, unless otherwise provided in the agreement evidencing the restricted stock award or any other agreement between the participant and us.

At any time, our board of directors may, in its sole discretion, provide that any award under the 2017 Plan will become immediately exercisable in full or in part, free of some or all restrictions or conditions, or otherwise realizable in whole or in part as the case may be.

No awards may be granted under the 2017 Plan on or after June 22, 2033. Our board of directors may amend, suspend or terminate the 2017 Plan at any time, except that stockholder approval may be required to comply with applicable law or stock market requirements.

As of December 31, 2025, options to purchase 643,354 shares of common stock were exercisable under the 2017 Plan at a weighted average exercise price of $12.19 per share. As of March 1, 2025, RSUs with respect to 186,463 shares of common stock were outstanding under the 2017 Plan.

As of December 31, 2025, 527,508 shares of common stock were available for future issuance under our 2017 Plan.

Amended and Restated 2017 Employee Stock Purchase Plan

Our 2017 ESPP, which became effective on July 19, 2017, was adopted by our board of directors and approved by our stockholders in July 2017 and amended and restated by our board of directors in December 2018. The 2017 ESPP is administered by our board of directors or by a committee appointed by our board of directors. The 2017 ESPP initially provides participating employees with the opportunity to purchase an aggregate of 4,466 shares of our Common Stock. The number of shares of our Common Stock reserved for issuance under the 2017 ESPP will automatically increase on the first day of each fiscal year, beginning on January 1, 2019 and ending on December 31, 2029, in an amount equal to the lowest of: (1) 17,868 shares of our Common Stock ; (2) 1% of the total number of shares of our Common Stock outstanding on the first day of the applicable fiscal year; and (3) an amount determined by our board of directors. The number of shares authorized for issuance under the 2017 ESPP has increased each year, pursuant to the foregoing evergreen provision, on the first of January beginning in 2019.

All of our employees and employees of any of our designated subsidiaries, as defined in the 2017 ESPP, are eligible to participate in the 2017 ESPP, provided that:

- such person is customarily employed by us or a designated subsidiary for more than 20 hours a week and for more than five months in a calendar year; and
- such person was our employee or an employee of a designated subsidiary on the first day of the applicable offering period under the 2017 ESPP.

We retain the discretion to determine which eligible employees may participate in an offering under applicable Treasury regulations.

We may make one or more offerings to our eligible employees to purchase stock under the 2017 ESPP beginning at such time and on such dates as our board of directors may determine, or the first business day thereafter. Each offering will consist of a six-month offering period during which payroll deductions will be made and held for the purchase of our Common Stock at the end of the offering period. Our board of directors or a committee appointed by our

board, may, at its discretion, choose a different period of not more than 12 months for offerings. Offering periods under our 2017 ESPP commenced on each January 1 and July beginning with January 1, 2019.

On each offering commencement date, each participant will be granted the right to purchase, on the last business day of the offering period, up to 500 shares of our Common Stock. No employee may be granted an option under the 2017 ESPP that permits the employee's rights to purchase shares under the 2017 ESPP and any other employee stock purchase plan of ours or of any of our subsidiaries to accrue at a rate that exceeds $25,000 of the fair market value of our Common Stock (determined as of the first day of each offering period) for each calendar year in which the option is outstanding. In addition, no employee may purchase shares of our Common Stock under the 2017 ESPP that would result in the employee owning 5% or more of the total combined voting power or value of our stock or the stock of any of our subsidiaries.

On the commencement date of each offering period, each eligible employee may authorize up to a maximum of 15% of such employee's compensation to be deducted by us during the offering period. Each employee who continues to be a participant in the 2017 ESPP on the last business day of the offering period will be deemed to have exercised an option to purchase from us the number of whole shares of our Common Stock that such employee accumulated payroll deductions on such date will buy, not in excess of the maximum numbers set forth above. Under the terms of the 2017 ESPP, the purchase price shall be determined by our board of directors for each offering period and will be at least 85% of the applicable closing price of our Common Stock. If our board of directors does not make a determination of the purchase price, the purchase price will be 85% of the lesser of the closing price of our Common Stock on the first business day of the offering period or on the last business day of the offering period.

An employee may at any time prior to the close of business on the fifteenth business day prior to the end of an offering period, and for any reason, permanently withdraw from participation in an offering prior to the end of an offering period and permanently withdraw the balance accumulated in the employee's account. Any balance remaining in an employee's payroll deduction account at the end of an offering period will be automatically refunded to the employee. If a participating employee's employment ends before the last business day of an offering period, no additional payroll deductions will be taken and the balance in the employee's account will be paid to the employee.

We are required to make equitable adjustments to the extent determined by our board of directors or a committee of our board of directors to the number and class of securities available under the 2017 ESPP, the share limitations under the 2017 ESPP and the purchase price for an offering period under the 2017 ESPP to reflect stock splits, reverse stock splits, stock dividends, recapitalizations, combinations of shares, reclassifications of shares, spin-offs and other similar changes in capitalization or events or any dividends or distributions to holders of our Common Stock other than ordinary cash dividends.

In connection with a merger or other reorganization event (as defined in the 2017 ESPP), our board of directors or a committee of our board of directors may take any one or more of the following actions as to outstanding options to purchase shares of our Common Stock under the 2017 ESPP on such terms as our board of directors or committee determines:

- provide that options shall be assumed, or substantially equivalent options shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof);

- upon written notice to employees, provide that all outstanding options will be terminated immediately prior to the consummation of such reorganization event and that all such outstanding options will become exercisable to the extent of accumulated payroll deductions as of a date specified by our board of directors or committee in such notice, which date shall not be less than ten days preceding the effective date of the reorganization event;

- upon written notice to employees, provide that all outstanding options will be cancelled as of a date prior to the effective date of the reorganization event and that all accumulated payroll deductions will be returned to participating employees on such date;

- in the event of a reorganization event under the terms of which holders of our Common Stock will receive upon consummation thereof a cash payment for each share surrendered in the reorganization event, change the last day of the offering period to be the date of the consummation of the reorganization event and make or provide

for a cash payment to each employee equal to (1) the cash payment for each share surrendered in the reorganization event times the number of shares of our Common Stock that the employee's accumulated payroll deductions as of immediately prior to the reorganization event could purchase at the applicable purchase price, where the cash payment for each share surrendered in the reorganization event is treated as the fair market value of our Common Stock on the last day of the applicable offering period for purposes of determining the purchase price and where the number of shares that could be purchased is subject to the applicable limitations under the 2017 ESPP minus (2) the result of multiplying such number of shares by the purchase price; and/or

- provide that, in connection with our liquidation or dissolution, options shall convert into the right to receive liquidation proceeds (net of the purchase price thereof).

Our board of directors may at any time, and from time to time, amend or suspend the 2017 ESPP, or any portion of the 2017 ESPP. We will obtain stockholder approval for any amendment if such approval is required by Section 423 of the Internal Revenue Code of 1986, as amended, or the Code. Further, our board of directors may not make any amendment that would cause the 2017 ESPP to fail to comply with Section 423 of the Code. The 2017 ESPP may be terminated at any time by our board of directors. Upon termination, we will refund all amounts in the accounts of participating employees.

401(k) Plan

We maintain a defined contribution employee retirement plan for our employees. Our 401(k) plan is intended to qualify as a tax-qualified plan under Section 401 of the Code so that contributions to our 401(k) plan, and income earned on such contributions, are not taxable to participants until withdrawn or distributed from the 401(k) plan. Our 401(k) plan provides that each participant may contribute up to 90% of such employee's pre-tax compensation, up to a statutory limit, which was $23,500 for 2025. Participants who are at least 50 years old can also make "catch-up" contributions, which in 2024 was up to an additional $7,500 above the statutory limit and in 2025 is up to an additional $7,500 above the statutory limit. We also make discretionary matching contributions to our 401(k) plan equal to 50% of the employee contributions up to 4% of the employee's salary, subject to the statutorily prescribed limit, which was equal to $23,000 in 2024 and $23,500 in 2025. The discretionary matching contributions were capped at $7,000 in 2025. Under our 401(k) plan, each employee is fully vested in their deferred salary contributions and our discretionary match. Employee contributions are held and invested by the plan's trustee, subject to participants' ability to give investment directions by following certain procedures.

Rule 10b5-1 Sales Plans

Our directors and executive officers have adopted and may in the future adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our Common Stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from the director or officer. It also is possible that the director or officer could amend or terminate the plan when not in possession of material, nonpublic information. In addition, our directors and executive officers may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

Anti-Hedging Policies

Our Insider Trading Policy expressly prohibits all of our employees, including our executive officers, and our directors from engaging in any purchases of financial instruments (including prepaid variable forward contracts, equity swaps, collars and exchange funds) or other transactions that hedge or offset, or are designed to hedge or offset, any decrease in the market value of our securities.

Dodd-Frank Compensation Recovery Policy or "Clawback" Policy

Effective October 2, 2023, we adopted a compensation recovery policy in accordance with Nasdaq Listing Rule 5608, which implements Rule 10D-1 under the Exchange Act. The policy provides that, in the event that we are required to prepare an accounting restatement due to our material noncompliance with any financial reporting requirement under U.S. federal securities laws, including any required accounting restatement to correct an error in previously issued

financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period, we will attempt to recover, reasonably promptly from each covered executive, any erroneously awarded incentive-based compensation received by our covered executives during the recovery period under the policy. The policy is administered by our compensation committee.

For purposes of this policy, covered executives means any person who served as an executive officer (as defined in Rule 16a-1(f) under the Exchange Act) at any time during the performance period for the applicable incentive-based compensation. Incentive-based compensation means any compensation that is granted, earned or vested based wholly or in part upon the attainment of (i) measures that are determined and presented in accordance with the accounting principles used in preparing our financial statements, and any measures that are derived wholly or in part from such measures, (ii) stock price and (iii) total shareholder return. Erroneously awarded incentive-based compensation means the amount of incentive-based compensation that was received that exceeds the amount of incentive-based compensation that otherwise would have been received had it been determined based on the restated amounts, computed without regard to any taxes paid by the covered executives (or by us on their behalf). If the incentive-based compensation is based on our stock price or total shareholder return and the amount of the erroneously awarded incentive-based compensation is not subject to recalculation directly from the information in an accounting restatement, the amount to be recovered shall be based on a reasonable estimate by the compensation committee of the effect of the accounting restatement on the stock price or total shareholder return upon which the incentive-based compensation was received. The policy does not apply to incentive-based compensation received prior to October 2, 2023 or to incentive-based compensation that was received by a covered executive before beginning service as an executive officer.

Director Compensation

The table below shows all compensation to our non-employee directors during 2025.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)[1][2]	Stock Awards ($)[1][3][4]	Total ($)
Mark Iwicki (4)	68,139	19,595	10,535	98,269
Marjan Farid	67,500	19,595	10,535	97,630
Andrew I. Koven	96,298	24,628	13,115	134,041
C. Daniel Myers	67,500	19,595	10,535	97,630
Gregory D. Perry	44,837	19,595	10,535	74,967
Howard B. Rosen	75,000	19,595	10,535	105,130

(1) The aggregate number of outstanding options and RSUs held by each non-employee director as of December 31, 2025 were as follows:

Name	Aggregate Options Outstanding (#)	Aggregate Restricted Stock Units Outstanding (#)
Mark Iwicki (4)	381,281	103,540
Marjan Farid	16,022	10,242
Andrew I. Koven	23,920	16,972
C. Daniel Myers	16,146	10,374
Gregory D. Perry	10,367	8,941
Howard B. Rosen	21,751	16,240

(2) The amounts reported in the "Option Awards" column reflect the aggregate grant date fair value of options awarded during 2025 computed in accordance with the provisions of FASB ASC Topic 718. For the assumptions underlying the valuation of the stock option grants, see Note 11, "Stock-based Compensation" to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K. For additional information regarding the options granted to our directors in 2025 see "— Narrative Disclosure to Director Compensation Table — Director Compensation Policy" below.

(3) The amounts reported in the "Stock Awards" column reflect the aggregate grant date fair value of RSUs granted during 2025. For the assumptions underlying the valuation of the RSUs, see Note 2, "Summary of Significant Accounting Policies" to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K. For additional information regarding the RSUs granted to our directors during 2025, see Narrative Disclosure to Director Compensation Table — Director Compensation Policy" below.

(4) Mr. Iwicki resigned as our Chief Executive Officer on February 11, 2025.

Narrative Disclosure to Director Compensation Table

Director Compensation Policy

During the year ended December 31, 2025, our non-employee directors were entitled to compensation for their services on our board of directors as follows:

- each non-employee director was entitled to receive an option to purchase 8,750 shares of our Common Stock , upon his or her initial election or appointment to our board of directors, which option vests with respect to one third of the shares on the first anniversary of the grant and with respect to an additional 1/36th of the shares on each monthly anniversary thereafter and vest automatically as to 100% of the unvested portion of such option upon specified change in control events;

- each non-employee director who has then served on our board of directors for at least six months was entitled to receive, on the date of the first board meeting held after each annual meeting of stockholders, an option to purchase 3,150 shares of our Common Stock and RSUs for 1,400 shares of our Common Stock , and if then serving as the Lead Independent Director, an option to purchase 3,900 shares of our Common Stock and RSUs for 1,750 shares of our Common Stock , which options and RSUs will vest (A) on the earlier of (i) the first anniversary date of the previous year's annual meeting or (ii) the date of the first annual meeting following the grant date, and (B) automatically as to 100% of the unvested portion of such options upon specified change in control events;

- each non-employee director was entitled to receive an annual fee of $50,000;

- each non-employee director who served as member of a committee of our board of directors was entitled to receive additional compensation as follows:

    - audit committee-an annual non-chair retainer of $10,000; chair annual retainer of $20,000;

    - compensation committee-an annual non-chair retainer of $7,500; chair annual retainer of $15,000; and

    - nominating and corporate governance committee-an annual non-chair retainer of $5,000; chair annual retainer of $10,000.

Each member of our board of directors also is entitled to be reimbursed for reasonable travel and other expenses incurred in connection with attending meetings of our board of directors and any committee of our board of directors on which he or she serves.

Effective June 2023, pursuant to the terms of the 2017 Plan, the maximum aggregate amount of cash and value of awards (calculated based on grant date fair value for financial reporting purposes) granted in any calendar year to any

individual non-employee director for services as a director shall not exceed $750,000 in the case of an incumbent director; provided, however, that such maximum aggregate amount shall not exceed $1 million in any calendar year for any individual non-employee director for services as a director in such non-employee director's initial year of election or appointment. Fees paid by us on behalf of any non-employee director in connection with regulatory compliance, amounts paid and the value of equity awards granted pursuant to a bona fide consulting agreement for services other than as a director and any amounts paid to a non-employee director as reimbursement of an expense will not count against the foregoing limit. Our board of directors may make exceptions to this limit for individual non-employee directors in extraordinary circumstances, as our board of directors may determine in its discretion, provided that the non-employee director receiving such additional compensation may not participate in the decision to award such compensation.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Security Ownership of Certain Beneficial Owners and Management

Unless otherwise provided below, the following table sets forth information regarding beneficial ownership of our Common Stock as of March 31, 2026 by:

- each person, or group of affiliated persons, known to us to be the beneficial owner of 5% or more of the outstanding shares of our Common Stock;
- each of our current directors;
- our principal executive officer and other most highly compensated executive officers who served during the year ended December 31, 2025, named in the Summary Compensation table above, whom, collectively, we refer to as our named executive officers; and
- all of our executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our Common Stock. Percentage of beneficial ownership is based on 929,491,578 shares of our Common Stock outstanding as of March 31, 2026. In addition, shares of common stock subject to options or other rights currently exercisable, or exercisable within 60 days of March 31, 2026, are deemed outstanding and beneficially owned for the purpose of computing the percentage beneficially owned by (i) the individual holding such options, warrants or other rights (but not any other individual) and (ii) the directors and executive officers as a group. Except as otherwise noted, the persons and entities in this table have sole voting and investing power with respect to all of the shares of our Common Stock beneficially owned by them, subject to community property laws, where applicable. Except as otherwise set forth below, the address of the beneficial owner is c/o KALA BIO, Inc., 1167 Massachusetts Avenue, Arlington, Massachusetts 02476.

Name and Address of Beneficial Owner	Shares of Common Stock Beneficially Owned	Percentage of Common Stock
5% Stockholders:		
David Lazar (1)	49,500,000	5.33 %
Directors and Named Executive Officers:		
Avi Minkowitz	-	- %
Hillel Posen	-	-
Chaim (Dovi) Berger	-	-
Yonatan Colman	-	-
Brendan Purdy	-	-
Mark Iwicki	-	-
Todd Bazemore	-	-
Kim Brazzell, Ph.D.	-	-
Mary Reumuth	-	-
All current directors and officers as a group (5 persons)	-	- %

(1) Represents (i) 12,000,010 of Common Stock and 218,182 of Series AA Preferred Stock convertible to 55 Common Stock for each Preferred Stock.

Securities Authorized for Issuance under Equity Compensation Plans

The following table contains information about our equity compensation plans as of December 31, 2025. As of December 31, 2025, we had three equity compensation plans, our 2009 Plan, our 2017 Plan and our 2017 ESPP, each of which was approved by our stockholders. We have also made inducement awards to certain new hires, which awards were not approved by our stockholders.

	Number of securities to be issued upon exercise of outstanding options warrants and rights (a)	Weighted-Average exercise price of outstanding options warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	1,418,006 (1)	$ 11.24 (2)	565,096 (3)
Equity compensation plans not approved by security holders	1,981 (4)	$ 10.35	—
Total	1,419,987	$ 11.24	565,096

(1) Includes shares of our Common Stock issuable upon exercise of options to purchase Common Stock awarded under our 2009 Plan and 2017 Plan and shares of our common subject to outstanding RSUs awarded under our 2017 Plan.

(2) The calculation does not take into account the 230,947 shares of Common Stock subject to outstanding RSUs under the 2017 Plan. Such shares will be issued at the time such awards vest (or upon the earlier of the director's cessation of service or certain "change in control events", if a non-employee director elects to defer the receipt of such RSUs), without any cash consideration payable for those shares.

(3) Includes 527,508 shares of our Common Stock available for issuance under our 2017 Plan and 37,588 shares of common stock available for issuance under our 2017 ESPP.

(4) Represents inducement option awards granted to employees in accordance with Nasdaq Listing Rule 5635(c)(4). Each inducement option award has an exercise price equal to closing price of our Common Stock on the date of grant and vests over four years with 25% of the shares underlying each option vesting on the first anniversary of the applicable employee's new hire date and 2.0833% vesting monthly thereafter.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Certain Relationships and Related Transactions

Policies and Procedures for Related Person Transactions

Our board of directors has adopted written policies and procedures for the review of any transaction, arrangement or relationship in which our company is a participant, the amount involved exceeds $120,000 or 1% of the average of the Company's total assets as of the end of the last two completed fiscal years, and one of our executive officers, directors, director nominees or 5% stockholders, or their immediate family members, each of whom we refer to as a "related person," has a direct or indirect material interest.

If a related person proposes to enter into such a transaction, arrangement or relationship, which we refer to as a "related person transaction," the related person must report the proposed related person transaction to our general counsel or, if none, to our chief financial officer, or individual performing a similar function. The policy calls for the proposed related person transaction to be reviewed and, if deemed appropriate, approved by our audit committee. Whenever practicable, the reporting, review and approval will occur prior to entry into the transaction. If advance review and approval is not practicable, the committee will review, and, in its discretion, may ratify the related person transaction. The policy also permits the chair of the audit committee to review and, if deemed appropriate, approve proposed related person transactions that arise between committee meetings, subject to ratification by the committee at its next meeting. Any related person transactions that are ongoing in nature will be reviewed annually.

A related person transaction reviewed under the policy will be considered approved or ratified if it is authorized by the audit committee after full disclosure of the related person's interest in the transaction. As appropriate for the circumstances, the audit committee will review and consider:

- the related person's interest in the related person transaction;
- the approximate dollar value of the amount involved in the related person transaction;
- the approximate dollar value of the amount of the related person's interest in the transaction without regard to the amount of any profit or loss;
- whether the transaction was undertaken in the ordinary course of our business;
- whether the terms of the transaction are no less favorable to us than terms that could have been reached with an unrelated third party;
- the purpose of, and the potential benefits to us of, the transaction; and
- any other information regarding the related person transaction or the related person in the context of the proposed transaction that would be material to investors in light of the circumstances of the particular transaction.

Our audit committee may approve or ratify the transaction only if it determines that, under all of the circumstances, the transaction is in our best interests. Our audit committee may impose any conditions on the related person transaction that it deems appropriate.

In addition to the transactions that are excluded by the instructions to the SEC's related person transaction disclosure rule, our board of directors has determined that the following transactions do not create a material direct or indirect interest on behalf of related persons and, therefore, are not related person transactions for purposes of this policy:

- interests arising solely from the related person's position as an executive officer of another entity, whether or not the person is also a director of the entity, that is a participant in the transaction where the related person and all other related persons own in the aggregate less than a 10% equity interest in such entity, the related person and such person's immediate family members are not involved in the negotiation of the terms of the transaction and do not receive any special benefits as a result of the transaction and the amount involved in the transaction is less than the greater of $200,000 or 5% of the annual gross revenues of the company receiving payment under the transaction; and

- a transaction that is specifically contemplated by provisions of our certificate of incorporation or by-laws.

The policy provides that transactions involving compensation of executive officers shall be reviewed and approved by our compensation committee in the manner specified in the compensation committee's charter.

With respect to related person transactions, it is the practice of our board of directors to consider the nature of and business reasons for such transactions, how the terms of such transactions compared to those which might be obtained from unaffiliated third parties and whether such transactions were otherwise fair to and in the best interests of, or not contrary to, our best interests.

Related Person Transactions

SEC rules require us to disclose any transaction or currently proposed transaction in which we are a participant and in which any related person has or will have a direct or indirect material interest involving an amount that exceeds the lesser of $120,000 or 1% of the average of the Company's total assets as of the end of the last two completed fiscal years. A related person is any executive officer, director, nominee for director, or holder of 5% or more of the Company's Common Stock, or an immediate family member of any of those persons.

2024 Private Placement

On December 29, 2024, we entered into a securities purchase agreement with certain purchasers, or the Series I Purchasers, pursuant to which we issued and sold to the Series I Purchasers, (i) 1,340,603 shares of our Common Stock , at a price per share equal to $6.44 and (ii) 3,286 shares of our Series I Convertible Non-Redeemable Preferred Stock, or the Series I Preferred Stock, at a price per share equal to $644.00, for aggregate gross proceeds of approximately $10.75 million, which we refer to collectively as the Series I Private Placement. The following holders of more than 5% of our voting securities and their affiliates purchased securities in the Series I Private Placement and paid the aggregate purchase prices are set forth: 667, L.P. purchased 30,620 shares of common stock for an aggregate purchase price of $197,192.80; Baker Brothers Life Sciences, L.P. purchased 279,939 shares of common stock for an aggregate purchase price of $1,802,807.16; SR One Capital Fund II Aggregator, LP purchased 155,279 shares of common stock for an aggregate purchase price of $999,996.76; and Cormorant Global Healthcare Master Fund, LP purchased 603,027 shares of common stock and 3,286 shares of Series I Preferred Stock for an aggregate purchase price of $5,999,677.88. We agreed that we will not without the prior approval of the requisite Series I Purchasers issue or authorize the issuance of any equity security that is senior or pari passu to the Series I Preferred Stock with respect to liquidation preference.

November 2025 Securities Purchase Agreement

On November 23, 2025, we entered into a Securities Purchase Agreement with David Lazar, pursuant to which, in a private placement, we agreed to issue and sell (in two closings) shares of our preferred stock for aggregate gross proceeds of up to $6.0 million. At the first closing on November 24, 2025, we issued and sold 900,000 shares of our Series AA Convertible Non-Redeemable Preferred Stock ("Series AA Preferred Stock") at a price per share of $2.00, for aggregate gross proceeds of $1.8 million. The second closing is expected to occur promptly following the receipt of stockholder approval and prior to 31 March 2026, subject to (i) the approval by our stockholders of (A) an increase in the number of authorized shares of our Common Stock to enable the issuance of the shares of common stock issuable

upon conversion of the preferred shares and (B) the conversion of the preferred shares into shares of common stock in accordance with Nasdaq listing rules, (ii) the filing of a charter amendment effecting such share increase, (iii) the filing of a Certificate of Designations for the Series AAA Convertible Non-Redeemable Preferred Stock, and (iv) other customary closing conditions. At the second closing, we have agreed to issue and sell 2,100,000 shares of our Series AAA Convertible Non-Redeemable Preferred Stock ("Series AAA Preferred Stock") at a price per share of $2.00, for aggregate gross proceeds of $4.2 million, $1.0 million of which was paid to Oxford as partial consideration for Oxford's entry into the loan settlement described below.

In connection with the Securities Purchase Agreement, on November 21, 2025, our board appointed Mr. Lazar as our Chief Executive Officer (effective immediately following the first closing) and principal financial officer (effective the business day following the first closing) and elected him as a Class II director (effective immediately prior to the execution and effectiveness of the Securities Purchase Agreement). The Securities Purchase Agreement also grants Mr. Lazar participation rights to purchase up to 25% of new equity securities in firm-commitment underwritten offerings during the participation period, and, subject to Nasdaq Listing Rule 5640 and stockholder approval, the right to recommend up to eight individuals to be nominated for election at the stockholder meeting.

On November 23, 2025, we entered into a Voting Agreement with David Lazar and Oxford in connection with the private placement and the settlement of our outstanding loan obligations with Oxford.

Convertible Loan Agreement

On November 9, 2025, we entered into a Convertible Loan Agreement with David Lazar for an aggregate principal amount of $375,000 with an annual interest rate of 15%. A portion of the proceeds was permitted to be used to facilitate negotiation and finalization of the additional investment transaction with Mr. Lazar and to prepare and file our Form 10-Q for the quarter ended September 30, 2025. The loan was due on November 9, 2026, and subject to extension until November 9, 2027 under certain conditions. The loan was repaid on December 18, 2025.

Oxford Loan Settlement

As a condition to the first closing, on November 23, 2025, we and our subsidiary Combangio, Inc. entered into a loan settlement agreement with Oxford, pursuant to which Oxford agreed to settle all of our payment obligations under the Loan and Security Agreement in consideration for (i) a $2.0 million cash payment and (ii) our issuance to Oxford of 1,620,000 shares of our Common Stock. On November 23, 2025, we also entered into a Voting Agreement with Oxford and Mr. Lazar, pursuant to which, for four months following that date, Oxford agreed to vote 1,620,000 settlement shares (and any additional shares it acquired during the term) in favor of all proposals recommended by our board at the stockholder meeting.

On December 11, 2025, following Mr. Lazar's sale of his rights and obligations under the Securities Purchase Agreement solely with respect to the Series AAA Preferred Shares to AK Holdings Group Inc., a Panamanian company, we engaged Nissim Amram as a consultant to advise the Company on potential strategic alternatives. Mr. Lazar retained his holdings of the Series AA Preferred Shares and the Convertible Loan Agreement which we repaid in full on December 18, 2025.

Board Determination of Independence

Applicable Nasdaq rules require a majority of a listed company's board of directors to be comprised of independent directors. In addition, the Nasdaq rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under applicable Nasdaq rules, a director will only qualify as an "independent director" if, in the opinion of the listed company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an

affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (1) the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director; and (2) whether the director is affiliated with the company or any of its subsidiaries or affiliates.

Our Board has reviewed the independence of our directors based on the listing standards of Nasdaq. Based on this review, the Board determined that Mr. Berger, Mr. Posen, Mr. Colman and Mr. Purdy are independent, as defined in Rule 5605(a)(2) of the Nasdaq rules, as well as the applicable independence standards for committee members under the Exchange Act. In making this determination, our Board considered the relationships that each of these non-employee directors has with us and all other facts and circumstances our Board deemed relevant in determining their independence.

Item 14. Principal Accountant Fees and Services

Audit Fees and Services

HTL International, LLC ("HTL"), was our independent registered public accounting firm for the year ended December 31, 2025. Deloitte & Touche LLP, or Deloitte, was our independent registered public accounting firm for the year ended December 31, 2024. The following table summarizes the fees billed to us for the last two fiscal years. All such services and fees were pre-approved by our audit committee in accordance with the "Pre-Approval Policies and Procedures" described below.

	Years Ended December 31,	
Fee Category	**2025**	**2024**
Audit Fees(1)	$ 472,775	$ 778,587
All Other Fees(2)	1,895	1,895
Total Fees	$ 474,670	$ 780,482

(1) Audit fees consist of fees billed for professional services rendered for the audits of our annual consolidated financial statements, the reviews of our interim consolidated financial statements, and related services that are normally provided in connection with statutory and regulatory filings or engagements, including, our registration statements.

(2) All other fees include fees and expenses for services which do not fall within the categories described above. All other fees consisted of a subscription to Accounting and Research Tool.

Pre-approval Policies and Procedures

The audit committee of our board of directors has adopted policies and procedures for the pre-approval of audit and non-audit services for the purpose of maintaining the independence of our independent auditor. We may not engage our independent auditor to render any audit or non-audit service unless either the service is approved in advance by the audit committee, or the engagement to render the service is entered into pursuant to the audit committee's pre-approval policies and procedures. In 2020, the audit committee delegated to its chair the authority to pre-approve any audit or non-audit services to be provided to us by our independent registered public accounting firm. By the terms of this delegated authority, the chair must report on any such approval of services pursuant to such authority at the first regularly scheduled meeting of the audit committee following such approval. The audit committee does not delegate its responsibility to approve services performed by the independent auditor to any member of management.

The standard applied by the audit committee, or the chair of the audit committee, in determining whether to grant approval of any type of non-audit service, or of any specific engagement to perform a non-audit service, is whether the services to be performed, the compensation to be paid therefore and other related factors are consistent with the independent registered public accounting firm's independence under guidelines of the SEC and applicable professional

standards. Relevant considerations include whether the work product is likely to be subject to, or implicated in, audit procedures during the audit of our financial statements, whether the independent registered public accounting firm would be functioning in the role of management or in an advocacy role, whether the independent registered public accounting firm's performance of the service would enhance our ability to manage or control risk or improve audit quality, whether such performance would increase efficiency because of the independent registered public accounting firm's familiarity with our business, personnel, culture, systems, risk profile and other factors, and whether the amount of fees involved, or the non-audit services portion of the total fees payable to the independent registered public accounting firm in the period would tend to reduce the independent registered public accounting firm's ability to exercise independent judgment in performing the audit.

Part IV

Item 15. Exhibits and Financial Statement Schedules

(1) **Financial Statements.**

The following documents are included beginning on page F-1 attached hereto and are filed as part of this Annual Report on Form 10-K.

KALA BIO, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

(2) **Financial Statement Schedules.**

No financial statement schedules have been filed as part of this Annual Report on Form 10-K because they are not applicable, not required or because the information is otherwise included in our financial statements or notes thereto.

(3) **Exhibits**.

The following is a list of exhibits filed or furnished as part of this Annual Report on Form 10-K.

Exhibit Number	Description of Exhibit
2.1#	Agreement and Plan of Merger, dated as of November 15, 2021, by and among the Registrant, Ceres Merger Sub, Inc., Combangio, Inc. and, solely in its capacity as Combangio Equityholder Representative, Fortis Advisors LLC. (incorporated by reference to Exhibit 2.1 of the Registrant's current report on Form 8-K (File No. 001-38150) filed on November 15, 2021)
2.2#	Asset Purchase Agreement, by and between the Registrant, Alcon Pharmaceuticals Ltd. and Alcon Vision, LLC (incorporated by reference to Exhibit 2.1 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on May 23, 2022)

Exhibit Number	Description of Exhibit
3.1	Restated Certificate of Incorporation of the Registrant, as amended, including Certificate of Designation of the Series D Preferred Stock of the Registrant, Certificate of Elimination of Number of Shares of Preferred Stock Designated as Series D Preferred Stock of the Registrant, Certificate of Designations, Preferences and Rights of Series E Convertible Non-Redeemable Preferred Stock of the Registrant, Certificate of Designations, Preferences and Rights of Series F Convertible Non-Redeemable Preferred Stock of the Registrant, Certificate of Designations, Preferences and Rights of Series G Convertible Non-Redeemable Preferred Stock of the Registrant, Certificate of Designations, Preferences and Rights of Series H Convertible Non-Redeemable Preferred Stock of the Registrant and Certificate of Designations, Preferences and Rights of Series I Convertible Non-Redeemable Preferred Stock of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's registration statement on Form S-8 (File No. 333-284117) filed on January 3, 2025)
3.1.1	Certificate of Amendment to Restated Certificate of Incorporation, as amended, of KALA BIO, Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on February 2, 2026)
3.2	Third Amended and Restated By-Laws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on August 2, 2023)
3.3	Certificate of Designations, Preferences and Rights of Series AA Convertible Non-Redeemable Preferred Stock of KALA BIO, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on November 25, 2025)
3.4	Certificate of Designations, Preferences and Rights of Series AA Convertible Non-Redeemable Preferred Stock of KALA BIO, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on February 2, 2026)
4.1	Specimen Stock Certificate evidencing the shares of common stock (incorporated by reference to Exhibit 4.1 to the Registrant's annual report on Form 10-K (File No. 001-38150) filed on March 3, 2023)
4.2	Registration Rights Agreement, dated March 2, 2023, by and among the Registrant and the persons party thereto (incorporated by reference to Exhibit 4.5 to the Registrant's annual report on Form 10-K (File No. 001-38150) filed on March 3, 2023)
4.3*	Description of the Registrant's Securities Registered under Section 12 of the Exchange Act
4.4	Registration Rights Agreement, dated June 26, 2024, by and among the Registrant and the other parties thereto (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on June 27, 2024)
4.5	Form of Series AA Preferred Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on November 25, 2025)
4.6	Form of Pre-Funded Warrant issued on December 5, 2025 (incorporated by reference to Exhibit 4.1 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on December 5, 2025)
10.1+	2009 Employee, Director and Consultant Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's registration statement on Form S-1 (File No. 333-218936) filed on June 23, 2017)
10.2+	Form of Stock Option Agreement under the 2009 Employee, Director and Consultant Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's registration statement on Form S-1 (File No. 333-218936) filed on June 23, 2017)
10.3+	Amended and Restated 2017 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.1 to the Registrant's quarterly report on Form 10-Q (File No. 001-38150) filed on May 9, 2019)
10.4+	2017 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K (File No. 001-38150) filed on June 26, 2020)
10.5+	Amended and Restated 2017 Equity Incentive Plan of the Registrant (incorporated by reference to Exhibit 99.1 to the Registrant's registration statement on Form S-8 (File No. 333-272834) filed on June 22, 2023)
10.6+	Form of Incentive Stock Option Agreement under 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registrant's registration statement on Form S-1/A (File No. 333-218936) filed on July 10, 2017)

Exhibit Number	Description of Exhibit
10.7+	Forms of Non-Qualified Option Agreement under 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.6 to the Registrant's registration statement on Form S-1/A (File No. 333-218936) filed on July 10, 2017)
10.8+	Form of Non-Employee Director Restricted Stock Unit Award under 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's quarterly report on Form 10-Q (File No. 001-38150) filed on May 7, 2020)
10.9+	Form of Non-Employee Director Deferred Restricted Stock Unit Award under 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's quarterly report on Form 10-Q (File No. 001-38150) filed on May 7, 2020)
10.10+	Form of Employee Restricted Stock Unit Award under 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's quarterly report on Form 10-Q (File No. 001-38150) filed on August 6, 2020)
10.11+	Form of Incentive Stock Option Agreement under Amended and Restated 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's quarterly report on Form 10-Q (File No. 001-38150) filed on August 4, 2023)
10.12+	Forms of Non-Qualified Option Agreement under Amended and Restated 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's quarterly report on Form 10-Q (File No. 001-38150) filed on August 4, 2023)
10.13+	Form of Non-Employee Director Restricted Stock Unit Award under Amended and Restated 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's quarterly report on Form 10-Q (File No. 001-38150) filed on August 4, 2023)
10.14+	Form of Non-Employee Director Deferred Restricted Stock Unit Award under Amended and Restated 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registrant's quarterly report on Form 10-Q (File No. 001-38150) filed on August 4, 2023)
10.15+	Form of Employee Restricted Stock Unit Award under Amended and Restated 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.6 to the Registrant's quarterly report on Form 10-Q (File No. 001-38150) filed on August 4, 2023)
10.16+	Form of Inducement Stock Option Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's quarterly report on Form 10-Q (File No. 001-38150) filed on November 8, 2018)
10.17+	Form of Inducement Restricted Stock Unit Agreement (incorporated by reference to Exhibit 10.7 to the Registrant's quarterly report on Form 10-Q (File No. 333-218936) filed on August 4, 2023)
10.18#	Exclusive License Agreement, dated October 11, 2019, by and between Combangio, Inc. and The Board of Trustees of the Leland Stanford Junior University (incorporated by reference to Exhibit 10.18 to the Registrant's annual report on Form 10-K (File No. 001-38150) filed on March 29, 2022)
10.19	Second Amendment to Offer Letter, dated August 29, 2025, between the Company and Todd Bazemore (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on September 2, 2025)
10.20+	Form of Amendment to Offer Letters (incorporated by reference to Exhibit 10.30 to the Registrant's annual report on Form 10-K (File No. 001-38150) filed on March 12, 2019)
10.21+	Form of Indemnification Agreement between the Registrant and each of its Executive Officers and Directors (incorporated by reference to Exhibit 10.14 to the Registrant's registration statement on Form S-1/A (File No. 333-218936) filed on July 10, 2017)
10.22	Common Stock Purchase Warrant (incorporated by reference to Exhibit 10.4 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on October 2, 2018)
10.23#	Loan and Security Agreement, dated May 4, 2021, by and among the Registrant and Oxford Finance LLC, as collateral agent and lender (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38150) filed on May 5, 2021)
10.24#	First Amendment to Loan and Security Agreement, dated November 15, 2021, by and among the Registrant, Combangio, Inc. and Oxford Finance LLC, as collateral agent and lender (incorporated by reference to Exhibit 10.1 to the Registrant's quarterly report on Form 10-Q (File No. 001-38150) filed on August 11, 2022)

Exhibit Number	Description of Exhibit
10.25	Second Amendment to Loan and Security Agreement, dated May 21, 2022, by and among the Registrant, Combangio, Inc. and Oxford Finance LLC, as collateral agent and lender (incorporated by reference to Exhibit 10.2 to the Registrant's quarterly report on Form 10-Q (File No. 001-38150) filed on August 11, 2022)
10.26	Third Amendment to Loan and Security Agreement, dated December 27, 2022, by and among the Registrant, Combangio, Inc. and Oxford Finance LLC, as collateral agent and lender (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on December 27, 2022)
10.27	Fourth Amendment to Loan and Security Agreement, dated August 1, 2023, by and among the Registrant, Combangio, Inc. and Oxford Finance LLC, as collateral agent and lender (incorporated by reference to Exhibit 10.8 to the Registrant's quarterly report on Form 10-Q (File No. 001-38150) filed on August 4, 2023)
10.28	Fifth Amendment to Loan and Security Agreement, dated August 2, 2023, by and among the Registrant, Combangio, Inc. and Oxford Finance LLC, as collateral agent and lender (incorporated by reference to Exhibit 10.9 to the Registrant's quarterly report on Form 10-Q (File No. 001-38150) filed on August 4, 2023)
10.29	Securities Purchase Agreement, dated November 28, 2022, by and among the Registrant and the purchasers party thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38150) filed on November 28, 2022)
10.30	Securities Purchase Agreement, dated December 21, 2023, by and among the Registrant and the purchasers party thereto (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on December 22, 2023)
10.31	Securities Purchase Agreement, dated March 25, 2024, by and among the Registrant and the purchasers party thereto (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on March 26, 2024)
10.32	Securities Purchase Agreement, dated June 26, 2024, by and among the Registrant and the other parties thereto (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on June 27, 2024)
10.33	Securities Purchase Agreement, dated December 29, 2024, by and among the Registrant and the other parties thereto (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on December 30, 2024)
10.34	Form of Retention Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on April 11, 2025) Form of Retention Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on October 2, 2025)
10.35	Convertible Loan Agreement, dated November 9, 2025, by and between the Registrant and David Lazar (incorporated by reference to Exhibit 10.2 to the Registrant's quarterly report on Form 10-Q (File No. 001-38150) filed on November 19, 2025)
10.36	Securities Purchase Agreement, dated November 23, 2025, by and among KALA BIO, Inc. and David Lazar (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on November 25, 2025)
10.37	Loan Settlement Agreement, dated November 23, 2025, by and among KALA BIO, Inc., Combangio, Inc. and Oxford Finance LLC, as collateral agent and lender (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on November 25, 2025)
10.38	Voting Agreement, dated November 23, 2025, by and among KALA BIO, Inc., David Lazar and Oxford Finance LLC (incorporated by reference to Exhibit 10.3 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on November 25, 2025)
10.39	Form of Officer Settlement Agreement (incorporated by reference to Exhibit 10.4 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on November 25, 2025)

Exhibit Number	Description of Exhibit
10.40	Securities Purchase Agreement, dated December 4, 2025, by and among KALA BIO, Inc. and the investor named therein (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on December 5, 2025)
10.41	Settlement Agreement and Mutual Release, dated December 30, 2025, by and between KALA BIO Inc. and Baker Bros. Advisors LP (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on January 6, 2026)
10.42	Voting Agreement, dated December 30, 2025, by and between KALA BIO Inc. and Baker Bros. Advisors LP (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on January 6, 2026)
10.43	Settlement Agreement and Mutual Release, dated December 30, 2025, by and between KALA BIO Inc. and LifeSci Capital LLC (incorporated by reference to Exhibit 10.3 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on January 6, 2026)
10.44	Settlement Agreement, dated December 30, 2025, by and between KALA BIO Inc. and Delaware IR LLC. (incorporated by reference to Exhibit 10.4 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on January 6, 2026)
10.45	At the Market Offering Agreement, dated as of January 8, 2026, by and between the Company and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 1.1 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on January 8, 2026)
10.46	Form of Securities Purchase Agreement, dated as of January 30, 2026, by and among the Company and each of the Series AAA Investors signatory thereto (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on February 2, 2026)
10.47	Platform Development and Exclusive License Agreement, dated March 3, 2026 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on March 4, 2026).
10.48*	Secured Promissory Note, dated as of February 9, 2026, by and between the Company and Minglemint Solutions LLC
10.49*	Security Agreement, dated February 9, 2026, by and between the Company and Minglemint Solutions LLC
16.1	Letter from Deloitte & Touche LLP to the U.S. Securities and Exchange Commission, dated December 16, 2025 (incorporated by reference to Exhibit 16.1 to the Registrant's current report on Form 8-K (File No. 001-38150) filed on December 16, 2025).
19.1	Amended and Restated Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Registrant's Annual Report on Form 10-K (001-38150) filed on March 31, 2025)
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Annual Report on Form 10-K (001-38150) filed on March 31, 2025)
23.1*	Consent of HTL International, LLC
23.2*	Consent of Deloitte & Touche LLP
31.1*	Rule 13a-14(a) Certification of Principal Executive Officer
31.2*	Rule 13a-14(a) Certification of Principal Financial Officer
32.1**	Certification of Principal Executive Officer pursuant to 18 U.S.C. §1350
32.2**	Certification of Principal Financial Officer pursuant to 18 U.S.C. §1350
97.1+	Dodd-Frank Compensation Recovery Policy (incorporated by reference to Exhibit 97.1 to the Registrant's annual report on Form 10-K (file No. 001-38150) filed on March 29, 2024).
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)

* Filed herewith.

** Furnished herewith.

Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

+ Management contract or compensatory plan or arrangement filed in response to Item 15(a)(3) of the Instructions to the Annual Report on Form 10-K.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

KALA BIO, INC.

Dated: April 15, 2026

By: /s/ *Avi Minkowitz*
Avi Minkowitz
Chief Executive Officer, Chief Financial Officer and Director

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

Signature	Title	Date
/s/ Avi Minkowitz Avi Minkowitz	Chief Executive Officer, Chief Financial Officer and Director (Principal Executive Officer and Principal Financial Officer)	April 15, 2026
/s/ Hillel Posen Hillel Posen	Director	April 15, 2026
/s/ Chaim (Dovi) Berger Chaim (Dovi) Berger	Director	April 15, 2026
/s/ Yonatan Colman Yonatan Colman	Director	April 15, 2026
/s/ Brendan Purdy Brendan Purdy	Director	April 15, 2026

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of KALA BIO, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of KALA BIO, Inc. and its subsidiaries (collectively, the "Company") as of December 31, 2025, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for the year ended December 31, 2025, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025, and the results of its operations and its cash flows for the year ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Evaluation of Management's Assessment of the Company's Ability to Continue as a Going Concern

Critical Audit Matter Description

As described in Note 2 to the consolidated financial statements, the Company has incurred recurring losses from operations and negative cash flows from operations since inception, had an accumulated deficit of $694.9 million as of December 31, 2025, and disclosed going concern uncertainty during the first, second and third quarters of 2025. During the fourth quarter of 2025, the Company also experienced significant liquidity constraints in connection with its debt arrangement with Oxford Finance LLC. Management concluded that, after considering its plans and recent developments,

substantial doubt about the Company's ability to continue as a going concern was alleviated for the twelve months following the date the consolidated financial statements were issued.

We determined this matter to be a critical audit matter because evaluating management's conclusion required especially challenging auditor judgment, particularly with respect to the impact of the Company's historical losses and negative cash flows, the Oxford default and related liquidity constraints, the effect of the Company's debt and other obligation settlements, the sufficiency of unrestricted cash and working capital at year end, and the reasonableness of management's forecasted cash requirements.

How the Critical Audit Matter Was Addressed in the Audit

The primary procedures we performed to address this matter included evaluating the Company's historical operating results and prior interim going concern disclosures; inspecting the Oxford default, settlement, and release documentation; testing the settlement of significant obligations; testing year-end cash and working capital balances; evaluating management's forecasted cash requirements; and evaluating the related disclosures in Note 2 to the consolidated financial statements.

/s/ HTL International, LLC

We have served as the Company's auditor since December 2025.

Houston, Texas

April 15, 2026

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of KALA BIO, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of KALA BIO, Inc. and subsidiaries (formerly Kala Pharmaceuticals, Inc.) (the "Company") as of December 31, 2024, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 audit, 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 audit included performing procedures to assess the risks of material misstatement of the 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 financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 31, 2025

We began serving as the Company's auditor in 2013. In 2025 we became the predecessor auditor.

KALA BIO, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 7,557	$ 51,181
Prepaid expenses and other current assets	1,933	1,616
Total current assets	9,490	52,797
Non-current assets:		
Property and equipment, net	—	749
Right-of-use assets	—	1,691
Other long-term assets	—	246
Total assets	$ 9,490	$ 55,483
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 986	$ 628
Accrued expenses and other current liabilities	1,508	4,975
Deferred grant income	—	637
Current portion of lease liabilities	—	380
Current portion of long-term debt	—	10,336
Total current liabilities	2,494	16,956
Long-term liabilities:		
Long-term lease liabilities	—	1,434
Long-term debt, net of current portion	—	20,102
Long-term contingent consideration	—	4,659
Total long-term liabilities	—	26,195
Total liabilities	2,494	43,151
Commitments and Contingencies (Note 14)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized as of December 31, 2025 and 2024; 9,278 and 51,246 shares of Series E Convertible Non-Redeemable Preferred Stock issued and outstanding as of December 31, 2025 and 2024, 2,928 shares of Series F Convertible Non-Redeemable Preferred Stock issued and outstanding as of December 31, 2025 and 2024, 10,901 shares of Series G Convertible Non-Redeemable Preferred Stock issued and outstanding as of December 31, 2025 and 2024, 2,299 and 9,393 shares of Series H Convertible Non-Redeemable Preferred Stock issued and outstanding as of December 31, 2025 and 2024, 0 and 3,286 shares of Series I Convertible Non-Redeemable Preferred Stock issued and outstanding as of December 31, 2025 and 2024, 900,000 and 0 shares of Series AA Convertible Non-Redeemable Preferred Stock issued and outstanding as of December 31, 2025 and 2024, respectively	1	—
Common stock, $0.001 par value; 120,000,000 shares authorized as of December 31, 2025 and December 31, 2024; 27,849,725 and 6,091,182 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively	28	6
Additional paid-in capital	701,867	680,246
Accumulated deficit	(694,900)	(667,920)
Total stockholders' equity	6,996	12,332
Total liabilities and stockholders' equity	$ 9,490	$ 55,483

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

KALA BIO, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2025	**2024**
Costs and expenses:		
General and administrative	$ 23,629	$ 18,340
Research and development	18,780	22,094
(Gain) loss on fair value remeasurement of contingent consideration	(4,659)	549
Impairment of right-of-use assets	1,411	—
Total costs and expenses	39,161	40,983
Loss from operations	(39,161)	(40,983)
Other income (expense):		
Interest income	1,140	2,056
Interest expense	(3,276)	(5,783)
Grant income	3,377	6,199
Gain on extinguishment of debt	5,793	—
Other income (expense), net	5,147	—
Total other income (expense)	12,181	2,472
Net loss	$ (26,980)	$ (38,511)
Net loss per share attributable to common stockholders—basic and diluted	$ (3.31)	$ (10.15)
Weighted average shares outstanding—basic and diluted	8,148,275	3,796,047
Net loss	$ (26,980)	$ (38,511)
Other comprehensive loss:		
Change in fair value of investments	—	—
Total other comprehensive loss	—	—
Total comprehensive loss	$ (26,980)	$ (38,511)

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

KALA BIO, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(In thousands, except share amounts)

	Year Ended December 31, 2025																	
	Series E Convertible Non-Redeemable Preferred Stock $0.001 Par Value		Series F Convertible Non-Redeemable Preferred Stock $0.001 Par Value		Series G Convertible Non-Redeemable Preferred Stock $0.001 Par Value		Series H Convertible Non-Redeemable Preferred Stock $0.001 Par Value		Series I Convertible Non-Redeemable Preferred Stock $0.001 Par Value		Series AA Convertible Non-Redeemable Preferred Stock $0.001 Par Value		Common Stock $0.001 Par Value		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance as of December 31, 2023	51,246	$ —	2,928	$ —	—	$ —	—	$ —	—	$ —	—	$ —	2,759,372	$ 3	$ 636,910	(629,409)	$ 7,504
At the market offering, net of offering costs of $69	—	—	—	—	—	—	—	—	—	—	—	—	527,940	1	3,393	—	3,394
Exercise of stock options	—	—	—	—	—	—	—	—	—	—	—	—	1,281	—	9	—	9
Issuance of common stock for vested restricted stock units	—	—	—	—	—	—	—	—	—	—	—	—	249,224	—	—	—	—
Issuance of common stock under employee stock purchase plan	—	—	—	—	—	—	—	—	—	—	—	—	11,448	—	68	—	68
Issuance of common stock to satisfy service contract	—	—	—	—	—	—	—	—	—	—	—	—	4,000	—	29	—	29
Common stock offering, net of offering costs of $218	—	—	—	—	—	—	—	—	—	—	—	—	2,537,917	2	15,418	—	15,420
Issuance of convertible Series G preferred stock, net of issuance cost of $62	—	—	—	—	10,901	—	—	—	—	—	—	—	—	—	8,538	—	8,538
Issuance of convertible Series H preferred stock, net of issuance cost of $96	—	—	—	—	—	—	9,393	—	—	—	—	—	—	—	5,399	—	5,399
Issuance of convertible Series I preferred stock, net of issuance cost of $24	—	—	—	—	—	—	—	—	3,286	—	—	—	—	—	2,093	—	2,093
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	8,389	—	8,389
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(38,511)	(38,511)
Balance as of December 31, 2024	51,246	$ —	2,928	$ —	10,901	$ —	9,393	$ —	3,286	$ —	—	$ —	6,091,182	$ 6	$ 680,246	(667,920)	$ 12,332
Issuance of common stock for vested restricted stock units	—	—	—	—	—	—	—	—	—	—	—	—	287,231	—	—	—	—
Exercise of stock options	—	—	—	—	—	—	—	—	—	—	—	—	885	—	6	—	6
Issuance of common stock under employee stock purchase plan	—	—	—	—	—	—	—	—	—	—	—	—	15,627	—	67	—	67
Issuance of Preferred Stock	—	—	—	—	—	—	—	—	—	—	900,000	1	—	—	1,799	—	1,800
Conversion of Preferred Stock	(41,968)	—	—	—	—	—	(7,094)	—	(3,286)	—	—	—	5,234,800	5	(5)	—	—
Issuance of Common Stock, net of $866 issuance cost	—	—	—	—	—	—	—	—	—	—	—	—	10,000,000	10	9,124	—	9,134
Issuance of Common Stock _ Service Rendered	—	—	—	—	—	—	—	—	—	—	—	—	3,400,000	3	1,550	—	1,553
Issuance of Common Stock - Oxford Settlement Agreements	—	—	—	—	—	—	—	—	—	—	—	—	1,620,000	2	1,563	—	1,565
Issuance of Common Stock - Settlement Agreements	—	—	—	—	—	—	—	—	—	—	—	—	900,000	2	522	—	524
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	300,000	—	6,995	—	6,995
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(26,980)	(26,980)
Balance as of December 31, 2025	9,278	$ —	2,928	$ —	10,901	$ —	2,299	$ —	—	$ —	900,000	$ 1	27,849,725	$ 28	$ 701,867	$ (694,900)	$ 6,996

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

KALA BIO, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (26,980)	$ (38,511)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	317	259
Non-cash operating lease cost	280	334
Impairment of right-of-use assets	1,411	—
Gain on extinguishment of debt	(5,793)	—
(Gain) loss on fair value remeasurement of contingent consideration	(4,659)	549
Amortization of debt discount and other non-cash interest	(667)	1,248
Stock-based compensation	6,995	8,389
Issuance of Common Stock for service rendered	1,553	—
Issuance of Common Stock for Settlement Agreements	524	—
Loss on sale or disposal of property and equipment	549	—
Other non-cash losses	—	129
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(317)	359
Other long-term assets	144	—
Accounts payable	358	(291)
Accrued expenses and other current liabilities	(3,893)	(1,528)
Lease liabilities and other long-term liabilities	(1,813)	(319)
Net cash used in operating activities	(31,991)	(29,382)
Cash flows from investing activities:		
Purchases of property and equipment and other assets	(15)	(208)
Net cash used in investing activities	(15)	(208)
Cash flows from financing activities:		
Payment of principal and payment fee on debt	(22,413)	(5,000)
Payment of issuance costs from issuance of common stock and Series I preferred stock	(120)	—
Proceeds from issuance of Series AA preferred stock	1,800	—
Proceeds from issuance of Series G preferred stock, net of issuance costs of $62	—	8,538
Proceeds from issuance of common stock and Series H preferred stock, net of issuance costs of $218	—	12,281
Proceeds from common stock offerings, net of offering costs of $866	9,134	3,394
Proceeds from issuance of common stock and Series I preferred stock	—	10,750
Contingent consideration related to Combangio acquisition	—	(119)
Payment of principal on finance lease	(92)	(45)
Proceeds from exercise of stock options and issuance of common stock under employee stock purchase plan	73	77
Net cash (used in) provided by financing activities	(11,618)	29,876
Net (decrease) increase in cash and cash equivalents:	(43,624)	286
Cash and cash equivalents at beginning of period	51,181	50,895
Cash and cash equivalents at end of period	$ 7,557	$ 51,181
Non-cash investing and financing activities:		
Issuance of common stock to satisfy service contract in additional paid-in capital	$ 1,553	$ 29
Issuance costs included in accrued expenses	—	120
Supplemental disclosure:		
Cash paid for interest	$ 2,701	$ 4,610
Right-of-use assets obtained in exchange of finance lease obligations	—	160

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

KALA BIO, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(In thousands, except share and per share amounts)

Note 1: Nature of Business

Nature of Business— KALA BIO, Inc. (the "Company") was incorporated on July 7, 2009, and is a clinical-stage biopharmaceutical company dedicated to the research, development and commercialization of innovative therapies for rare and severe diseases of the front and back of the eye.

On September 29, 2025, the Company announced that the CHASE trial of KPI-012 for the treatment of PCED did not meet the primary endpoint of complete healing of PCED as measured by corneal fluorescein staining. The CHASE trial also failed to achieve statistical significance for key secondary efficacy endpoints and did not show any meaningful difference between either KPI-012 treatment arm and the placebo arm. Based on the CHASE trial results, the Company determined to cease development of KPI-012 and our MSC-S platform.

Following the discontinuation of KPI-012 development in September 2025 after the CHASE Phase 2b clinical trial failed to meet its primary endpoints, the Company strategically repositioned ourselves to capitalize on the substantial intellectual property and research data generated during its mesenchymal stem cell secretome (MSC-S) platform development. the Company identified a significant market opportunity to transform our proprietary biological research assets into a next-generation artificial intelligence or AI platform specifically designed for biotechnology research applications.

This strategic pivot represents a fundamental transformation from a traditional clinical-stage biopharmaceutical company to an AI-powered biotechnology research intelligence platform provider, targeting the rapidly expanding artificial intelligence in the drug discovery market.

Strategic Initiative - On March 3, 2026, the Company and 2624465 Ontario Inc. o/a Younet AI, an Ontario corporation ("Younet") entered into a Platform Development and Exclusive License Agreement (the "Agreement") pursuant to which the Company obtained a worldwide exclusive license (the "Exclusive License") of Younet's proprietary, custom biomedical artificial intelligence research platform (the "Researgency Platform"), together with associated trademarks and intellectual property. See Note 16-Subsequent events for more details.

On November 15, 2021, the Company acquired Combangio, Inc. ("Combangio"), including its mesenchymal stem cell secretomes ("MSC-S") platform and product candidate, which the Company refers to as KPI-012, for the treatment of persistent corneal epithelial defects ("PCED")(collectively, the "Combangio Acquisition"). For accounting purposes, the transaction was accounted for as an asset acquisition, as substantially all of the fair value of the gross assets acquired was concentrated in a single asset, KPI-012.

LifeSci and Baker Settlement Agreements - On December 30, 2025, the Company entered into the Baker Settlement Agreement with Baker Bros. Advisors LP, pursuant to which the Company agreed to issue the Baker Shares to resolve certain claims relating to participation rights under prior financing arrangements (the "Baker Settlement"). In connection with the Baker Settlement, the Company and Baker Bros. Advisors LP also entered into a voting agreement pursuant to which Baker Bros. Advisors LP granted an irrevocable proxy in favor of us to vote the settlement shares and other specified shares in line with our Board of Directors' recommendations for a period of six months. On December 30, 2025, the Company also entered into the LifeSci Settlement Agreement pursuant to which we agreed to issue the LifeSci Shares to settle certain payment obligations for financial advisory services.

Recent Equity Financings - *Private Placements*— On March 25, 2024, the Company entered into a Securities Purchase Agreement (the "March 2024 Securities Purchase Agreement") with certain institutional investors named therein, pursuant to which the Company agreed to issue and sell, in a private placement priced at-the-market under Nasdaq rules, shares of Series G Convertible Non-Redeemable Preferred Stock, par value $0.001 per share, of the Company (the "Series G Preferred Stock"), for aggregate gross proceeds of approximately $8,600 (the "March 2024 Private Placement"). Pursuant to the March 2024 Securities Purchase Agreement, the Company issued and sold to the purchasers at the closing

of the March 2024 Private Placement, 10,901 shares of Series G Preferred Stock, at a price per preferred share equal to $788.90. Costs incurred in connection with the March 2024 Private Placement were $62, which were recorded as a reduction to additional paid-in capital.

On June 26, 2024, the Company entered into a Securities Purchase Agreement (the "June 2024 Securities Purchase Agreement") with certain institutional investors named therein, pursuant to which the Company agreed to issue and sell, in a private placement, shares of common stock and shares of Series H Convertible Non-Redeemable Preferred Stock, par value $0.001 per share, of the Company (the "Series H Preferred Stock"), for aggregate gross proceeds of approximately $12,499 (the "June 2024 Private Placement"). Pursuant to the June 2024 Securities Purchase Agreement, the Company issued and sold to the purchasers at the closing of the June 2024 Private Placement, 1,197,314 shares of common stock, at a price per common share equal to $5.85, and 9,393 shares of Series H Preferred Stock, at a price per preferred share equal to $585.00. Costs incurred in connection with the June 2024 Private Placement were $218, which were recorded as a reduction to additional paid-in capital.

On December 29, 2024, the Company entered into a Securities Purchase Agreement (the "December 2024 Securities Purchase Agreement") with certain institutional investors named therein, pursuant to which the Company agreed to issue and sell, in a private placement, shares of common stock and shares of Series I Convertible Non-Redeemable Preferred Stock, par value $0.001 per share, of the Company (the "Series I Preferred Stock"), for aggregate gross proceeds of approximately $10,750 (the "December 2024 Private Placement"). Pursuant to the December 2024 Securities Purchase Agreement, the Company issued and sold to the purchasers at the closing of the December 2024 Private Placement, 1,340,603 shares of common stock, at a price per common share equal to $6.44, and 3,286 shares of Series I Preferred Stock, at a price per preferred share equal to $644.00. Costs incurred in connection with the December 2024 Private Placement were $120, which were recorded as a reduction to additional paid-in capital.

On November 23, 2025 (the "SPA Effective Date"), we entered into a Securities Purchase Agreement (the "November 2025 Purchase Agreement") with David Lazar, pursuant to which we agreed to issue and sell, in a private placement, shares of our Series AA Preferred Convertible Preferred Stock, par value $0.001 per share (the "Series AA Preferred Stock") and our Series AAA Preferred Stock in two closings for aggregate gross proceeds of up to $6,000, subject to the terms and conditions set forth in the Securities Purchase Agreement (collectively, the "Private Placement").

The first closing of the Private Placement occurred on November 24, 2025, pursuant to which we issued and sold to David Lazar an aggregate of 900,000 shares of Series AA Preferred Stock at a price per share equal to $2.00, for aggregate gross proceeds of $1,800. Each share of Series AA Preferred Stock is convertible into 55 shares of Common Stock for an aggregate total of 49,500,000 shares of Common Stock issuable upon conversion of the Series AA Preferred Stock. As of the date of this Annual Report on Form 10-K, there are 681,818 shares of Series AA Preferred Stock outstanding, which are convertible into 37,499,900 shares of Common Stock.

On December 11, 2025, David Lazar transferred his rights and obligations under the November 2025 Purchase Agreement solely with respect to the shares of Series AAA Preferred and the director nomination rights, to AK Holdings Group Inc., a Panamanian company ("AK Holdings"). On January 29, 2026, pursuant to the terms of that certain Rights Purchase Agreement by and among AK Holdings and each signatory thereto (the "Series AAA Investors"), AK Holdings sold its rights to purchase the Series AAA Preferred Stock (but not its director nomination rights under the November 2025 Purchase Agreement) to the Series AAA Investors.

KALA BIO, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(In thousands, except share and per share amounts)

On January 30, 2026, pursuant to the terms of a Securities Purchase Agreement (the "January 2026 Purchase Agreement" and together with the November 2025 Purchase Agreement, the "Purchase Agreements"), we issued and sold to the Series AAA Investors in a second closing of the Private Placement (the "Second Closing"), an aggregate of 2,100,000 shares of Series AAA Preferred Stock at a price per share of Series AAA Preferred Stock equal to $2.00, for aggregate gross proceeds of $4,200. The Second Closing occurred on January 30, 2026. The terms of the Series AAA Preferred Stock are substantially similar to the terms of the Series AA Preferred Stock. Each share of Series AAA Preferred Stock was convertible into 420 shares of common stock for an aggregate total of 882,000,000 shares of Common Stock issuable upon conversion of the Series AAA Preferred Stock. As of the date of this annual report, all of the shares of Series AAA Preferred Stock have been converted into common stock.

On January 8, 2026, the Company entered into an At The Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC ("Wainwright") providing for the sale and issuance by the Company of shares of its Common Stock from time to time, through or to Wainwright as the Company's sales agent or principal in an "at the market offering" program and as set forth in the ATM Agreement (the "ATM Offering"). The aggregate market value of the shares of Common Stock eligible for sale under the prospectus supplement is currently $15,000.

Note 2: Summary of Significant Accounting Policies

Principles of Consolidation—The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Kala Pharmaceuticals Security Corporation, which is a Massachusetts subsidiary created to buy, sell and hold securities, and Combangio. All intercompany transactions and balances have been eliminated.

Basis of Presentation—The accompanying consolidated financial statements have been prepared on a going concern basis which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company generated only limited revenues from product sales of EYSUVIS and INVELTYS prior to the sale of the Commercial Business to Alcon in July 2022 and has incurred recurring losses and negative cash flows from operations, including a net loss of $26,980 and $38,511, for the years ended December 31, 2025 and 2024, respectively, and used cash in operations of $31,991 and $29,382, in the years ended December 31, 2025 and 2024, respectively. The Company has financed its operations to date primarily through proceeds from the sale of the Commercial Business to Alcon, its initial public offering of common stock, follow-on public offerings of common stock and sales of its common stock under its at-the-market offering facility, private placements of common stock and preferred stock, borrowings under credit facilities and the Loan and Security Agreement with Oxford Finance LLC (the "Loan Agreement"), disbursements under a grant from California Institute for Regenerative Medicine ("CIRM") upon achievement of specified milestones, convertible promissory notes and warrants.

Liquidity and Ability to Continue as a Going Concern— Since inception, the Company has incurred significant losses from operations and negative cash flows from operations including a net loss of $26,980 and $38,511 for the years ended December 31, 2025 and 2024, respectively, and cash used in operating activities of $31,991 and $29,382 in the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, the Company had an accumulated deficit of $694,900.

Prior to the recent cessation of our research and development activities, the Company had devoted substantially all of its financial resources and efforts to research and development, including preclinical studies and clinical trials, and, prior to the sale of the Commercial Business to Alcon in July 2022, engaging in activities to launch and commercialize EYSUVIS and INVELTYS. The Company devoted substantially all of its financial resources to the research and development of KPI-012 for PCED and any other indications the Company determined to pursue, including Limbal Stem Cell Deficiency. The Company may never achieve or maintain profitability. Net losses may fluctuate significantly from quarter-to-quarter and year-to-year.

KALA BIO, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(In thousands, except share and per share amounts)

During the first, second and third quarters of 2025, the Company concluded there was substantial doubt regarding the Company's ability to continue as a going concern. However, on September 29, 2025, the Company announced that it was determined to cease development of KPI-012 and its MSC-S platform and to take steps to preserve cash as the Company explores its strategic options. In connection with such decisions, the Company stopped all spending on the KPI-012 project and approved a major reduction in the Company's workforce. During the fourth quarter of 2025, the Company entered into purchase agreement with certain institutional investors, raised capital and changed management. The Company also recently shifted its focus to develop an on-premises Artificial Intelligence ("AI") infrastructure platform for the biotech industry. Based on these recent developments and as a result, the Company has concluded that management's plans do alleviate substantial doubt about the Company's ability to continue as a going concern for the twelve months after the date these consolidated financial statements are issued.

Use of Estimates— The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expense, and related disclosures. The Company bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis. Estimates and assumptions relied upon in preparing these consolidated financial statements relate to, but are not limited to, the present value of lease liabilities and the corresponding right-of-use assets, the fair value of warrants, stock-based compensation, accrued expenses, contingent consideration, grant income and deferred grant income, the valuation of embedded derivatives and the recoverability of the Company's net deferred tax assets and related valuation allowance. Actual results may differ from these estimates under different assumptions or conditions.

Grant Income— Grant income consists of amounts earned from incurring costs to support the CHASE Phase 2b clinical trial of KPI-012 for PCED, as well as product process characterization and analytical development from the program due to the receipt of the CIRM Award. The grant between the Company and CIRM is subject to a co-funding requirement and generally provides for the Company to meet certain milestones in order for funds to be provided. The Company accounts for grants received to perform research and development activities in accordance with Accounting Standards Codification ("ASC") Topic 730-20, *Research and Development Arrangements*, which requires an assessment, at the inception of the grant, of whether the grant is a liability or a contract to perform research and development activities. If the Company is obligated to repay the grant funds to the grantor regardless of the outcome of the research and development activities, then the Company is required to estimate and recognize that liability. Alternatively, if the Company is not required to repay, or if it is required to repay the grant funds to the grantor only if the research and development activities are successful, then the grant agreement is accounted for as a contract to perform research and development activities, in which case, grant income is recognized as the related research and development expenses are incurred. Costs of grant income are recorded as a component of research and development expenses in the Company's consolidated statements of operations and comprehensive loss.

Grant funds received in advance were recorded as deferred grant income on the consolidated balance sheets. Management had determined that the Company was the principal participant under the Company's CIRM Award, and accordingly, the Company recorded amounts earned under this arrangement as grant income on the consolidated statements of operations and comprehensive loss.

Contingent Consideration—In addition to upfront consideration and Deferred Purchase Consideration (as defined below) (see Note 3), the Company's asset acquisitions may also include contingent consideration payments to be made for future milestone events. The Company assesses whether such contingent consideration is required to be recorded at fair value on the date of the acquisition and subsequently remeasured to fair value at each reporting date. Contingent consideration payments in an asset acquisition not required to be accounted for at fair value are recognized when the contingency is resolved, and the consideration is paid or becomes payable. Changes to contingent consideration obligations can result from changes to discount rates, accretion of the liability due to the passage of time,

changes in the Company's estimates of the likelihood or timing of achieving certain milestones. Any changes in the fair value of these contingent consideration liabilities are included in loss from operations in the consolidated statements of operations and comprehensive loss.

Derivative Instruments—ASC 815, *Derivatives and Hedging*, ("ASC 815") requires companies to bifurcate certain conversion options and redemption features from their host instruments and account for them as free-standing derivative financial instruments should certain criteria be met. The Company evaluates its financial instruments, including its debt arrangements, to determine whether such instruments are derivatives or contain features that qualify as embedded derivatives. Embedded derivatives must be separately measured from the host contract if all the requirements for bifurcation are met. The assessment of the conditions surrounding the bifurcation of embedded derivatives depends on the nature of the host contract and the features of the derivatives. Bifurcated embedded derivatives are recognized at fair value, with changes in fair value recognized in the consolidated statement of operations and comprehensive income each period. Bifurcated embedded derivatives are classified with the related host contract in the Company's consolidated balance sheet.

Cash and Concentration of Credit Risk—Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents, short-term investments, if any, and accounts receivable, if any. Periodically, the Company maintains cash, cash equivalents, short-term investments in accredited financial institutions in excess of federally insured limits. The Company deposits its cash, cash equivalents, short-term investments, if any, in financial institutions that it believes have high credit quality and has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company had no revenue during the years ended December 31, 2025 and 2024. The Company has no financial instruments with off-balance sheet risk of loss.

Cash Equivalents—The Company considers all short-term, highly liquid investments with original maturities of 90 days or less at acquisition date to be cash equivalents.

Investments—The Company determines the appropriate classification of its investments at the time of purchase. The Company's investments are classified as available-for-sale in accordance with ASC Topic 320, *Investments—Debt and Equity Securities*. The Company classifies investments available to fund current operations as current assets on its consolidated balance sheets. Investments are classified as long-term assets on the consolidated balance sheets if (i) the Company has the intent and ability to hold the investments for a period of at least one year and (ii) the contractual maturity date of the investments is greater than one year.

Available-for-sale investments are recorded at fair value, with unrealized gains or losses included in comprehensive loss on the consolidated statements of operations and comprehensive loss and in accumulated other comprehensive income or loss on the consolidated balance sheets. Realized gains and losses, interest income earned on the Company's cash, cash equivalents and investments, and amortization or accretion of discounts and premiums on investments are included within other income (expense).

The Company reviews investments for other-than-temporary impairment whenever the fair value of an investment is less than the amortized cost and evidence indicates that an investment's carrying amount is not recoverable within a reasonable period of time. The Company did not record any such impairments during the years ended December 31, 2025 or 2024.

KALA BIO, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(In thousands, except share and per share amounts)

Leases—At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease. Most leases with a term greater than one year are recognized on the balance sheet as right-of-use assets, lease liabilities and, if applicable, long-term lease liabilities. The Company has elected not to recognize on the balance sheet leases with terms of one-year or less. Lease liabilities and their corresponding right-of-use assets are recorded 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 appropriate incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received.

The components of a lease should be split into three categories: lease components (e.g., land, building, etc.), non-lease components (e.g., common area maintenance, maintenance, consumables, etc.), and non-components (e.g., property taxes, insurance, etc.). Then the fixed and in-substance fixed contract consideration (including any related to non-components) must be allocated based on fair values to the lease components and non-lease components. Although separation of lease and non-lease components is required, certain practical expedients are available to entities. Entities electing the practical expedient would not separate lease and non-lease components. Rather, they would account for each lease component and the related non-lease component together as a single component. The Company's facilities operating leases had lease and non-lease components which the Company has elected to use the practical expedient and account for each lease component and related non-lease component as one single component. The lease component resulted in a right-of-use asset being recorded on the consolidated balance sheets and amortized as lease expense on a straight-line basis to the consolidated statements of operations and comprehensive loss.

Property and Equipment, net—Property and equipment are recorded at cost. Depreciation is provided using the straight-line method over the estimated useful lives of the related assets. Depreciation expense is included in loss from operations on the consolidated statements of operations and comprehensive loss. Laboratory equipment and office and computer equipment is depreciated over three to five years. Leasehold improvements are depreciated over the shorter of their useful life or the life of the lease. Major additions and upgrades are capitalized; maintenance and repairs, which do not improve or extend the life of the respective assets, are expensed as incurred. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in loss from operations on the consolidated statements of operations and comprehensive loss.

Patent Costs—Costs to secure and defend patents are expensed as incurred and are classified as general and administrative expenses in the Company's consolidated statements of operations and comprehensive loss.

Advertising Costs—Advertising costs are expensed as incurred. The Company incurred no advertising costs for the years ended December 31, 2025 and 2024.

Impairment of Long-Lived Assets—Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. When such events occur, the Company compares the carrying amounts of the assets to their undiscounted expected future cash flows. If the undiscounted cash flows are insufficient to recover the carrying value, the assets are recorded at the lesser of the carrying value or fair value. As a result of the recent decision to cease development of KPI-012 and our MSC-S platform, the Company recorded $549 impairment charges for the year ended December 31, 2025. No impairment charges were recorded for the year ended December 31, 2024.

KALA BIO, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(In thousands, except share and per share amounts)

Segment Information—Operating segments are identified as components of an enterprise about which separate discrete financial information is made available for evaluation by the chief operating decision maker ("CODM") in making decisions regarding resource allocation and assessing performance. The CODM is the Company's Chief Executive Officer. The Company manages its operations as one operating and reportable segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is on the development and commercialization of innovative therapies for rare and severe diseases of the front and back of the eye. All of the Company's tangible assets are held in the United States.

The CODM uses net loss as reported on the consolidated statements of operations and comprehensive loss to analyze cash flows in assessing performance of the segment and deciding how to allocate resources. The measure of segment assets is reported on the consolidated balance sheet as total assets.

The table below provides information about the Company's segment, including significant segment expenses, other segment items and a reconciliation to net loss:

	Year Ended December 31,	
	2025	2024
Costs and expenses:		
Research and development:		
KPI-012 development costs	$ 8,156	$ 10,170
Employee-related costs for research and development personnel	8,928	10,757
Other research and development costs (1)	1,696	1,167
General and administrative	23,629	18,340
Other segment expense (income), net (2)	(15,429)	(1,923)
Net loss	$ (26,980)	$ (38,511)

(1) Includes facility related costs and depreciation.

(2) Includes Impairment of right-of-use assets, (Gain) loss on fair value remeasurement of contingent consideration, Interest income, Interest expense, Grant income, gain on settlements, Gain on extinguishment of debt and Other income, net.

Research and Development Costs—Research and development expenses consist of expenses incurred in performing research and development activities, including compensation and benefits for full-time research and development employees, an allocation of facilities expenses, overhead expenses and other outside expenses. Research and development costs are expensed as incurred. The Company expenses costs relating to the production of inventory for its product candidates as research and development expenses within its consolidated statements of operations and comprehensive loss in the period incurred, until the point the Company believes regulatory approval and subsequent commercialization of the product candidate is probable and it expects the future economic benefit from sales of the drug to be realized. Research and development costs that are paid in advance of performance, including nonrefundable prepayments for goods or services, are deferred and capitalized as a prepaid expense. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Accrued Expenses—The Company accrues for variable consideration related to rebates, sales incentives and allowances, and returns. Such estimates are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of the accrued expense. The Company also accrues expenses related to development activities performed by third parties based on an evaluation of services received and efforts expended pursuant to the terms of the contractual arrangements. Payments under some of these contracts depend on clinical trial milestones. There may be instances in which payments made to the Company's vendors will exceed the level of services

provided and result in a prepayment of expenses. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual or prepaid expense accordingly.

Stock-Based Compensation—The Company accounts for all stock-based awards granted as compensation expense at fair value. The Company generally issues stock-based awards with the measurement date for awards as the date of grant. Stock-based compensation costs are recognized as expense over the employees' requisite service period, which is the vesting period, on a straight-line basis. For performance awards whose vesting is contingent upon a specified event, the Company recognizes stock-based compensation expense over the derived service period, based on the probability of achievement of the specified event. The Company recognizes compensation expense for the portion of awards that have vested. Forfeitures are recorded as they occur. Stock-based compensation is classified in the accompanying consolidated statements of operations and comprehensive loss based on the function to which the related services are provided, or until related expense is recognized.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The assumptions used in calculating the fair value of stock-based payment awards represent management's best estimates. The Company previously lacked sufficient company-specific historical and implied volatility information. Therefore, it estimated its expected stock volatility based on the historical volatility of a publicly traded set of peer companies in addition to its own historical volatility. Beginning in the second half of 2023, the Company determined it had adequate historical data regarding the volatility of its own traded stock price and began exclusively using its own historical volatility. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future. The fair value of restricted stock units ("RSUs") are equal to the closing sale price of the Company's common stock on the date of grant.

Income Taxes—Deferred tax assets and liabilities are recognized for the expected future tax consequences of events that have been included in the Company's consolidated financial statements and tax returns. Deferred tax assets and liabilities are determined based upon the differences between the consolidated financial statement carrying amounts and the tax basis of existing assets and liabilities and for loss and credit carryforwards using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

The Company provides reserves for potential payments of tax to various tax authorities related to uncertain tax positions and other issues. The Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements from such a position is measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. As a result, reserves are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized following resolution of any potential contingencies present.

Net Loss per Share Attributable to Common Stockholders—The Company follows the two-class method when computing net income (loss) per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been

distributed. The two-class method is not applicable during periods with a net loss, as the holders of the convertible preferred stock have no contractual obligation to share in losses. For all periods presented, the two-class method was not applicable.

Basic net loss per share attributable to common stockholders is computed using the weighted-average number of common shares outstanding during the period. Diluted net loss per share attributable to common stockholders is computed using the weighted average number of common shares outstanding during the period and, if dilutive, the weighted average number of potential shares of common stock, including the assumed exercise of stock options and warrants, the issuance of unvested RSUs and convertible preferred stock using the if-converted method.

The weighted average number of common shares included in the computation of diluted net loss gives effect to all potentially dilutive common equivalent shares, including outstanding stock options, warrants, unvested RSUs and convertible preferred stock using the if-converted method. Common stock equivalent shares are excluded from the computation of diluted net loss per share attributable to common stockholders if their effect is antidilutive. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the years ended December 31, 2025 and 2024. See Note 12, “Loss Per Share”, for further information.

Recently Issued and adopted Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which expands annual and interim disclosure requirements for reportable segments, primarily through enhanced disclosures about significant segment expenses. ASU 2023-07 is effective for the Company’s annual periods beginning January 1, 2024, and for interim periods beginning January 1, 2025, with early adoption permitted. As of December 31, 2024, the Company adopted ASU 2023-07. Other than additional disclosure, the adoption of ASU 2023-07 had no impact on the Company’s consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* (“ASU 2023-09”), which focuses on the rate reconciliation and income taxes paid. ASU 2023-09 requires public business entities to disclose, on an annual basis, specific categories in the effective tax rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold. In addition, ASU 2023-09 requires companies to disclose further information about income taxes paid. The standard is effective for annual periods beginning after December 15, 2024, and may be applied prospectively or retrospectively. The Company adopted ASU 2023-09 prospectively for the year ended December 31, 2025, and it affects only the Company's disclosures and does not impact its results of operations or financial condition.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which requires disaggregated expense information in the notes to the financial statements related to purchases of inventory, employee compensation, depreciation, intangible asset amortization and selling expenses for each statement of earnings line item that contains those expenses. ASU No. 2024-03 is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods within annual reporting periods beginning after December 15, 2027. The guidance is to be applied on a prospective basis with the option to apply the standard retrospectively and early adoption is permitted. During the year ended December 31, 2025, the Company retrospectively adopted this ASU and it did not have a material impact on the Company’s consolidated financial statements and related disclosures.

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Management has considered all recent accounting pronouncements issued since the last audit of our consolidated financial statements. The Company's management believes that these recent pronouncements will not have a material effect on our company's consolidated financial statements.

Note 3: Fair Value of Financial Instruments

ASC 820, *Fair Value Measurements and Disclosures*, establishes a fair value hierarchy for those instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and its own assumptions (unobservable inputs). The hierarchy consists of three levels:

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

The Company's financial instruments as of December 31, 2025 and 2024 consisted primarily of cash equivalents and contingent consideration. Cash equivalents and contingent consideration are reported at their respective fair values on the Company's consolidated balance sheets.

The Company acquired Combangio in November 2021 and in connection with the closing of the Combangio Acquisition, the Company agreed to issue an aggregate of 155,664 shares (the "Deferred Purchase Consideration") of the Company's common stock to former Combangio stockholders and other equityholders (the "Combangio Equityholders") consisting of (i) an aggregate of 136,314 shares of common stock issued on January 3, 2022 and (ii) an aggregate of 19,350 shares of common stock that were held back as partial security for the satisfaction of indemnification obligations and other payment obligations of the Combangio Equityholders and were issued on March 10, 2023 (the "Holdback Shares"). The Company established liabilities for these considerations.

Additionally, the purchase price in connection with the Combangio Acquisition included potential future payments of up to $105,000 that are contingent upon the achievement of specified development, regulatory and commercialization milestones and are required to be recorded at fair value.

As of December 31, 2025, of the $105,000 in contingent milestone payments, the Company has paid to the Combangio Equityholders an aggregate of $2,646 in cash and $2,354 in shares of the Company's common stock (representing an aggregate of 105,038 shares of the Company's common stock) following dosing of the first patient in the Company's CHASE Phase 2b clinical trial of KPI-012 for PCED in the United States in February 2023 (the "First Dosing Milestone"). Contingent consideration liabilities related to acquisitions are measured at fair value each reporting period using Level 3 unobservable inputs. The fair values of the contingent consideration liabilities were based on a probability-adjusted discounted cash flow calculation using Level 3 fair value measurements. Changes in these estimates and assumptions could have a significant impact on the fair value of the contingent consideration liabilities. Any changes in the fair value of these contingent consideration liabilities are included in loss from operations in the consolidated statements of operations and comprehensive loss.

On September 29, 2025, the Company announced that the CHASE trial of KPI-012 for the treatment of PCED did not meet the primary endpoint of complete healing of PCED as measured by corneal fluorescein staining. The CHASE trial also failed to achieve statistical significance for key secondary efficacy endpoints and did not show any

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meaningful difference between either KPI-012 treatment arm and the placebo arm. Based on the CHASE trial results, we determined to cease development of KPI-012 and our MSC-S platform. Therefore, the contingent consideration was fully remeasured to zero with no potential possibilities for any milestone payments.

During the years ended December 31, 2025 and 2024, the change in the fair value of the contingent consideration liabilities was a gain of $4,659 and a loss of $549, respectively, primarily due to changes in discount rates, the passage of time and changes in the expected timing and probability of payment, and were recognized as a (gain)/loss on fair value remeasurement of contingent consideration in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2025 and 2024.

The following tables set forth the fair value of the Company's financial instruments by level within the fair value hierarchy as of December 31, 2025 and 2024:

	December 31, 2025			
	Fair Value	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ -	$ -	$ —	$ —
Total Assets	$ -	$ -	$ —	$ —

	December 31, 2024			
	Fair Value	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 39,707	$ 39,707	$ —	$ —
Total Assets	$ 39,707	$ 39,707	$ —	$ —
Liabilities:				
Contingent consideration - Non-Current	$ 4,659	$ —	$ —	$ 4,659
Total Liabilities	$ 4,659	$ —	$ —	$ 4,659

The following tables summarize quantitative information and assumptions pertaining to the fair value measurement of the Level 3 inputs as of December 31, 2025 and 2024:

Financial Instrument	Fair Value at December 31, 2025	Valuation Technique	Unobservable Input	Range (Average)
Contingent consideration	$ -	Probability-adjusted discounted cash flow model	Period of expected milestone achievement	2026 - 2028 (2028)
			Probabilities of achievement	16.6% - 35.5% (23.4%)
			Discount rate	15.5%

Financial Instrument	Fair Value at December 31, 2024	Valuation Technique	Unobservable Input	Range (Average)
Contingent consideration	$ 4,659	Probability-adjusted discounted cash flow model	Period of expected milestone achievement	2026 - 2028 (2028)
			Probabilities of achievement	16.6% - 35.5% (23.4%)
			Discount rate	14.3%

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The following table summarizes the changes in the Deferred Purchase Consideration and contingent consideration liabilities measured at fair value using Level 3 inputs for the years ended December 31, 2025 and 2024:

Contingent consideration		
Balance at January 1, 2024	$	4,110
Fair value adjustments		549
Balance at December 31, 2024	$	4,659
Fair value adjustments		(4,659)
Balance at December 31, 2025	$	—

During the years ended December 31, 2025 and 2024, there were no transfers between Level 1, Level 2, and Level 3.

The carrying value reported on the accompanying consolidated balance sheets of cash, accounts payable and accrued expenses approximate their fair value due to their short-term nature.

Note 4: Grant Income

CIRM Award

On August 2, 2023, Combangio, a wholly owned subsidiary of the Company, entered into an award agreement with CIRM for a $15,000 grant (as amended from time to time, the "CIRM Award") to support Combangio's KPI-012 program for the treatment of PCED. The CIRM Award includes funding for the CHASE Phase 2b clinical trial of KPI-012 for PCED, as well as product and process characterization and analytical development for the program. The CIRM Award is subject to a co-funding requirement under which Combangio is obligated to spend a specified minimum amount on the development of KPI-012 to obtain the full award amount. Upon entry into the CIRM Award, Combangio received an initial $5,900 disbursement from CIRM. In August 2024 and December 2024, Combangio received disbursements of $3,240 and $2,520, respectively, from CIRM upon the achievement of specified milestones. The balance of the award is payable to Combangio upon the achievement of other specified milestones that are primarily related to Combangio's progress in conducting the CHASE Phase 2b clinical trial. CIRM may permanently cease disbursements if the milestones are not met within four months of the scheduled completion dates or if the delay is not addressed to CIRM's satisfaction, as determined by CIRM in its sole discretion. Additionally, if CIRM determines, in its sole discretion, that Combangio has not complied with the terms and conditions of the CIRM Award, CIRM may suspend or permanently cease disbursements. Under the terms of the CIRM Award, Combangio is obligated to pay a royalty on net sales of any product, service or approved drug resulting in whole or in part from the CIRM Award in the amount of 0.1% per $1,000 of funds utilized by the Company until the earlier of ten years from the date of first commercial sale of such product, service or approved drug and such time as nine times the amount of funds awarded by CIRM has been paid in royalties (the "Base Royalty"). In addition, following the satisfaction of the Base Royalty, Combangio is obligated to pay a 1.0% royalty on net sales of any CIRM-funded invention in excess of $500,000 per year until the last to expire patent covering such invention expires.

On September 29, 2025, the Company announced that the CHASE trial of KPI-012 for the treatment of PCED did not meet the primary endpoint of complete healing of PCED as measured by corneal fluorescein staining. The CHASE trial also failed to achieve statistical significance for key secondary efficacy endpoints and did not show any meaningful difference between either KPI-012 treatment arm and the placebo arm. Based on the CHASE trial results, we determined to cease development of KPI-012 and our MSC-S platform. During the years ended December 31, 2025 and 2024, the Company recognized $3,377 and $6,199, respectively, of grant income related to the CIRM Award on its consolidated statement of operations. As of December 31, 2025, the Company had $0 deferred grant income on its consolidated balance sheet.

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Note 5: Property and Equipment, Net

Property and equipment, net, consisted of the following:

	December 31, 2025	December 31, 2024
Equipment	$ —	$ 1,194
Computer hardware and software	869	869
Property and equipment—at cost	869	2,063
Less: Accumulated depreciation	(869)	(1,314)
Property and equipment—net	$ —	$ 749

Depreciation expense for the years ended December 31, 2025 and 2024 was $216 and $204, respectively.

Note 6: Accrued Expenses

Accrued expenses and other current liabilities consisted of the following:

	December 31, 2025	December 31, 2024
Professional services	$ 800	$ 414
Development costs	269	736
Compensation and benefits	180	2,390
Accrued revenue reserves (1)	155	350
Contract manufacturing	—	672
Other	104	413
Accrued expenses and other current liabilities	$ 1,508	$ 4,975

(1) These amounts represent estimated provisions for product returns, rebates and discounts, prior to the sale of the Commercial Business to Alcon. Estimated provisions were deducted from gross revenues at the time revenues were recognized and are included in accrued expenses and other current liabilities on the Company's consolidated balance sheets. These provisions reflected the Company's best estimates of the amount of consideration to which it was entitled based on the terms of the contract.

Note 7: Lease

Operating leases

Menlo Park, California Office Lease

In April 2023, Combangio entered into a lease agreement with Menlo Prepi I, LLC, pursuant to which Combangio leases approximately 6,135 square feet of office, laboratory and research and development space in Menlo Park, California. The Company entered into a guaranty of lease agreement guarantying the obligations of Combangio under the lease agreement. The initial term of the lease is for 62 months which commenced on the lease commencement date of July 1, 2023, unless earlier terminated pursuant to the terms of the lease. The lease provides Combangio with an option to extend the lease for an additional five-year term. Combangio was required to make a payment in the amount of $144, as a security deposit pursuant to the lease during the year ended December 31, 2023, which is included in other long-term assets on the consolidated balance sheet as of December 31, 2024. Upon the lease commencement, the Company recorded a right-of-use asset of $2,154 and corresponding $2,133 of lease liability.

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As a result of the CHASE trial of KPI-012 decision to cease development, on November 21, 2025, the Company terminated the lease with the landlord and signed a settlement to return the space and release the Company from its obligations and liabilities. The settlement was paid prior to December 31, 2025.

The components of lease expense and related cash flows were as follows:

	Year Ended December 31,	
	2025	2024
Lease cost		
Operating lease cost	$ 546	$ 596
Short-term lease cost	37	34
Variable lease cost	179	209
Total lease cost	$ 762	$ 839
Operating cash outflows from operating leases	$ 550	$ 581

The weighted average remaining lease term and weighted average discount rate of operating leases were as follows:

	December 31, 2025	December 31, 2024
Weighted average remaining lease term	-	3.7 years
Weighted average discount rate	-	13.1%

Note 8: Debt

Loan and Security Agreement

On May 4, 2021, the Company entered into the Loan Agreement with Oxford Finance, in its capacity as lender (in such capacity, the "Lender"), and in its capacity as collateral agent (in such capacity, the "Agent"), pursuant to which a term loan of up to an aggregate principal amount of $125,000 was available to the Company, consisting of a tranche A term loan that was disbursed on the closing date in the aggregate principal amount of $80,000 and additional tranches that are no longer available to the Company. The Company utilized substantially all of the proceeds from the tranche A term loan to repay a prior credit facility.

Through June 30, 2023, the term loan bore interest at a floating rate equal to the greater of (i) 30-day LIBOR and (ii) 0.11%, plus 7.89%. Effective July 1, 2023, the term loan bears interest at a floating rate equal to the greater of (i) 8.00% and (ii) the sum of (a) the 1-Month CME Term Secured Overnight Financing Rate, (b) 0.10% and (c) 7.89%. The Loan Agreement, prior to the Second Loan Amendment and Third Loan Amendment (as defined below), provided for interest-only payments until December 1, 2024 if neither the tranche B term loan nor the tranche C term loan are made, and until June 1, 2025 if either the tranche B term loan or the tranche C term loan is made (the "Amortization Date"). The aggregate outstanding principal balance of the term loans were required to be repaid in monthly installments starting on the Amortization Date based on a repayment schedule equal to (i) 18 months if neither the tranche B term loan nor the tranche C term loan is made and (ii) 12 months if either the tranche B term loan or the tranche C term loan is made. All unpaid principal and accrued and unpaid interest with respect to each term loan was due and payable in full on May 1, 2026 (the "Maturity Date").

The Company paid a facility fee of $400 on the closing date of the Loan Agreement and agreed to pay a facility fee of $100 upon closing of the tranche B term loan and a $125 facility fee upon the closing of the tranche C term loan.

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The Company will be required to make a final payment fee of 7.00% of the original principal amount of any funded term loan payable on the earlier of (i) the prepayment of the term loan in full or (ii) the Maturity Date. At the Company's option, the Company may elect to make partial repayments of the term loan to the Lender, subject to specified conditions, including the payment of applicable fees and accrued and unpaid interest on the principal amount of the term loan being repaid.

In connection with its entry into the Loan Agreement, the Company granted the Agent a security interest in substantially all of the Company's personal property owned or later acquired, including intellectual property and the Commercial Business. The Company also agreed to maintain its cash balance in one or more controlled accounts in favor of the Agent, subject to specified exceptions. The Loan Agreement also contains customary representations and warranties and affirmative and negative covenants, as well as customary events of default. Certain of the customary negative covenants limit the ability of the Company and certain of its subsidiaries, among other things, to incur future debt, grant liens, make investments, make acquisitions, distribute dividends, make certain restricted payments and sell assets, subject in each case to certain exceptions. Certain of the affirmative covenants include, but are not limited to, a failure to pay principal or interest on its due date or any other obligations within three business days of such obligations' due date, and a delisting from the Nasdaq Stock Market because of failure to comply with the continued listing standards of the listing tier of the Nasdaq Stock Market on which the Company's common stock is listed. Events of default under the Loan Agreement include: (i) a material impairment in the perfection or priority of lien in the collateral or in the value of such collateral; (ii) a material adverse change in the business, operations or condition (financial or otherwise) of the Company; or (iii) a material impairment of the prospect of repayment of any portion of the obligations under the Loan Agreement (each, a "Material Adverse Change").

The Loan Agreement includes features requiring (i) additional interest rate upon an event of default accrued at an additional 5%, and (ii) the Lender's right to declare all outstanding principal and interest immediately payable upon an event of default.

On May 21, 2022, in connection with its entry into the Asset Purchase Agreement with Alcon, the Company entered into an amendment to the Loan Agreement (the "Second Loan Amendment"). Pursuant to the Second Loan Amendment, the Lender and Agent consented to the entry by the Company into the Asset Purchase Agreement and the sale of the Commercial Business to Alcon and agreed to release its liens on the Commercial Business in consideration for the payment by the Company at the closing of the Alcon Transaction of an aggregate amount of $40,000 (the "Second Amendment Prepayment") to the Lender and Agent, representing a partial prepayment of principal in the amount of $36,697 of the $80,000 principal amount outstanding under the term loan advanced by the Lender under the Loan Agreement, plus a prepayment fee of $734 and a final payment fee of $2,569. In addition, the Company was required to pay all accrued and unpaid interest on the principal amount of the term loan being repaid.

In addition, under the Second Loan Amendment, the Lender and Agent agreed that, following the closing of the Alcon Transaction and the Second Amendment Prepayment, the Amortization Date would be extended from December 1, 2024 to January 1, 2026, at which time the aggregate principal balance of the term loan then outstanding under the Loan Agreement is required to be repaid in five monthly installments. Pursuant to the Second Loan Amendment, the Company may also make partial prepayments of the term loan to the Lender, subject to specified conditions, including the payment of applicable fees and accrued and unpaid interest on the principal amount of the term loan being repaid.

On July 8, 2022, the Second Amendment Prepayment was paid in connection with the closing of Alcon Transaction, and as such, the Amortization Date was extended to January 1, 2026. The transaction resulted in a loss on extinguishment of debt of $2,583 for the year ended December 31, 2022, consisting of the prepayment premium, a pro-rata portion of the unamortized debt discount and issuance costs and the unaccreted exit fee due upon the Second Amendment Prepayment.

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On December 27, 2022, the Company entered into an amendment to the Loan Agreement (the "Third Loan Amendment"). Pursuant to the Third Loan Amendment, the Lender and Agent agreed to amend certain provisions of the Loan Agreement to permit the transfer of the listing of the Company's common stock from The Nasdaq Global Select Market to The Nasdaq Capital Market. Pursuant to the Third Loan Amendment, the Company agreed (A) to make partial prepayments of the principal amount of the term loan outstanding under the Loan Agreement as follows (the "Third Amendment Prepayments"): (1) a payment of $5,000 on or before June 30, 2023, representing a partial prepayment of principal in the amount of $4,673, plus a final payment fee of $327 and (2) a payment of $5,000 on or before January 31, 2024, representing a partial prepayment of principal in the amount of $4,673, plus a final payment fee of $327 and (B) that the Amortization Date under the Loan Agreement shall be changed from January 1, 2026 to January 1, 2025. The Company paid the Third Amendment Prepayments on January 25, 2023, following which the Company became required to repay the Loan Agreement in monthly installments from January 1, 2025 through May 1, 2026. The principal loan balance under the Loan Agreement following the Third Amendment Prepayments was $33,957.

Pursuant to the Third Loan Amendment, in addition to the Third Amendment Prepayments, if the Company made an additional prepayment under the Loan Agreement equal to $5,000 (inclusive of the final payment fee) on or prior to December 31, 2024 (the "First Extension Prepayment"), the Amortization Date would be automatically changed to July 1, 2025, and the maturity date of the Loan Agreement would be automatically changed from May 1, 2026 to November 1, 2026. On December 26, 2024, the Company paid the First Extension Prepayment of $5,000 (inclusive of the final payment fee), and as a result, the Amortization Data was changed to July 1, 2025 and the maturity date was changed to November 1, 2026.

If the Company made an additional prepayment under the Loan Agreement equal to $2,500 (inclusive of the final payment fee) on or prior to June 30, 2025 (the "Second Extension Prepayment"), the Amortization Date would be automatically changed to January 1, 2026, and the maturity date of the Loan Agreement would be automatically changed to May 1, 2027. On June 26, 2025, the Company paid the Second Extension Prepayment, and as a result, the Amortization Data was automatically changed to January 1, 2026 and the maturity date was automatically changed to May 1, 2027.

Under the Third Loan Amendment, the Lender and Agent also agreed to waive the prepayment fees for the Third Amendment Prepayments, the First Extension Prepayment, the Second Extension Prepayment and any other prepayments under the Loan Agreement. Pursuant to the Loan Agreement, the Company also will be required to pay all accrued and unpaid interest on the principal amounts of the term loan being repaid at the time of repayment.

On August 1, 2023, the Company entered into an amendment to the Loan Agreement with Combangio and Oxford Finance (the "Fourth Loan Amendment"). Pursuant to the Fourth Loan Amendment, certain provisions of the Loan Agreement were amended in connection with the change of the Company's name and the cessation of the U.S. Dollar LIBOR rate. On August 2, 2023, the Company entered into an amendment to the Loan Agreement with Combangio and Oxford Finance (the "Fifth Loan Amendment"). Pursuant to the Fifth Loan Amendment, Oxford Finance consented to the Company's entry into the CIRM Award and certain provisions of the Loan Agreement were amended in connection therewith.

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In addition, in connection with the Loan Agreement, the Company paid certain fees to the Lender and other third-party service providers. The fees paid to the Lender were recorded as a debt discount while the fees paid to other third-party service providers were recorded as debt issuance cost. These costs are being amortized using the effective interest method over the term of the Loan Agreement. The amortization of debt discount and debt issuance cost is included in interest expense within the condensed consolidated statements of operations and comprehensive loss. As of September 30, 2025, the effective interest rate was 19.0%, which takes into consideration the additional 5.0% interest rate as a result of the Event of Default, the non-cash accretion of the exit fee and the amortization of the debt discount and issuance costs.

On September 29, 2025, the Company received the Default Notice from Oxford Finance under the Loan Agreement, which asserted that an Event of Default had occurred and was continuing under Section 8.3 (Material Adverse Change) of the Loan Agreement and alleged that other events of default under the Loan Agreement may exist.

In the Default Notice, Oxford Finance declared, by reason of the Event of Default, that all obligations of the Company under the Loan Agreement were immediately due and payable. In addition, the Default Notice indicated that the Company's obligations under the Loan Agreement began accruing interest at the Default Rate (as defined in the Loan Agreement) effective immediately upon occurrence of the Event of Default. The total amount of the Company's obligations under the Loan Agreement as of September 29, 2025 that were accelerated and declared payable by Oxford was $29.1 million plus any additional interest due upon final payment and any expenses that become payable by the Company under the Loan Agreement.

On October 18, 2025, pursuant to the terms of the Loan Agreement, Oxford Finance informed the Company that it intended to foreclose on all of the Company's remaining assets and that Oxford Finance would not consent to the Company's use of cash for any reason other than for minimal payroll expenses pending Oxford Finance's foreclosure of the Company's assets. In addition, Oxford swept substantially all of the Company's cash resources from its bank accounts. As a result, on October 19, 2025, the board of directors of the Company terminated all remaining employees not deemed necessary by Oxford to execute a foreclosure of the Company's assets.

On November 3, 2025, Oxford Finance informed the Company that it intended to pause its foreclosure of the Company's assets and permitted the Company to use $125.0 of cash it previously swept to fund the negotiation execution of the Convertible Loan Agreement (as defined below) and to fund essential work only.

On November 9, 2025, the Company entered into a Convertible Loan Agreement (the "Convertible Loan Agreement") with David Lazar (the "Individual Lender"), pursuant to which the Individual Lender agreed to provide the Company a convertible loan in the aggregate amount of up to $375.0 (the "Loan Principal"), which was received in November 2025 and repaid in December 2025.

During the year ended December 31, 2025, the Company recognized interest expense of $3,276 for the Loan Agreement. This consisted of amortization of debt discount of $120, accretion of the final payment fee of $354 and the contractual coupon interest expense of $2,802. During the year ended December 31, 2024, the Company recognized interest expense of $5,766 for the Loan Agreement. This consisted of amortization of debt discount of $306, accretion of the final payment fee of $942 and the contractual coupon interest expense of $4,518.

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On November 25, 2025, the Company entered into a Loan Settlement Agreement (the "Settlement Agreement") with Oxford pursuant to which the Company owed Oxford $2,000 to be paid pursuant to the terms of the Settlement Agreement. The Settlement Agreement was entered into in connection with events of default by the Company, under the Loan and Security Agreement dated May 4, 2021 (the "Loan Agreement"). On December 26, 2025, the Company paid Oxford the settlement agreement amount of $2,000. As a result of such payment, all of its obligations under the Settlement Agreement and the Loan Agreement have been satisfied and the aggregate liability due Oxford of approximately $10,600 has been settled and released.

The components of the carrying value of the debt as of December 31, 2025 and 2024 are detailed below:

	December 31, 2025	December 31, 2024
Principal loan balance	$ —	$ 29,284
Unamortized debt discount and issuance cost	—	(225)
Cumulative accretion of exit fee	—	1,379
Total debt	$ —	$ 30,438
Less: current portion of long-term debt	—	(10,336)
Long-term debt, net	$ —	$ 20,102

Note 9: Warrants

The Company has issued warrants in connection with debt transactions that were completed in 2018 and prior.

The following table summarizes the common stock warrants outstanding as of December 31, 2025 and 2024, each exercisable into the number of shares of common stock set forth below as of the specified dates:

Issued	Exercise Price Per Share	Expiration Date	Exercisable From	Shares Exercisable at December 31, 2025	Shares Exercisable at December 31, 2024
2016	$ 413.50	October 2026	September 2017	290	290
2018	$ 609.23	October 2025	October 2018	—	3,693
				290	3,983

Note 10: Common and Preferred Stock

Preferred Stock

The Company was authorized to issue up to 5,000,000 shares of preferred stock as of December 31, 2025 and 2024. As of December 31, 2025, the Company had designated 54,000 shares of preferred stock as Series E Preferred Stock, 2,928 shares of preferred stock as Series F Preferred Stock, 10,901 shares of preferred stock as Series G Preferred Stock, 9,393 shares of preferred stock as Series H Preferred Stock, 3,286 shares of preferred stock as Series I Preferred Stock, and 900,000 shares of preferred stock as Series AA Preferred Stock, of which 9,278 shares of Series E Preferred Stock, 2,928 shares of Series F Preferred Stock, 10,901 shares of Series G Preferred Stock, 2,299 shares of Series H Preferred Stock, 0 shares of Series I Preferred Stock and 900,000 shares of Series AA Preferred Stock were outstanding as of December 31, 2025. On January 20, 2026, all of the Series E Preferred Stock, Series F Preferred Stock, Series H Preferred Stock were converted to common stock. On January 30, 2026, the Company designated 2,100,000 shares of preferred stock as Series AAA Preferred Stock. All of the shares of Series AAA Preferred Stock have been converted to common stock.

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Series AA Private Placement

On November 23, 2025, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with David Lazar ("Investor"), pursuant to which the Company agreed to issue and sell, in a private placement, shares of Series AA Convertible Non-Redeemable Preferred stock (the "Series AA Preferred Shares"), par value $0.001 per share, of the Company and shares of Series AAA Convertible Non-Redeemable Preferred Stock (the "Series AAA Preferred Shares", and together with the Series AA Preferred Shares, the "Placement Shares"), par value $0.001 per share, of the Company, in two closings for aggregate gross proceeds of up to $6.0 million. Pursuant to the Securities Purchase Agreement, Company agreed to issue and sell to the Investor at a first closing 900,000 Series AA Preferred Shares, at a price per Series AA Preferred Share equal to $2.00, for aggregate gross proceeds of $1.8 million. The closing for the Series AA Preferred Shares occurred on November 24, 2025 (the "Series AA Preferred Share Closing"). The closing for the Series AAA Preferred Shares occurred on January 30, 2026 (the "Series AA Preferred Share Closing").

Series AA Preferred Stock

Conversion

Each outstanding share of Series AA Preferred Stock is initially convertible into 55 shares of the Company's common stock, subject to adjustment as provided in the applicable Certificate of Designations, at any time at the option of the holder.

Voting

Shares of Series AA Preferred Stock generally have no voting rights, except to the extent provided by applicable law, and except that the consent of the holders of Series AA Preferred Stock will be required to alter, repeal or change the powers, preferences or rights of the Series AA Preferred Stock.

Dividends

Shares of Series AA Preferred Stock are entitled to receive dividends equal to (on an as-if-converted-to-common stock basis), and in the same form and manner as, dividends actually paid on shares of common stock.

Liquidation Rights

The Series AA Preferred Stock ranks on parity with the Series AAA Preferred Stock. Upon any dissolution, liquidation or winding up of the Company, whether voluntary or involuntary ("Dissolution"), subject to any superior rights of holders of senior securities, if any, holders of Series AA Preferred Stock will be entitled to receive, on a *pari passu* basis as applicable (A) an amount per share of Series AA Preferred Stock equal to the greater of (i) $2.00 (as adjusted for stock splits, combinations, reorganizations and the like) plus any dividends declared but unpaid thereon or (ii) such amount per share as would have been payable had all shares of the Series AA Preferred Stock or Series AAA Preferred Stock, as applicable, been converted into common stock immediately prior to such Dissolution, before any distributions shall be made to holders of common stock.

If, upon any such Dissolution, the assets of the Company are insufficient to pay the holders of shares of the Series AA Preferred Stock, the holders of shares of Series AA Preferred Stock will share in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares of Series AA Preferred Stock held by them upon such distribution if all amounts payable on or with respect to such shares of were paid in full.

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Common Stock

The Company was authorized to issue up to 120,000,000 shares of common stock with a $0.001 par value per share as of December 31, 2025 and 2024. The Company had 27,849,725 and 6,091,182 shares of common stock issued and outstanding as of December 31, 2025 and 2024, respectively.

Holders of the Company's common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. Each election of directors by the Company's stockholders will be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by the Company's Board of Directors, subject to any preferential dividend rights of any preferred stock that the Company may issue in the future.

In the event of the Company's dissolution, whether voluntary or involuntary, the holders of its common stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of the Series AA Preferred Stock, and any preferred stock that the Company may issue in the future. Holders of the Company's common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of the Company's common stock are subject to and may be adversely affected by the rights of the holders of the Series AA Preferred Stock and shares of any series of its preferred stock that the Company may designate and issue in the future.

Reserved Shares

As of December 31, 2025 and 2024, the Company has reserved the following shares of common stock for issuance upon exercise of rights under warrants, under the Amended and Restated 2017 Employee Stock Purchase Plan (the "ESPP"), upon the exercise of stock options, upon the vesting of RSUs, and upon conversion of the Series E Preferred Stock, Series F Preferred Stock, Series G Preferred Stock, Series H Preferred Stock and Series AA Preferred Stock:

	December 31, 2025	December 31, 2024
Warrant rights to acquire common stock	290	3,983
ESPP	37,588	35,347
Outstanding inducement stock option awards	1,981	10,496
2009 Plan	26	26
2017 Plan	1,945,488	1,675,807
Convertible preferred stock (as converted to common stock)	52,040,600	7,775,400
Total	54,025,973	9,501,059

ASC 480 - *Distinguishing Liabilities from Equity* determination

The Series F Preferred Stock issued pursuant to the 2023 Securities Purchase Agreement, the Series G Preferred Stock issued pursuant to the March 2024 Securities Purchase Agreement, the Series H Preferred Stock issued pursuant to the June 2024 Securities Purchase Agreement, the Series I Preferred Stock issued pursuant to the December 2024 Securities Purchase Agreement, and the Series AA Preferred Stock issued pursuant to the Series A Securities Purchase Agreement were not within the scope of ASC 480. These instruments did not contain any embedded derivatives required to be bifurcated from the Series F Preferred Stock, Series G Preferred Stock, Series H Preferred Stock, Series I Preferred Stock and Series AA Preferred Stock and these instruments were equity classified within permanent equity.

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Note 11: Stock-based Compensation

Stock Incentive Plans

On June 22, 2023, the Company's stockholders approved the Company's Amended and Restated 2017 Equity Incentive Plan (the "2017 Plan"), which amended and restated the Company's 2017 Equity Incentive Plan, as amended, to (i) increase the number of shares of common stock authorized for issuance thereunder by 1,250,000 shares; (ii) limit the number of incentive stock options that can be granted under the plan to 7,738,761 shares of common stock; (iii) add an annual limit on non-employee director compensation, including cash and the value of equity awards, of $750,000 for incumbent directors and $1,000,000 in a director's first year of service; and (iv) extend the term of the plan (including the duration of the evergreen) to 10 years from June 22, 2023, the date that stockholders approved the plan. In addition, the 2017 Plan provides for an annual increase to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2024 and continuing for each fiscal year until, and including, the fiscal year ending December 31, 2033, equal to the lower of (i) 4% of the sum of (I) the number of outstanding shares of common stock on such date and (II) the number of shares of common stock issuable upon conversion of any outstanding shares of convertible preferred stock of the Company on such date (without giving effect to any restrictions or limitations on conversion) and (ii) an amount determined by the Company's board of directors.

As of December 31, 2025, there were 527,508 shares of common stock available for grant under the 2017 Plan.

Under the plans, the Board or the compensation committee determines the number of shares of common stock to be granted pursuant to the awards, as well as the exercise price and terms of such awards. The exercise price of incentive stock options cannot be less than the fair value of the common stock on the date of grant. Stock options awarded under the plans expire 10 years after the grant date, unless the Board or the compensation committee sets a shorter term. Options granted under the plans generally vest over a four-year period. A portion of the unvested stock options will vest upon the sale of all or substantially all of the stock or assets of the Company.

Stock Option Awards

During the years ended December 31, 2025 and 2024, the Company granted options for the purchase of 689,525 and 317,139 shares, respectively, of common stock.

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A summary of option activity is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of January 1, 2025	878,003	$ 13.22	8.6	$ 23
Granted	689,525	8.30		
Exercised	(885)	7.23		
Forfeited	(377,603)	10.49		
Outstanding as of December 31, 2025	1,189,040	$ —	6.7	$ —
Vested or expected to vest as of December 31, 2025	1,189,040	$ —	6.7	$ —
Options exercisable as of December 31, 2025	643,354	$ 12.19	5.0	$ —

The Company records stock-based compensation related to stock options granted at fair value. The Company utilizes the Black-Scholes option-pricing model to estimate the fair value of stock option grants and to determine the related compensation expense. The assumptions used in calculating the fair value of stock-based payment awards represent management's best estimates. The assumptions used in determining fair value of the stock options granted during the years ended December 31, 2025 and 2024 are as follows:

	2025		2024	
Expected volatility	107.8% – 114.1%		107.9% – 110.3%	
Risk-free interest rate	3.80% – 4.47%		3.46% – 4.41%	
Expected dividend yield	0%		0%	
Expected term (in years)	5.24 – 6.02		5.50 – 6.07	

The Company derived the risk-free interest rate assumption from the U.S. Treasury rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the awards being valued. The Company based the expected dividend yield on its expectation of not paying dividends in the foreseeable future. The Company calculated the expected term of options using the simplified method, as the Company lacks relevant historical data due to the Company's limited operating experience. The expected volatility is based upon the historical volatility of the Company. The impact of forfeitures on compensation expense is recorded as they occur.

The weighted average grant-date fair value of options granted during the years ended December 31, 2025 and 2024, was $7.42 and $5.79, respectively. The fair value is being expensed over the vesting period of the options on a straight-line basis as the services are being provided.

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

	Year Ended December 31,	
	2025	2024
Research and development	$ 1,292	$ 2,635
General and administrative	5,703	5,754
Total	$ 6,995	$ 8,389

During the years ended December 31, 2025 and 2024, 885 and 1,281 options, respectively, were exercised.

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Restricted Stock Units—During the years ended December 31, 2025 and 2024, the Company issued 106,725 and 71,830 RSUs, respectively, to certain executives and other employees which will vest no sooner than one-third per year over three years on the anniversary of the date of grant.

As of December 31, 2025, a total of 230,947 RSUs were outstanding, consisting of 186,463 unvested shares and 44,484 vested and deferred shares by directors.

A summary of activity for RSUs for the year ended December 31, 2025 is as follows:

	Shares	Weighted Average Grant Date Fair Value
Unvested and outstanding balance as of January 1, 2025	544,117	$ 21.67
Changes during the period:		
Granted	106,725	7.07
Vested	(311,509)	24.64
Forfeited	(152,870)	15.36
Unvested and outstanding balance as of December 31, 2025	186,463	
Vested and deferred balance as of December 31, 2025	44,484	

Employee Stock Purchase Plan—In 2017, the Company approved the 2017 Employee Stock Purchase Plan, which was amended and restated in December 2018 (as amended, the "ESPP"). The ESPP reserved an aggregate of 4,466 shares of common stock and provides for an annual increase on the first day of each fiscal year, beginning on January 1, 2019 and ending on December 31, 2029, in an amount equal to the lowest of: (1) 17,868 shares of the Company's common stock; (2) 1% of the total number of shares of the Company's common stock outstanding on the first day of the applicable fiscal year; and (3) an amount determined by the Company's board of directors. On January 1, 2025, 17,868 shares of common stock were added and were available for grant under the ESPP.

The ESPP provides for two six-month offering periods each year: the first offering period begins on the first trading day on or after each January 1 and the second offering period begins on the first trading day on or after each July 1. Under the ESPP, participating employees can authorize the Company to withhold a portion of their base pay during consecutive six-month payment periods for the purchase of shares of the Company's common stock. At the conclusion of the period, participating employees can purchase shares of the Company's common stock at 85% of the lesser of the closing price of the common stock on (i) the first business day of the plan period or (ii) the exercise date. The fair value of the purchase rights granted under the ESPP was estimated on the date of grant, using the Black-Scholes option-pricing model. During the years ended December 31, 2025 and 2024, employees of the Company purchased an aggregate of 15,627 and 11,448 shares, respectively, under the ESPP.

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Note 12: Loss Per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows for the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
Numerator:		
Net loss attributable to common stockholders	$ (26,980)	$ (38,511)
Denominator:		
Weighted-average common shares outstanding, basic and diluted (1)	8,148,275	3,796,047
Net loss per share attributable to common stockholders, basic and diluted	$ (3.31)	$ (10.15)

(1) Included in the weighted-average common shares outstanding, basic and diluted are vested but deferred shares for which all contingencies have been satisfied.

The following potential common stock equivalents were excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect. The share amounts presented below represent the average of the number of incremental shares included in each quarterly calculation:

	Year Ended December 31,	
	2025	2024
Options to purchase shares of common stock	1,373,291	905,645
Unvested RSUs	360,039	621,886
Unexercised warrants	3,060	4,223
Convertible preferred stock (as converted to common stock)	18,433,000	7,294,125
	20,169,390	8,825,879

Note 13: Income Taxes

The Company has had no income tax expense due to operating losses incurred for the years ended December 31, 2025 and 2024. The Company has also not recorded any income tax benefits for the net operating losses incurred in each period due to its uncertainty of realizing a benefit from those items. All of the Company's losses before income taxes were generated in the United States.

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Beginning in 2025 annual reporting, the Company has adopted ASU 2023-09 prospectively. The difference between the Company's effective income tax rate and the U.S. federal statutory rate of 21% was primarily driven by the change in the valuation allowance. A reconciliation of the federal statutory income tax rate to the Company's effective tax rate pursuant to the disclosure requirements of ASU 2023-09 for the year ended December 31, 2025 is as follows:

	Year Ended December 31, 2025	
Federal statutory income tax rate	$ (5,733)	21.0 %
Effect of:		
State income taxes, net of federal benefit	—	—
Change in Valuation Allowance	7,449	(27.3)
Nontaxable or Nondeductible Items:		
Stock Based Compensation Permanent	2,139	(7.8)
Mark to Market	(978)	3.6
Other Nontaxable or Nondeductible Items	82	(0.3)
Tax Credits:		
Federal R&D and Orphan Drug Credits	(2,945)	10.8
Other	(14)	0.1
	$ —	— %

A reconciliation of the U.S. federal statutory income tax rate to the Company’s effective income tax rate for the year ended December 31, 2024 is as follows:

	Year Ended December 31, 2024	
Federal statutory income tax rate	21.0	%
Effect of:		
State income taxes, net of federal benefit	6.5	
Research and development tax credits	3.0	
Stock-based compensation	(3.9)	
Change in valuation allowance	(26.3)	
Other	(0.3)	
Effective income tax rate	—	%

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Net deferred tax assets as of December 31, 2025 and 2024 consisted of the following:

	December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 131,286	$ 121,135
Capitalized research and development and start-up expenditures	9,865	13,878
Research and development tax credit carryforwards	5,492	2,476
Stock-based compensation	—	1,203
Lease liabilities	—	535
Rebates, incentives, trade discounts and allowances	43	103
Other	177	676
Total deferred tax assets	$ 146,863	$ 140,006
Deferred tax liabilities:		
Right-of-use assets	—	(499)
Total deferred tax liabilities	$ —	$ (499)
Valuation allowance	$ (146,863)	$ (139,507)
Net deferred tax assets	$ —	$ —

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2025 and 2024. The valuation allowance increased by $7,356 and $10,776 during the years ended December 31, 2025 and 2024, respectively. The current year and prior year increase is largely the result of an increase to federal net operating losses and generation of federal and state research and development tax credits. Management reevaluates the positive and negative evidence at each reporting period.

As required under ASU 2023-09, the Company has included only the portion of the valuation allowance related to federal deferred tax assets in the "change in valuation allowance" line of the rate reconciliation. The following table presents a reconciliation of the total change in the valuation allowance:

	Year Ended December 31,
	2025
Beginning Balance	$ 139,507
Change charged to income tax expense	7,356
Changes charged to OCI	—
Changed charged to goodwill	—
Ending Balance	$ 146,863

As of December 31, 2025 and 2024, the Company had federal net operating loss carryforwards of $561,353 and $405,544, respectively, which may be available to offset future federal tax liabilities and expire at various dates beginning in 2030. As of December 31, 2025 and 2024, the Company had state net operating loss carryforwards of $491,801 and $469,053, respectively, which may be available to offset future state income tax liabilities and expire at various dates beginning in 2025. As of December 31, 2025 and 2024, the Company had federal and state research and development credit carryforwards of $5,492 and $2,476, respectively.

Realization of the future tax benefits is dependent on many factors, including the Company's ability to generate taxable income within the net operating loss carryforward period. Under the provisions of Section 382 of the Internal Revenue Code of 1986, certain substantial changes in the Company's ownership, including a sale of the Company, or significant changes in ownership due to sales of equity, may have limited, or may limit in the future, the amount of net operating loss carryforwards, which could be used annually to offset future taxable income. The Company has completed an analysis as of December 31, 2022 and determined that an additional ownership change occurred during December 2022 as a result of the issuance of Series E Preferred Stock, further limiting the net operating loss carryforwards and research and development tax credits due to the expiration of those attributes. As a result, the utilization of the Company's net operating loss carryforwards is subject to an annual limitation of $222, which is reflected in the numbers presented above.

The Tax Cuts and Jobs Act resulted in significant changes to the treatment of research and developmental expenditures under Section 174 of the Internal Revenue Code. For tax years beginning after December 31, 2021, taxpayers are required to capitalize and amortize all research and development expenditures that are paid or incurred in connection with their trade or business. Per the One Big Beautiful Bill Act, effective July 4, 2025, taxpayers are still required to capitalize foreign research and development expenditures over 15 years, but now have the opportunity to deduct domestic research and development expenditures under IRC 174A. The Company has elected to continue to amortize prior year domestic capitalized costs until the amortization of such costs is complete.

The Company files its corporate income tax returns in the United States and various states. All tax years since the date of incorporation remain open to examination by the major taxing jurisdictions (state and federal) to which the Company is subject, as carryforward attributes generated in years past may still be adjusted upon examination by the Internal Revenue Service (''IRS'') or other authorities if they have or will be used in a future period. The Company is not currently under examination by the IRS or any other jurisdictions for any tax year.

As of December 31, 2025 and 2024 the Company had no uncertain tax positions. The Company's policy is to recognize interest and penalties related to income tax matters as a component of income tax expense, of which no interest or penalties were recorded for the years ended December 31, 2025 and 2024.

Note 14: Commitments and Contingencies

Stanford License Agreement— In October 2019, Combangio entered into a license agreement with The Board of Trustees of The Leland Stanford Junior University ("Stanford"), which was amended in February 2020 and subsequently transferred to the Company by operation of law upon the Combangio Acquisition. Pursuant to the license agreement with Stanford (the "Stanford Agreement"), the Company has a worldwide, exclusive, sublicensable license under certain patent rights ("licensed patents"), directed to methods to promote eye wound healing, to make, have made, use, import, offer to sell and sell products ("licensed products") that are covered by the licensed patents for use in all fields. Under the Stanford Agreement, the Company is required to pay Stanford annual license maintenance fees in the low-to-mid five figures which are creditable against earned royalties owed to Stanford for the same year, an aggregate of up to $1,075 for the achievement of specified development and regulatory milestones, and an aggregate of up to $1,100 for the achievement of specified sales milestones. Stanford is also entitled to receive tiered royalties in a low single digit percentage range on net sales of licensed products that are covered by a valid claim of a licensed patent. During the years ended December 31, 2025 and 2024, amounts paid to Stanford were *de minimis*. On September 29, 2025, the Company announced that the CHASE trial of KPI-012 for the treatment of PCED did not meet the primary endpoint of complete healing of PCED as measured by corneal fluorescein staining. The CHASE trial also failed to achieve statistical significance for key secondary efficacy endpoints and did not show any meaningful difference between either KPI-012 treatment arm and the placebo arm. Based on the CHASE trial results, we determined to cease development of KPI-012 and our MSC-S platform.

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Contingencies related to the Merger Agreement— In connection with the Combangio Acquisition, the Company agreed to make additional payments based on the achievement of certain milestone events related to KPI-012. The Company recognized certain contingent consideration liabilities at fair value on the acquisition date, and revalues the remaining obligations each reporting period. The total potential maximum payout for the milestone payments, which have been recorded as liabilities at fair value, is $40,000 and the milestone payments are contingent upon the achievement of specified development, regulatory and commercialization milestones. Following the achievement of the First Dosing Milestone in February 2023, the Company paid an aggregate of $2,500 in cash and $2,354 in shares of the Company's common stock (representing an aggregate of 105,038 shares of the Company's common stock) to the former Combangio Equityholders in March 2023. The Company paid the remaining amount due in connection with the First Dosing Milestone of $146 in cash in January 2024. Additionally, pursuant to the merger agreement for the Combangio Acquisition, the Company could trigger potential future sales-based milestone payments of up to $65,000 and cash royalty payment obligations in the mid-to-high single digits. Because the achievement of these sales-based milestones related to KPI-012 was not considered probable as of December 31, 2025 or December 31, 2024, such contingencies have not been recorded in the Company's consolidated financial statements. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory or commercial milestones.

Litigation—The Company is not currently subject to any material legal proceedings.

Guarantees and Indemnifications—The Company's Certificate of Incorporation authorizes the Company to indemnify and advance expenses to its officers and directors and agents to the fullest extent permitted by law.

The Company's equity agreements and certain other arrangements include standard indemnifications against claims, actions, or other matters that may arise in connection with these arrangements.

As of December 31, 2025 and 2024, the Company had not experienced any losses related to these indemnification obligations, and no claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and has no amount accrued related to these contingencies. The Company does not expect these indemnifications to have a material adverse effect on these consolidated financial statements.

Note 15: Defined Contribution Plan

The Company has a 401(k) defined contribution plan (the "401(k) Plan") for substantially all of its employees. Eligible employees may make pretax contributions to the 401(k) Plan up to statutory limits.

The Company made discretionary matching contributions of $134 and $160 to the 401(k) Plan during the years ended December 31, 2025 and 2024, respectively.

Note 16: Subsequent Events

Series AAA Private Placement

As disclosed in Note 10, on November 25, 2025, the Company entered into a Securities Purchase Agreement, with the Series AA Investor, pursuant to which the Company agreed to issue and sell, in a private placement, shares of the Series AA Preferred Stock and the Series AAA Preferred Stock of the Company in two closings for aggregate gross proceeds of up to $6.0 million.

On December 11, 2025, the Series AA Investor transferred his rights and obligations under the Securities Purchase Agreement solely with respect to the shares of Series AAA Preferred and the director nomination right to AK Holdings Group Inc., a Panamanian company ("AK Holdings"). On January 29, 2026, pursuant to the terms of that certain Rights Purchase Agreement by and among AK Holdings and each signatory thereto (the "Series AAA

Investors"), AK Holdings sold its rights to purchase the Series AAA Preferred Stock (but not its director nomination rights under the November 2025 Purchase Agreement) to the Series AAA Investors.

On January 30, 2026, the Company entered into that certain Securities Purchase Agreement (the "Series AAA Purchase Agreement") with each of the Series AAA Investors pursuant to which the Company agreed to issue and sell to the Series AAA Investors at second closing of the Private Placement, an aggregate of 2,100,000 shares of Series AAA Preferred Stock at a price per share of Series AAA Preferred Stock equal to $2.00, for aggregate gross proceeds of $4,200. The Closing occurred on January 30, 2026, following (A) the approval at the Annual Meeting of the Issuance Proposal and the Share Increase Proposal (each as defined herein), (B) the filing with the Secretary of State of the State of Delaware of the (i) Certificate of Amendment (as defined herein) and (ii) Certificate of Designations, Preferences and Rights of Series AAA Convertible Non-Redeemable Preferred Stock (the "Certificate of Designations"), and (C) the satisfaction of other customary closing conditions. The terms of the Series AAA Preferred Stock are substantially similar to the terms of the Series AA Preferred Stock. Each share of Series AAA Preferred Stock was convertible into 420 shares of Common Stock for an aggregate total of 882,000,000 shares of Common Stock issuable upon conversion of the Series AAA Preferred Stock. The Purchase Agreement contains customary representations, warranties and agreements by the Company and customary closing conditions. The representations, warranties and covenants contained in the Purchase Agreement were made solely for the benefit of the parties thereto and as of specific dates and may be subject to limitations agreed upon by the contracting parties. All of the shares of Series AAA Preferred Stock have been converted to common stock.

License Agreement

On March 3, 2026 (the "Effective Date"), the Company and 2624465 Ontario Inc. o/a Younet AI, an Ontario corporation ("Younet") entered into a Platform Development and Exclusive License Agreement (the "Agreement") pursuant to which the Company obtained a worldwide exclusive license (the "Exclusive License") of Younet's proprietary, custom biomedical artificial intelligence research platform (the "Researgency Platform"), together with associated trademarks and intellectual property. The term of the Agreement is for 12 months following the Effective Date (the "Initial Term"), with the option by the Company to renew the agreement for successive 12 months terms (each, a "Renewal Term"), in each case by providing notice to Younet pursuant to the terms of the Agreement (the "Extension Notice"). Pursuant to the Agreement, Younet shall also provide to the Company certain deliverables and services related to the Researgency Platform, with certain additional deliverables to be provided by Younet in the event of a Renewal Term, in each case with all operating costs relating to the Researgency Platform to be paid by the Company.

In consideration of the services to be performed by Younet under the Agreement, the Company has agreed to pay to Younet for the Initial Term a cash fee of up to $530 consisting of (i) $80 in cash, which was paid by the Company on the Effective Date, and (ii) in the event the Company delivers to Younet a written notice electing to engage Younet for the continued development of Researgency, $450 in cash, payable in 9 monthly installments of $50, pursuant to the terms of the Agreement. Such notice may be provided at any time on or after the first business day of the third month following the Effective Date and such continued development may be terminated upon 30 days notice by the Company. In addition, the Company has agreed to issue to Younet 5,000,000 shares of the Company's common stock, par value $0.001 per share (the "Common Stock"), within 10 business days of the Effective Date. In addition, each time the Agreement is extended for a Renewal Term, the Company shall (i) pay to Younet $250 in cash and (ii) issue to Younet 5,000,000 shares of Common Stock within 10 business days of the Extension Notice. Any shares of Common Stock issuable to Younet pursuant to the Agreement shall herein be referred to as the "Younet Shares." Except for certain block trades, during the Term (as defined in the Agreement) and for the twelve months thereafter, Younet shall not sell any Younet Shares on any Trading Day (as defined in the Agreement) in an amount that exceeds 3% of the Daily Trading Volume (as defined in the Agreement) for such Trading Day.

In addition, Younet has granted to the Company an irrevocable option, exercisable at any time during the Initial Term or any Renewal Terms, to acquire all of the issued and outstanding equity interests of Younet, or, at the Company's election, substantially all of the assets of Younet, for a total purchase price of $55,000, subject to the terms of the Agreement.

If the Company does not deliver an Extension Notice prior to the expiration of the Initial Term or any Renewal Term, the Agreement shall expire automatically at the end of the applicable term. In addition, the Agreement may be terminated by either party (i) for uncured material breach or (ii) due to the insolvency of the other party. Upon termination or expiration, (a) the Exclusive License will terminated, (b) all licenses granted to Younet with respect to KALA Data (as defined in the Agreement) will immediately terminate, (c) all licenses granted to the Company with respect to Younet Background IP (as defined in the Agreement) will survive in accordance with their terms, and (d) all Work Product (as defined in the Agreement) completed as of the date of termination shall be delivered to and owned by the Company.

The License Agreement additionally includes customary representations and warranties, covenants, and indemnification obligations for a transaction of this nature.

Loan and Security Agreement

On February 9, 2026, the Company made a loan (the "Loan") in the principal amount of $7,000, evidenced by a secured promissory note (the "Note") to Minglemint Solutions LLC ("Borrower") in connection with the Company's determination that a portion of its cash on hand was in excess of its near-term working capital requirements and operational needs. In order to optimize the return on such excess cash, rather than holding the full balance in a bank deposit account, which offered a materially lower yield, the Company elected to deploy that portion into the Loan, which bears interest at a rate of 8.0% per annum. The Company believes that the interest rate obtained under the Loan, together with the security interest granted to the Company over all fixtures and personal property of the Borrower, provides a more favorable risk-adjusted return on idle cash than the return available through conventional bank deposit arrangements, while preserving the Company's ability to meet its anticipated working capital and operational obligations. The Loan bears interest at a rate of 8.0% per annum, and is due and payable on February 9, 2027.

The Note includes customary event of default provisions, including, but not limited to, for a breach of any representations and warranties or covenants, any bankruptcy or insolvency proceedings of the Borrower, and the failure of the Borrower to pay, upon 15 days' written notice of default, any principal amount of the Loan or interest due. The Note provides for a default interest rate of 13.0%. As described in the Note, upon the occurrence of certain events of default, the Company may, among other remedies, declare the outstanding balance of the Note including all accrued interest thereon immediately due and payable.

Additionally, the Note is secured by a continuing first priority lien and security interest in all fixtures and personal property of the Borrower (the "Collateral"), pursuant to the security agreement with the Borrower dated February 9, 2026 (the "Security Agreement"). The Collateral includes, but is not limited to, all accounts, goods, documents, instruments, securities and investment properties, money, accounts and rights to payment of the Borrower, and any proceeds, records and obligations relating to the foregoing, as more fully detailed in the Security Agreement.

Exhibit 4.3

DESCRIPTION OF SECURITIES REGISTERED UNDER SECTION 12 OF THE EXCHANGE ACT

The following description of registered securities of KALA BIO, Inc. ("us," "our," "we" or the "Company") is intended as a summary only and therefore is not a complete description of our capital stock. This description is based upon, and is qualified by reference to, our certificate of incorporation, our bylaws and applicable provisions of the Delaware General Corporate Law (the "DGCL"). You should read our certificate of incorporation and our bylaws, which are incorporated by reference as Exhibit 3.1 and Exhibit 3.2, respectively, to the Annual Report on Form 10-K of which this Exhibit 4.3 is a part, for the provisions that are important to you.

Authorized Capital Stock

Our authorized capital stock consists of 120,000,000 shares of common stock, par value $0.001 per share, and 5,000,000 shares of preferred stock, par value $0.001 per share, of which (i) 54,000 shares of preferred stock are designated the "Series E Convertible Non-Redeemable Preferred Stock", or the Series E Preferred Stock, (ii) 2,928 shares of preferred stock are designated the "Series F Convertible Non-Redeemable Preferred Stock", or the Series F Preferred Stock, (iii) 10,901 shares of preferred stock are designated the "Series G Convertible Non-Redeemable Preferred Stock", or the Series G Preferred Stock, (iv) 9,393 shares of preferred stock are designated the "Series H Convertible Non-Redeemable Preferred Stock", or the Series H Preferred Stock, and (v) 3,286 shares of preferred stock are designated the "Series I Convertible Non-Redeemable Preferred Stock", or the Series I Preferred Stock. Our common stock is registered under Section 12(b) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our Series E Preferred Stock, Series F Preferred Stock, Series G Preferred Stock, Series H Preferred Stock and Series I Preferred Stock are not registered under Section 12(b) of the Exchange Act.

Common Stock

Annual Meeting. Annual meetings of our stockholders are held on the date designated in accordance with our by-laws. Written notice must be mailed to each stockholder entitled to vote not less than ten nor more than 60 days before the date of the meeting. The presence in person or by proxy of the holders of one third of the voting power of the shares of the capital stock of the corporation issued and outstanding and entitled to vote at such meeting constitutes a quorum for the transaction of business at meetings of the stockholders. Special meetings of the stockholders may be called for any purpose by the board of directors, the chairman of the board or the chief executive officer. Except as may be otherwise provided by applicable law, our certificate of incorporation or our by-laws, all elections of directors shall be decided by a plurality, and all other questions shall be decided by a majority, of the votes cast by stockholders entitled to vote thereon at a duly held meeting of stockholders at which a quorum is present.

Voting Rights. Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights.

Dividends. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock.

Liquidation and Dissolution. In the event of our liquidation or dissolution, the holders of our common stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to any preferential rights of any outstanding preferred stock.

Other Rights. Holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of our common stock are subject to and may be adversely affected by the rights of the holders of our Series E Preferred Stock, Series F Preferred Stock, Series G Preferred Stock, Series H Preferred Stock or Series I Preferred Stock and shares of any series of our preferred stock that we may designate and issue in the future.

Preferred Stock

We are authorized to issue "blank check" preferred stock, which may be issued in one or more series upon authorization of our board of directors. Our board of directors is authorized to fix the designations, powers, preferences and the relative, participating, optional or other special rights and any qualifications, limitations and restrictions of the shares of each series of preferred stock. The authorized shares of our preferred stock are available for issuance without further action by our stockholders, unless such action is required by applicable law or the rules of any stock exchange on which our securities may be listed. If the approval of our stockholders is not required for the issuance of shares of our preferred stock, our board may determine not to seek stockholder approval.

A series of our preferred stock could, depending on the terms of such series, impede the completion of a merger, tender offer or other takeover attempt. Our board of directors will make any determination to issue preferred shares based upon its judgment as to the best interests of our stockholders. Our directors, in so acting, could issue preferred stock having terms that could discourage an acquisition attempt through which an acquirer may be able to change the composition of our board of directors, including a tender offer or other transaction that some, or a majority, of our stockholders might believe to be in their best interests or in which stockholders might receive a premium for their stock over the then-current market price of the stock.

Series E Preferred Stock, Series F Preferred Stock, Series G Preferred Stock, Series H Preferred Stock and Series I Preferred Stock

Certificates of Designation. Pursuant to our Certificate of Designations, Preferences and Rights of Series E Convertible Non-Redeemable Preferred Stock, or the Series E Certificate of Designations, filed with the Secretary of State of the State of Delaware, we designated 54,000 shares of our authorized and unissued preferred stock as Series E Preferred Stock, and established the rights, preferences and privileges of the Series E Preferred Stock, which are summarized below. Pursuant to our Certificate of Designations, Preferences and Rights of Series F Convertible Non-Redeemable Preferred Stock, or the Series F Certificate of Designations, filed with the Secretary of State of the State of Delaware, we designated 2,928 shares of our authorized and unissued preferred stock as Series F Preferred Stock, and established the rights, preferences and privileges of the Series F Preferred Stock, which are summarized below. Pursuant to our Certificate of Designations, Preferences and Rights of Series G Convertible Non-Redeemable Preferred Stock, or the Series G Certificate of Designations, filed with the Secretary of State of the State of Delaware, we designated 10,901 shares of our authorized and unissued preferred stock as Series G Preferred Stock, and established the rights, preferences and privileges of the Series G Preferred Stock, which are summarized below. Pursuant to our Certificate of Designations, Preferences and Rights of Series H Convertible Non-Redeemable Preferred Stock, or the Series H Certificate of Designations, filed with the Secretary of State of the State of Delaware, we designated 9,393 shares of our authorized and unissued preferred stock as Series H Preferred Stock, and established the rights, preferences and privileges of the Series H Preferred Stock, which are summarized below. Pursuant to our Certificate of Designations, Preferences and Rights of Series I Convertible Non-Redeemable Preferred Stock, or the Series I Certificate of Designations, filed with the Secretary of State of the State of Delaware, we designated 3,286 shares of our authorized and unissued preferred stock as Series I Preferred Stock, and established the rights, preferences and privileges of the Series I Preferred Stock, which are summarized below.

Conversion. Each share of Series E Preferred Stock, Series F Preferred Stock, Series G Preferred Stock, Series H Preferred Stock and Series I Preferred Stock is initially convertible into 100 shares of our common stock (subject to adjustment as provided in the applicable Certificate of Designations) at any time at the option of the holder, provided that the holder will be prohibited, subject to certain exceptions, from converting such shares of preferred stock for shares of our common stock to the extent that immediately prior to or following such conversion, the holder, together with its affiliates and other attribution parties, would own in excess of 9.99% of the total number of shares of our common stock then issued and outstanding after giving effect to such conversion, which percentage may be changed at the holder's election to a lower percentage at any time or to a higher percentage not to exceed 19.99% upon 61 days' notice to us, which we refer to, collectively, as the Beneficial Ownership Limitation.

Voting Rights. The shares of Series E Preferred Stock, Series F Preferred Stock, Series G Preferred Stock, Series H Preferred Stock and Series I Preferred Stock will generally have no voting rights, except to the extent provided by applicable law, and except that (i) the consent of the holders of a majority of the outstanding Series E Preferred Stock will be required to waive any provisions of our Series E Certificate of Designations, (ii) the consent

of the holders of a majority of the outstanding Series F Preferred Stock will be required to waive any provisions of our Series F Certificate of Designations, (iii) the consent of the holders of a majority of the outstanding Series G Preferred Stock will be required to waive any provisions of our Series G Certificate of Designations, (iv) the consent of the holders of at least two-thirds of the outstanding Series H Preferred Stock will be required to waive any provisions of our Series H Certificate of Designations and (v) the consent of the holders of at least two-thirds of the outstanding Series I Preferred Stock will be required to waive any provisions of our Series I Certificate of Designations.

Rank. The Series E Preferred Stock, the Series F Preferred Stock, the Series G Preferred Stock, the Series H Preferred Stock and the Series I Preferred Stock shall rank:

- on parity with each other and on parity with any class or series of our capital stock created in the future specifically ranking by its terms on parity with such series of preferred stock, or collectively, the Parity Securities;

- senior to all of our common stock;
- senior to any class or series of our capital stock created in the future specifically ranking by its terms junior to the each such series of preferred stock, or the Junior Securities;
- junior to any class or series of our capital stock created in the future specifically ranking by its terms senior to such series of preferred stock, or the Senior Securities;

in each case, as to distributions of assets upon our liquidation, dissolution or winding up, whether voluntarily or involuntarily, each of which we refer to as a Dissolution.

Dissolution. In the event of a Dissolution, subject to any prior or superior rights of the holders of Senior Securities, if any, the holders of the Series E Preferred Stock, the holders of Series F Preferred Stock, the holders of Series G Preferred Stock, the holders of Series H Preferred Stock and the holders of Series I Preferred Stock will be entitled to receive on a *pari passu* basis with each other and all other Parity Securities, and before any distributions to the holders of our common stock and to the holders of Junior Securities, if any: (A) an amount per share of Series E Preferred Stock equal to the greater of (i) $575.00 (subject to adjustment in the event of any stock split, combination or reclassification), plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Series E Preferred Stock been converted into our common stock (without regard to any restrictions on conversion, including the Beneficial Ownership Limitation) immediately prior to such Dissolution, (B) an amount per share of Series F Preferred Stock equal to the greater of (i) $683.00 (subject to adjustment in the event of any stock split, combination or reclassification), plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Series F Preferred Stock been converted into our common stock (without regard to any restrictions on conversion, including the Beneficial Ownership Limitation) immediately prior to such Dissolution, (C) an amount per share of Series G Preferred Stock equal to the greater of (i) $788.90 (subject to adjustment in the event of any stock split, combination or reclassification), plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Series G Preferred Stock been converted into our common stock (without regard to any restrictions on conversion, including the Beneficial Ownership Limitation) immediately prior to such Dissolution, (D) an amount per share of Series H Preferred Stock equal to the greater of (i) $585.00 (subject to adjustment in the event of any stock split, combination or reclassification), plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Series H Preferred Stock been converted into our common stock (without regard to any restrictions on conversion, including the Beneficial Ownership Limitation) immediately prior to such Dissolution, and (E) an amount per share of Series I Preferred Stock equal to the greater of (i) $644.00 (subject to adjustment in the event of any stock split, combination or reclassification), plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Series I Preferred Stock been converted into our common stock (without regard to any restrictions on conversion, including the Beneficial Ownership Limitation) immediately prior to such Dissolution. If, upon any such Dissolution, the assets of the Company shall be insufficient to pay the holders of shares of the Series E Preferred Stock, Series F Preferred Stock, Series G Preferred Stock, Series H Preferred Stock and Series I Preferred Stock the amounts required under the preceding sentence, the holders of such shares of preferred stock shall share in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise have been payable in respect of the shares of preferred stock held by them upon such distribution if all amounts

payable on or with respect to such shares of preferred stock were paid in full. For the avoidance of any doubt, neither a change in control of the Company, the merger or consolidation of the Company with or into any other entity, nor the sale, lease, exchange or other disposition of all or substantially all of our assets shall, in and of itself, be deemed to constitute a Dissolution.

Shares of Series E Preferred Stock, Series F Preferred Stock, Series G Preferred Stock, Series H Preferred Stock and Series I Preferred Stock will be entitled to receive dividends equal to (on an as-if-converted-to-common stock basis), and in the same form and manner as, dividends actually paid on shares of our common stock.

Provisions of Our Certificate of Incorporation and By-laws and Delaware Law That May Have Anti-Takeover Effects

Delaware Law. We are subject to Section 203 of the DGCL. Subject to certain exceptions, Section 203 prevents a publicly held Delaware corporation from engaging in a "business combination" with any "interested stockholder" for three years following the date that the person became an interested stockholder, unless either the interested stockholder attained such status with the approval of our board of directors, the business combination is approved by our board of directors and stockholders in a prescribed manner or the interested stockholder acquired at least 85% of our outstanding voting stock in the transaction in which it became an interested stockholder. A "business combination" includes, among other things, a merger or consolidation involving us and the "interested stockholder" and the sale of more than 10% of our assets. In general, an "interested stockholder" is any entity or person beneficially owning 15% or more of our outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person.

Staggered Board; Removal of Directors. Our certificate of incorporation and our bylaws divide our board of directors into three classes with staggered three-year terms. In addition, our certificate of incorporation and our bylaws provide that directors may be removed only for cause and only by the affirmative vote of the holders of 75% of our shares of capital stock present in person or by proxy and entitled to vote. Under our certificate of incorporation and bylaws, any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office. Furthermore, our certificate of incorporation provides that the authorized number of directors may be changed only by the resolution of our board of directors. The classification of our board of directors and the limitations on the ability of our stockholders to remove directors, change the authorized number of directors and fill vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our company.

Stockholder Action; Special Meeting of Stockholders; Advance Notice Requirements for Stockholder Proposals and Director Nominations. Our certificate of incorporation and our bylaws provide that any action required or permitted to be taken by our stockholders at an annual meeting or special meeting of stockholders may only be taken if it is properly brought before such meeting and may not be taken by written action in lieu of a meeting. Our certificate of incorporation and our bylaws also provide that, except as otherwise required by law, special meetings of the stockholders can only be called by the chairman of our board of directors, our chief executive officer or our board of directors. In addition, our bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of candidates for election to our board of directors. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors, or by a stockholder of record on the record date for the meeting who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities. These provisions also could discourage a third party from making a tender offer for our common stock because even if the third party acquired a majority of our outstanding voting stock, it would be able to take action as a stockholder, such as electing new directors or approving a merger, only at a duly called stockholders meeting and not by written consent.

Super-Majority Voting. The DGCL provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws unless a corporation's certificate of incorporation or bylaws, as the case may be, requires a greater percentage. Our bylaws

may be amended or repealed by a majority vote of our board of directors or the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in any annual election of directors. In addition, the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in any election of directors is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of our certificate of incorporation described above.

Exclusive Forum Selection. Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (1) any derivative action or proceeding brought on behalf of our company, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or employees to our company or our stockholders, (3) any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware or as to which the General Corporation Law of the State of Delaware confers jurisdiction on the Court of Chancery of the State of Delaware, or (4) any action asserting a claim arising pursuant to any provision of our certificate of incorporation or bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine. Although our certificate of incorporation contains the choice of forum provision described above, we do not expect this choice of forum provision will apply to suits brought to enforce a duty or liability created by the Securities Act of 1933, as amended, the Exchange Act, or any other claim for which federal courts have exclusive jurisdiction.

Exhibit 10.48

SECURED PROMISSORY NOTE

made by

MINGLEMINT SOLUTIONS LLC

in favour of

KALA BIO, INC.

dated as of

February 9, 2026

SECURED PROMISSORY NOTE

FOR VALUE RECEIVED, and subject to the terms and conditions set forth herein, **Minglemint Solutions LLC** (the "**Borrower**"), hereby unconditionally promises to pay to the order of **Kala Bio, Inc**. or their assigns (the "**Noteholder**", and together with the Borrower, the "**Parties**"), the principal amount of US$7,000,000.00 (the "**Loan**"), together with all accrued interest thereon, as provided in this promissory note, as the same may be amended, amended and restated, renewed, extended, supplemented, replaced or otherwise modified from time to time in accordance with its terms (the "**Note**").

ARTICLE I Definition

Capitalized terms used herein shall have the meanings set forth in this 0.

"**Advance**" means each disbursement made by the Noteholder to the Borrower under this Agreement.

"**Affiliate**" means, with respect to any Person, any other Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such Person. The term "control" (including the terms "controlled by" and "under common control with") means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

"**Anti-Terrorist Financing and Anti-Money Laundering Laws**" means all Applicable Laws concerning or related to money laundering or financing terrorism, government sanctions and "know your client" laws and which are applicable to the Borrower and the Noteholder including the Trading with the Enemy Act (United States), Executive Order No. 13224, and the USA PATRIOT Act.

"**Applicable Law**" means, in relation to any Person, property, transaction or event, all applicable provisions of: (a) statutes, laws (including common law), rules, regulations, decrees, ordinances, codes, proclamations, treaties, declarations or orders of any Governmental Authority; (b) any consents or approvals of any Governmental Authority; and (c) any orders, decisions, advisory or interpretative opinions, injunctions, judgments, awards, decrees of, or agreements with, any Governmental Authority, in each case applicable to or binding upon such Person, property, transaction or event.

"**Applicable Rate**" means the annual rate equal to Eight (8) percent.

"**Borrower**" has the meaning set forth in the introductory paragraph.

"**Borrowing Notice**" has the meaning set forth in Section 1.02.

"**Business Day**" means any day, other than a Saturday, Sunday or other day on which commercial banks in New York are authorized or required by law to be closed for business.

"**Commitment Period**" means the period from the date hereof to the Maturity Date.

"**Debt**" of the Borrower, means all (a) indebtedness for borrowed money; (b) obligations for the deferred purchase price of property or services, except trade payables arising in the ordinary course of business; (c) obligations evidenced by notes, bonds, debentures or other similar instruments; (d) obligations as lessee under capital leases and sale and lease-back transactions; (e) obligations in respect of any interest rate swaps, currency exchange agreements, commodity swaps, or similar arrangements entered into by the Borrower providing for protection against fluctuations in interest rates, currency exchange rates or commodity prices or the exchange of nominal interest obligations, either generally or under specific contingencies; (f) obligations under bankers' acceptance facilities and letters of credit; (g) purchase money security obligations; (h) guarantees, surety bonds, and other contingent obligations to purchase, to provide funds for payment, to supply funds to invest in a Person, or otherwise to assure a creditor against loss, in each case, in respect of indebtedness set out in clauses (a) through (g) of a Person other than the Borrower; and (i) indebtedness set out in clauses (a) through (h) of any Person other

than Borrower secured by any encumbrance on any asset of the Borrower, whether or not such indebtedness has been assumed by the Borrower.

"**Default**" means any of the events specified in ARTICLE VIII which constitutes an Event of Default or which, upon the giving of notice, the lapse of time, or both pursuant to ARTICLE VIII would, unless cured or waived, become an Event of Default.

"**Default Rate**" means, at any time, the Applicable Rate plus an additional 5% per annum.

"**Distribution**" means, (a) any declaration or payment of dividends, or other return on capital in respect of any Equity Interests of the Borrower; (b) any purchase, redemption, defeasance, retirement or other acquisition of, any Equity Interests of the Borrower; (c) any other payment or distribution of money or equivalents (including principal, interest, royalties and management fees) by or to the shareholders or creditors of the Borrower.

"**Encumbrance**" means any security interest, mortgage, debenture, pledge, hypothec, assignment (as security), deposit arrangement, lien (statutory or other), charge, title retention, consignment, lease or other security agreement or trust, right of set-off or other arrangement having the effect of security for the payment of any debt, liability or obligation.

"**Equity Interests**" means any and all shares, interests, participations, or other equivalents of shares in a corporation, any and all equivalent ownership (or profit) interests in a Person, securities convertible into or exchangeable for shares of capital stock of (or other ownership or profit interests in) such Person, and any and all warrants, rights or options to purchase any of the foregoing, whether voting or non-voting, and whether or not such shares, warrants, options, rights or other interests are authorized or otherwise existing on any date of determination.

Event of Default" has the meaning set forth in ARTICLE VIII.

"**GAAP**" means generally accepted accounting principles which are in effect from time to time, applied in a consistent manner from period to period.

"**Governmental Authority**" means: (a) any government, parliament or legislature, any regulatory or administrative authority, agency, commission or board and any other statute, rule or regulation making entity having jurisdiction in the relevant circumstances; (b) any Person acting within and under the authority of any of the foregoing or under a statute, rule or regulation thereof; and (c) any judicial, administrative or arbitral court, authority, tribunal or commission having jurisdiction in the relevant circumstances.

"**Indemnified Taxes**" means: (a) Taxes imposed on or with respect to any payment made by the Borrower; and (b) to the extent not otherwise described in (a), any and all present or future stamp, court, recording, filing, intangible, documentary or similar Taxes or any other excise or property Taxes, charges or similar levies arising from any payment made hereunder or from the execution, delivery or enforcement or registration of, or performance under, or from the receipt or perfection of a security interest under or otherwise with respect to this Agreement.

"**Interest Payment Date**" means the Maturity Date, or such other date or dates as may be agreed in writing by the Parties.

"**Investments**" means any advance, loan, extension of credit (by way of guarantee or otherwise) or capital contribution to, or the purchase or acquisition of any Equity Interests, bonds, notes, debentures or other debt securities of, or any assets constituting a business unit of, or the making of any other investment in, any Person.

"**Loan**" has the meaning set forth in the introductory paragraph.

"**Material Adverse Effect**" means any such matter, event or circumstance that individually, or in the aggregate, could, in the opinion of the Noteholder, acting reasonably, be expected to have a material adverse effect on (a) the business, assets, properties, liabilities (actual or contingent), operations, condition (financial or otherwise) or

prospects of the Borrower; (b) the validity or enforceability of the Note; (c) the rights or remedies of the Noteholder hereunder; or (d) the Borrower's ability to perform any of its material obligations hereunder.

"**Maturity Date**" means the date that is twelve months from the date of the this Note, unless otherwise modified in writing by the Parties.

"**Note**" has the meaning set forth in the introductory paragraph.

"**Noteholder**" has the meaning set forth in the introductory paragraph.

"**Order**" as to any Person, means any order, decree, judgment, writ, injunction, settlement agreement, requirement or determination of an arbitrator or a court or other Governmental Authority, in each case, applicable to or binding on such Person or any of its properties or to which such Person or any of its properties is subject.

"**Parties**" has the meaning set forth in the introductory paragraph.

"**Permitted Investments**" means (a) Investments in Cash Equivalents; (b) intercompany Investments by any Loan Party in the Borrower or any other Person that, prior to such Investment, is a Loan Party; and (c) extensions of trade credit in the ordinary course of business.

"**Person**" means an individual, legal or natural person, corporation, company, firm, body corporate, partnership, joint venture, Governmental Authority, unincorporated organization, trust, association, estate or other entity.

"**Taxes**" means any and all present or future income, stamp or other taxes, levies, imposts, duties, deductions, charges, fees or withholdings imposed, levied, withheld or assessed by any Governmental Authority, together with any interest, additions to tax or penalties imposed thereon and with respect thereto.

ARTICLES II The Credit Facilities

Section 1.01 Subject to Section 1.02, the Noteholder has advanced to the Borrower one or more Advances during the Commitment Period in an aggregate amount not to exceed the Loan.

Section 1.02 **Advances.** The Noteholder has advanced to the Borrower the principal amount of US$7,000,000.00.

ARTICLE II Repayment

Section 2.01 **Payment Date.** The aggregate unpaid principal amount of the Loan, all accrued and unpaid interest and all other amounts payable under this Note shall be due and payable on the Maturity Date.

ARTICLE III Interest

Section 3.01 **Interest Rate.** Except as otherwise provided herein, the outstanding principal amount of the Loan made hereunder shall bear interest at the Applicable Rate from the date the Loan was made until the Loan is paid in full on the Maturity Date.

Section 3.02 **Interest Payment Dates.** Interest shall be calculated daily and shall be payable to the Noteholder on the Maturity Date, or at such other times as may be agreed in writing by the Parties.

Section 3.03 **Default Interest.** If any amount payable hereunder is not paid when due (without regard to any applicable grace periods), whether at stated maturity, by acceleration or otherwise, such overdue amount shall bear interest at the Default Rate from the date of such non-payment until such amount is paid in full.

Section 3.04 **Computation of Interest.**

(a) All computations of interest shall be made on the basis of a year of 365 or 366 days, as the case may be, and the actual number of days elapsed and using the nominal rate method of calculation, and will not be calculated using the effective rate method of calculation or on any other basis that gives effect to the principle of deemed reinvestment of interest. Interest shall accrue on the Loan on the day on which such Advance is made, and shall not accrue on the Loan for the day on which it is paid.

Section 3.05 Interest Rate Limitation. If, at any time and for any reason whatsoever, the interest rate payable on the Loan shall exceed the maximum rate of interest permitted to be charged by the Noteholder to the Borrower under Applicable Law, or would result in receipt by the Noteholder of interest at a criminal rate such interest rate shall be reduced automatically to the maximum rate of interest permitted under Applicable Law.

ARTICLE IV Place of Payment and Taxes

Section 4.01 Manner of Payments. All payments of interest and principal shall be made by bank draft, certified cheque or by wire transfer of immediately available funds to the Noteholder's account at a bank specified by the Noteholder in writing to the Borrower from time to time, on the Maturity Date or at such other times as may be agreed in writing by the Parties.

Section 4.02 Application of Payments. All payments made hereunder shall be applied first to the payment of any fees or charges outstanding hereunder, second to accrued interest, and third to the payment of the principal amount outstanding under the Note.

Section 4.03 Business Day Convention. Whenever any payment to be made hereunder shall be due on a day that is not a Business Day, such payment shall be made on the next succeeding Business Day and such extension will be taken into account in calculating the amount of interest payable under this Note.

Section 4.04 Evidence of Debt. The Noteholder is authorized to record on the grid attached hereto as Exhibit A the Loan made to the Borrower and each payment thereof. The entries made by the Noteholder shall, to the extent permitted by Applicable Law, be prima facie evidence of the existence and amounts of the obligations of the Borrower therein recorded; *provided, however*, that the failure of the Noteholder to record such payments or any inaccuracy therein, shall not in any manner affect the obligation of the Borrower to repay (with applicable interest) the Loan in accordance with the terms of this Note.

Section 4.05 Rescission of Payments. If at any time any payment made by the Borrower under this Note is rescinded or must otherwise be restored or returned upon the insolvency, bankruptcy or reorganization of the Borrower or otherwise, the Borrower's obligation to make such payment shall be reinstated as though such payment had not been made.

Section 4.06 Taxes. Any and all payments by or on account of any obligation of the Borrower hereunder shall be made free and clear of and without reduction or withholding for any taxes; provided that if the Borrower is required by Applicable Law to deduct or withhold any Taxes from such payment, then:

(a) If such tax is an Indemnified Tax, the amount payable by the Borrower shall be increased so that after making all required deductions or withholdings, the Noteholder receives an amount equal to the amount it would have received had no such deduction or withholdings been made; and

(b) The Borrower shall make such deductions, timely pay the full amount deducted to the relevant Governmental Authority in accordance with Applicable Law, and provide the Noteholder with official receipts or other evidence satisfactory to the Noteholder for each payment.

ARTICLE V Representations and Warranties

The Borrower hereby represents and warrants to the Noteholder on the date hereof as follows:

Section 5.01 **Incorporation and Existence.** The Borrower is (a) duly incorporated and validly existing under the laws of its jurisdiction of incorporation, and (b) is duly qualified or registered as an extra-provincial corporation to carry on business in each jurisdiction in which it owns property or assets or carries on business.

Section 5.02 **Power and Capacity.** The Borrower has the corporate power and capacity, and the legal right, to execute and deliver this Note and to perform its obligations hereunder.

Section 5.03 **Authorization; Execution and Delivery.** The execution and delivery of this Note by the Borrower and the performance of its obligations hereunder have been duly authorized by all necessary corporate action in accordance with all Applicable Laws. The Borrower has duly executed and delivered this Note.

Section 5.04 **No Approvals.** No consent or authorization of, filing with, notice to or other act by, or in respect of, any Governmental Authority or any other Person is required in order for the Borrower to execute, deliver, or perform any of its obligations under this Note.

Section 5.05 **No Violations.** The execution and delivery of this Note and the consummation by the Borrower of the transactions contemplated hereby do not and will not (a) violate any provision of the Borrower's articles, by- laws, or any unanimous shareholders agreement; (b) violate any Applicable Law or Order applicable to the Borrower or by which any of its properties or assets may be bound; or (c) constitute a default under any material agreement or contract by which the Borrower may be bound.

Section 5.06 **Enforceability.** The Note is a valid, legal and binding obligation of the Borrower, enforceable against the Borrower in accordance with its terms except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, arrangement, moratorium or similar laws affecting the enforcement of creditors' rights generally and by general equitable principles (whether enforcement is sought by proceedings in equity or at law.

Section 5.07 **No Litigation.** No action, suit, litigation, investigation or proceeding of, or before, any arbitrator or Governmental Authority is pending or, to the knowledge of the Borrower, threatened by or against the Borrower or any of its property or assets (a) with respect to the Note or any of the transactions contemplated hereby or (b) that could be expected to have a Material Adverse Effect.

Section 5.08 **Taxes.** The Borrower has filed on a timely basis all Tax returns, elections and reports that are required to be filed by it under Applicable Law and has paid, collected, withheld and remitted all Taxes and remittances shown thereon to be due and payable, collectible or remittable by it under Applicable Law, and all other Taxes, fees or other charges imposed on it or any of its property by any Governmental Authority. No tax liens have been filed, and, to the knowledge of the Borrower, no claim is being asserted, with respect to any such Tax, fee or other charge.

ARTICLE VI Positive Covenants

Until all amounts outstanding in this Note have been paid in full, the Borrower shall:

Section 6.01 **Maintenance of Existence.** (a) Preserve, renew and maintain in full force and effect its corporate or organizational existence; and (b) take all reasonable action to maintain all rights, privileges, permits, licences and franchises necessary or desirable in the normal conduct of its business, except, in each case, where the failure to do so could not reasonably be expected to have a Material Adverse Effect.

Section 6.02 **Compliance.** Comply with (a) all of the terms and provisions of its articles, by-laws and any unanimous shareholder agreement; (b) its obligations under its material contracts and agreements; and (c) all Applicable Laws and Orders applicable to it and its business, except where the failure to do so could not reasonably be expected to have a Material Adverse Effect.

Section 6.03 **Payment Obligations.** Pay, discharge or otherwise satisfy at or before maturity or before they become delinquent, as the case may be, all its material obligations of whatever nature, including without limitation

all Taxes, except where the amount or validity thereof is currently being contested in good faith by appropriate proceedings, and reserves in conformity with GAAP with respect thereto have been provided on its books.

Section 6.04 Compliance with Anti-Terrorist Financing and Anti-Money Laundering Laws. Comply with all applicable Anti-Terrorist Financing and Anti-Money Laundering Laws.

Section 6.05 Notice of Events of Default. As soon as possible and in any event within 10 Business Days after it becomes aware that a Default or an Event of Default has occurred, notify the Noteholder in writing of the nature and extent of such Default or Event of Default and the action, if any, it has taken or proposes to take with respect to such Default or Event of Default.

Section 6.06 Further Assurances. Upon the request of the Noteholder, promptly execute and deliver such further instruments and do or cause to be done such further acts as may be necessary or advisable to carry out the intent and purposes of this Note.

ARTICLE VII Negative Covenants

Until all amounts outstanding under this Note have been paid in full, the Borrower shall not:

Section 7.01 Indebtedness. Incur, create or assume any Debt.

Section 7.02 Encumbrances. Incur, create, assume or suffer to exist any Encumbrance on any of its property or assets, whether now owned or hereinafter acquired.

Section 7.03 Line of Business. Enter into any business, directly or indirectly, except for those businesses in which the Borrower is engaged on the date of this Note or that are reasonably related thereto.

Section 7.04 Limitation on Changes to Capital Structure. Make any change to its capital structure, authorize or issue any Equity Interests of the Borrower.

Section 7.05 Limitation on Dispositions. Sell, lease, assign, transfer or otherwise dispose of any of its assets or property outside of the ordinary course of business, whether now owned or hereafter acquired, or sell any Equity Interests of the Borrower to any Person.

Section 7.06 Limitation on Distributions. Make any Distributions to shareholders or creditors.

Section 7.07 Limitation on Investments. Make any Investments, except so long as no Default or Event of Default has occurred or is continuing, or would result therefrom, Permitted Investments.

ARTICLE VIII Events of Default

The occurrence and continuance of any of the following shall constitute an Event of Default hereunder:

Section 8.01 Failure to Pay. The Borrower fails to pay (a) any principal amount of the Loan when due or (b) interest or any other amount when due and such failure continues for 15 days after written notice to the Borrower.

Section 8.02 Breach of Representations and Warranties. Any representation or warranty made or deemed made by the Borrower to the Noteholder herein is incorrect in any material respect on the date as of which such representation or warranty was made or deemed made.

Section 8.03 Breach of Covenants. The Borrower fails to observe or perform (a) any covenant, condition or agreement contained in ARTICLE VII or (b) any other covenant, obligation, condition or agreement contained in this Note other than those specified in clause (a) and Section 8.01 and such failure continues for 30 days after written notice to the Borrower.

Section 8.04 **Cross-defaults.** The Borrower fails to pay when due any of its Debt (other than Debt arising under this Note) or any interest, premium, or other amount payable thereon, and such failure continues after the applicable grace period specified in the agreement or instrument relating to such Debt.

Section 8.05 **Bankruptcy and Insolvency.**

(a) the Borrower commences any application, proceeding or other action (i) under any existing or future Applicable Law relating to bankruptcy, insolvency, reorganization, or other relief of debtors, seeking to have an order for relief entered with respect to it, or seeking to adjudicate it as bankrupt or insolvent, or seeking reorganization, arrangement, proposal, adjustment, winding-up, liquidation, dissolution, composition or other relief with respect to it or its debts or (ii) seeking appointment of a receiver, interim receiver, receiver and manager, trustee, custodian, conservator or other similar official for it or for all or any part of its assets, or the Borrower makes a general assignment for the benefit of its creditors;

(b) there is commenced against the Borrower any application, proceeding or other action of a nature referred to in Section 8.05(a) which (i) results in the entry of an order for relief or any such adjudication or appointment or (ii) remains undismissed, undischarged or unbonded for a period of 60 days;

(c) there is commenced against the Borrower any application, proceeding or other action seeking issuance of a writ of seizure and sale, execution, garnishment, or similar process against all or any part of its assets which results in the entry of an order for any such relief which has not been vacated, discharged, stayed or bonded pending appeal within 60 days from the entry thereof;

(d) the Borrower takes any action in furtherance of, or indicating its consent to, approval of, or acquiescence in, any of the acts set forth in Section 8.05(a), Section 8.05(b) or Section 8.05(c); or

(e) the Borrower is generally not, or shall be unable to, or admits in writing its inability to, pay its debts as they become due.

Section 8.06 **Judgments and Executions.** One or more judgments or writs of seizure and sale shall be entered, issued or registered against the Borrower and all of such judgments or writs of enforcement shall not have been vacated, discharged, stayed or bonded pending appeal within 60 days from the entry thereof.

ARTICLE IX Remedies

Section 9.01 **Remedies.** Upon the occurrence of any Event of Default and at any time thereafter during the continuance of such Event of Default, the Noteholder may, at its option, by written notice to the Borrower (a) terminate its commitment to make any Advances hereunder; (b) declare the entire principal amount of this Note, together with all accrued interest thereon and all other amounts payable hereunder, immediately due and payable; and/or (c) exercise any or all of its rights, powers or remedies under Applicable Law; *provided, however* that, if an Event of Default described in Section 8.05 shall occur, the principal of and accrued interest on the Loan shall become immediately due and payable without any notice, declaration or other act on the part of the Noteholder.

ARTICLE X Miscellaneous

Section 10.01 **Notices.**

(a) All notices, requests or other communications required or permitted to be delivered hereunder shall be delivered in writing, in each case to the address specified below or to such other address as such Party may from time to time specify in writing in compliance with this provision:

If to the Borrower: 5361 Winter Dr., Tobyhanna, PA 18466-8126
Email: menachemwagner@gmail.com
Attention: Menachem Wagner

If to the Noteholder: 1167 Massachusetts Avenue, Arlington, MA 02476
Email: Avi Minkowitz
Attention: aviminksmail@gmail.com

(b) Notices if (i) mailed by certified or registered mail or sent by hand or overnight courier service shall be deemed to have been given when received; (ii) sent by facsimile during the recipient's normal business hours shall be deemed to have been given when sent (and if sent after normal business hours shall be deemed to have been given at the opening of the recipient's business on the next business day); and (iii) sent by e-mail shall be deemed received upon the sender's receipt of an acknowledgment from the intended recipient (such as by the "return receipt requested" function, as available, return e-mail or other written acknowledgment).

Section 10.02 Expenses. The Borrower agrees to reimburse the Noteholder for all reasonable out-of-pocket costs, expenses and fees (including reasonable expenses and fees of its counsel) incurred by the Noteholder in connection with the transactions contemplated hereby including (a) the negotiation, documentation and execution of this Note ; and (b) the enforcement of the Noteholder's rights hereunder on a substantial indemnity basis.

Section 10.03 Governing Law. This Note, and all matters arising out of or relating to this Note, shall be governed by, and construed in accordance with, the laws of the State of New York without giving effect to principles of conflicts of law. Each of the parties agrees to submit to the jurisdiction of the courts of competent jurisdiction located in the Borough of Manhattan in New York City in any actions or proceedings arising out of or relating to this Note. Each of the parties, by execution and delivery of this Note, expressly and irrevocably (i) consents and submits to the personal jurisdiction of any of such courts in any such action or proceeding; (ii) consents to the service of any complaint, summons, notice or other process relating to any such action or proceeding by delivery thereof to such party as set forth in Section 10.01 above and (iii) waives any claim or defense in any such action or proceeding based on any alleged lack of personal jurisdiction, improper venue or forum non conveniens or any similar basis.

EACH OF THE UNDERSIGNED HEREBY WAIVES FOR ITSELF AND ITS PERMITTED SUCCESSORS AND ASSIGNS THE RIGHT TO TRIAL BY JURY IN ANY ACTION OR PROCEEDING INSTITUTED IN CONNECTION WITH THIS NOTE.

Section 10.04 Counterparts; Electronic Delivery. This Note, any amendments, waivers, consents or supplements hereto may be executed in counterparts (and by different parties hereto in different counterparts), each of which shall constitute an original, but all taken together shall constitute a single contract. Delivery of an executed counterpart of a signature page to this Note by facsimile or in electronic (such as "pdf" or "tif") format shall be effective as delivery of a manually executed counterpart of this Note.

Section 10.05 Entire Agreement. This Note constitutes the sole and entire agreement of the parties hereto with respect to the subject matter contained herein and supersedes all prior and contemporaneous understandings, agreements, representations and warranties both written and oral, with respect to such subject matter.

Section 10.06 Successors and Assigns. This Note may be assigned or transferred by the Noteholder to any Person. The Borrower may not assign or transfer this Note or any of its rights hereunder without the prior written consent of the Noteholder which consent may be refused in the absolute discretion of the Noteholder without providing any reason whatsoever. This Note shall enure to the benefit of, and be binding upon, the Parties and their permitted assigns.

Section 10.07 Waiver of Notice. The Borrower hereby waives demand for payment, presentment for payment, protest, notice of payment, notice of dishonour, notice of nonpayment, notice of acceleration of maturity and diligence in taking any action to collect sums owing hereunder.

Section 10.08 Interpretation. For purposes of this Note (a) the words "include", "includes" and "including" shall be deemed to be followed by the words "without limitation"; (b) the word "or" is not exclusive; and (c) the words "herein", "hereof", "hereby", "hereto" and "hereunder" refer to this Note as a whole. The definitions given for any defined terms in this Note shall apply equally to both the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. Unless the context otherwise requires, references herein: (x) to Schedules, Exhibits and Sections mean the Schedules, Exhibits and Sections of this Note; (y) to an agreement, instrument or other document means such agreement, instrument or other document as amended, supplemented and modified from time to time to the extent permitted by the provisions thereof; and (z) to a statute means such statute as amended from time to time and includes any successor legislation thereto and any regulations promulgated thereunder. This Note shall be construed without regard to any presumption or rule requiring construction or interpretation against the party drafting an instrument or causing any instrument to be drafted. All dollar amounts referred to in this Note mean the lawful currency of the United States.

Section 10.09 Amendments and Waivers. None of the terms or provisions of this Note may be amended, modified, supplemented, terminated or waived, except by an instrument in writing signed by both of the parties hereto. Any waiver of the terms hereof shall be effective only in the specific instance and for the specific purpose given.

Section 10.10 Headings. The headings of the various sections and subsections herein are for reference only and shall not define, modify, expand or limit any of the terms or provisions hereof.

Section 10.11 No Waiver; Cumulative Remedies. No failure to exercise and no delay in exercising on the part of the Noteholder, of any right, remedy, power or privilege hereunder shall operate as a waiver thereof; nor shall any single or partial exercise of any right, remedy, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power or privilege. The rights, remedies, powers and privileges herein provided are cumulative and not exclusive of any rights, remedies, powers and privileges provided by law.

Section 10.12 Severability. Any provision hereof which is invalid, illegal or unenforceable in whole or in part in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such invalidity, illegality or unenforceability without invalidating the remaining provisions hereof or affecting the validity, legality or enforceability of such provision in any other jurisdiction.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Borrower has executed this Note as of February 9, 2026.

MINGLEMINT SOLUTIONS LLC

/s/ Menachem Wagner
Menachem Wagner, Authorized Signatory
I have authority to bind the corporation.

By its acceptance of this Note, the Noteholder acknowledges and agrees to be bound by the provisions of Section 1.02.

KALA BIO, INC.

/s/ Avi Minkowitz
Avi Minkowitz, CEO
I have authority to bind the corporation.

EXHIBIT A

Advances and Payments on the Loan

Date of Advance	**Amount of Advance in US$**	**Amount of Principal Paid in US$**	**Unpaid Principal Amount of Note in US$**	**Accrued Interest**	**Name of Person Making the Notation**
February 9, 2026	$7,000,000.00 to the wire instructions in Exhibit B	$0.00	$7,000,000.00	$0.00	/s/ Avi Minkowitz /s/ Menachem Wagner

EXHIBIT B

Wire Instructions

Bank name: Bank of America
Bank Address: 222 Broadway, New York, NY 10038

Account Name: Minglemint Solutions LLC
Routing Number: 026009593
Checking Account: 325202453716
Address: 5361 Winter Dr., Tobyhanna, PA 18466-8126

SECURITY AGREEMENT

This Security Agreement, dated as of February 9, 2026 (as amended, supplemented or otherwise modified from time to time in accordance with the provisions hereof, this "**Agreement**"), is made by and between Minglemint Solutions LLC, a limited liability corporation formed under the laws of the State of Pennsylvania (the "**Borrower**"), and Kala Bio, Inc., a Delaware corporation (the "**Secured Party,**" and together with the Borrower, the "**Parties**").

Capitalized terms used but not otherwise defined herein shall have the meanings assigned to such terms in the Secured Promissory Note (as defined herein).

WHEREAS, on the date hereof, the Secured Party has made a loan to the Borrower, in the form of a secured promissory note, in an aggregate principal amount of US$7,000,000.00 (the "**Loan**"), evidenced by that certain secured promissory note, dated as of February 9, 2026, by and between the Borrower and the Secured Party (as amended, supplemented or otherwise modified from time to time, the "**Secured Promissory Note**"); and

WHEREAS, this Agreement is given by the Borrower in favor of the Secured Party to secure the payment and performance of all of the Secured Obligations;

NOW, THEREFORE, in consideration of the mutual covenants, terms and conditions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, agree as follows:

1. Definitions.

(a) Unless otherwise specified herein, all references to Sections and Schedules herein are to Sections and Schedules of this Agreement.

(b) Unless otherwise defined herein, terms used herein that are defined in the UCC shall have the meanings assigned to them in the UCC. However, if a term is defined in Article 9 of the UCC differently than in another Article of the UCC, the term has the meaning specified in Article 9.

(c) For purposes of this Agreement, the following terms shall have the following meanings:

"**Collateral**" has the meaning set forth in Section 2.

"**Event of Default**" has the meaning set forth in the Secured Promissory Note.

"**First Priority**" means, with respect to any lien and security interest purported to be created in any Collateral pursuant to this Agreement, such lien and security interest is the most senior lien to which such Collateral is subject.

"**Proceeds**" means "proceeds" as such term is defined in section 9-102 of the UCC and, in any event, shall include, without limitation, all dividends or other income from the Collateral, collections thereon or distributions with respect thereto.

"**Secured Obligations**" has the meaning set forth in Section 3.

"**UCC**" means the Uniform Commercial Code as in effect from time to time in the State of Pennsylvania or, when the laws of any other state govern the method or manner of the perfection or enforcement of any security interest in any of the Collateral, the Uniform Commercial Code as in effect from time to time in such state.

2. Grant of Security Interest. The Borrower hereby pledges and grants to the Secured Party, and hereby creates a continuing First Priority lien and security interest in favor of the Secured Party in and to all of its right, title and interest in and to the following, wherever located, whether now existing or hereafter from time to time arising or acquired (collectively, the "**Collateral**"):

(a) all fixtures and personal property of every kind and nature including all accounts (including insurance receivables), goods (including inventory and equipment), documents (including, if applicable, electronic documents), instruments, promissory notes, chattel paper (whether tangible or electronic), letters of credit, letter-of-credit rights (whether or not the letter of credit is evidenced by a writing), securities and all other investment property, commercial tort claims described on Schedule I hereof as supplemented by any written notification given by the Borrower to the Secured Party pursuant to Section 4(e), general intangibles (including all payment intangibles), money, deposit accounts, and any other contract rights or rights to the payment of money; and

(b) all Proceeds and products of each of the foregoing, all books and records relating to the foregoing, all supporting obligations related thereto, and all accessions of and to, substitutions and replacements for, and rents, profits and products of, each of the foregoing, and any and all Proceeds of any insurance, indemnity, warranty or guaranty payable to the Borrower from time to time with respect to any of the foregoing.

3. Secured Obligations. The Collateral secures the due and prompt payment and performance of:

(a) The Secured Promissory Note;

(b) the obligation of the Borrower from time to time arising under the Secured Promissory Note and this Agreement or otherwise with respect to the due and prompt payment of (i) the principal of and premium, if any, and interest on the Loan (including interest accruing during the pendency of any bankruptcy, insolvency, receivership or other similar proceeding, regardless of whether allowed or allowable in such proceeding), when and as due, whether at maturity, by acceleration, upon one or more dates set for prepayment or otherwise and (ii) all other monetary obligations, including fees, costs, attorneys' fees and disbursements, reimbursement obligations, contract causes of action, expenses and indemnities, whether primary, secondary, direct or indirect, absolute or contingent, due or to become due, now existing or hereafter arising, fixed or otherwise (including monetary obligations incurred during the pendency of any bankruptcy, insolvency, receivership or other similar proceeding, regardless of whether allowed or allowable in such proceeding), of the Borrower under or in respect of the Secured Promissory Note and this Agreement; and

(c) all other covenants, duties, debts, obligations and liabilities of any kind of the Borrower under or in respect of the Secured Promissory Note and this Agreement or any other document made, delivered or given in connection with any of the

foregoing, in each case whether evidenced by a note or other writing, whether allowed in any bankruptcy, insolvency, receivership or other similar proceeding, whether arising from an extension of credit, issuance of a letter of credit, acceptance, loan, guaranty, indemnification or otherwise, and whether primary, secondary, direct or indirect, absolute or contingent, due or to become due, now existing or hereafter arising, fixed or otherwise (all such obligations, covenants, duties, debts, liabilities, sums and expenses set forth in Section 3 being herein collectively called the "**Secured Obligations**").

4. Perfection of Security Interest and Further Assurances.

(a) The Borrower shall, from time to time, as may be required by the Secured Party with respect to all Collateral, immediately take all actions as may be requested by the Secured Party to perfect the security interest of the Secured Party in the Collateral, including, without limitation, with respect to all Collateral over which control may be obtained within the meaning of sections 8-106, 9-104, 9-105, 9-106, 9- 107 and 9-107A of the UCC, section 201 of the federal Electronic Signatures in Global and National Commerce Act and, as the case may be, section 16 of the Uniform Electronic Transactions Act, as applicable, the Borrower shall immediately take all actions as may be requested from time to time by the Secured Party so that control of such Collateral is obtained and at all times held by the Secured Party. All of the foregoing shall be at the sole cost and expense of the Borrower.

(b) The Borrower hereby irrevocably authorizes the Secured Party at any time and from time to time to file in any relevant jurisdiction any financing statements and amendments thereto that contain the information required by Article 9 of the UCC of each applicable jurisdiction for the filing of any financing statement or amendment relating to the Collateral, including any financing or continuation statements or other documents for the purpose of perfecting, confirming, continuing, enforcing or protecting the security interest granted by the Borrower hereunder, without the signature of the Borrower where permitted by law, including the filing of a financing statement describing the Collateral as all assets now owned or hereafter acquired by the Borrower, or words of similar effect. The Borrower agrees to provide all information required by the Secured Party pursuant to this Section promptly to the Secured Party upon request.

(c) The Borrower hereby further authorizes the Secured Party to file with the United States Patent and Trademark Office and the United States Copyright Office (and any successor office and any similar office in any state of the United States or in any other country) this Agreement and other documents for the purpose of perfecting, confirming, continuing, enforcing or protecting the security interest granted by the Borrower hereunder, without the signature of the Borrower where permitted by law.

(d) If the Borrower shall at any time hold or acquire any certificated securities, promissory notes, tangible chattel paper, negotiable documents or warehouse receipts relating to the Collateral, the Borrower shall immediately endorse, assign and deliver the same to the Secured Party, accompanied by such instruments of transfer or assignment duly executed in blank as the Secured Party may from time to time specify.

(e) If the Borrower shall at any time hold or acquire a commercial tort claim, the Borrower shall (i) immediately notify the Secured Party in a writing signed by the

Borrower of the particulars thereof and grant to the Secured Party in such writing a security interest therein and in the proceeds thereof, all upon the terms of this Agreement, with such writing to be in form and substance satisfactory to the Secured Party and (ii) deliver to the Secured Party an updated Schedule I.

(f) If any Collateral is at any time in the possession of a bailee, the Borrower shall promptly notify the Secured Party thereof and, at the Secured Party's request and option, shall promptly obtain an acknowledgment from the bailee, in form and substance satisfactory to the Secured Party, that the bailee holds such Collateral for the benefit of the Secured Party and the bailee agrees to comply, without further consent of the Borrower, at any time with instructions of the Secured Party as to such Collateral.

(g) The Borrower agrees that at any time and from time to time, at the expense of the Borrower, the Borrower will promptly execute and deliver all further instruments and documents, obtain such agreements from third parties, and take all further action, that may be necessary or desirable, or that the Secured Party may request, in order to create and/or maintain the validity, perfection or priority of and protect any security interest granted or purported to be granted hereby or to enable the Secured Party to exercise and enforce its rights and remedies hereunder or under any other agreement with respect to any Collateral.

5. Representations and Warranties. The Borrower represents and warrants as follows:

(a) The Borrower is (i) duly organized, validly existing and in good standing under the laws of the jurisdiction of its formation, (ii) duly qualified as a foreign organization and in good standing under the laws of each jurisdiction where its ownership, lease or operation of property or the conduct of its business requires such qualification and (iii) in compliance with all requirements of law.

(b) The Collateral consisting of securities have been duly authorized and validly issued, and are fully paid and non-assessable and subject to no options to purchase or similar rights. The Borrower holds no commercial tort claims except as indicated on Schedule I. None of the Collateral constitutes, or is the proceeds of, (i) farm products, (ii) as-extracted collateral, (iii) manufactured homes, (iv) health-care- insurance receivables, (v) timber to be cut, (vi) aircraft, aircraft engines, satellites, ships or railroad rolling stock. None of the account debtors or other persons obligated on any of the Collateral is a governmental authority covered by the Federal Assignment of Claims Act or like federal, state or local statute or rule in respect of such Collateral. The Borrower has at all times operated its business in compliance with all applicable provisions of the federal Fair Labor Standards Act, as amended, and with all applicable provisions of federal, state and local statutes and ordinances dealing with the control, shipment, storage or disposal of hazardous materials or substances.

(c) At the time the Collateral becomes subject to the lien and security interest created by this Agreement, the Borrower will be the sole, direct, legal and beneficial owner thereof, free and clear of any lien, security interest, encumbrance, claim, option or right of others except for the security interest created by this Agreement and other liens permitted by the Secured Promissory Note.

(d) The pledge of the Collateral pursuant to this Agreement creates a valid and perfected First Priority security interest in the Collateral, securing the payment and performance when due of the Secured Obligations.

(e) It has full power, authority and legal right to pledge the Collateral pursuant to this Agreement.

(f) This Agreement has been duly authorized, executed and delivered by the Borrower and constitutes a legal, valid and binding obligation of the Borrower enforceable in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws affecting creditors' rights generally and subject to equitable principles (regardless of whether enforcement is sought in equity or at law).

(g) No authorization, approval, or other action by, and no notice to or filing with, any governmental authority or regulatory body is required for the pledge by the Borrower of the Collateral pursuant to this Agreement or for the execution and delivery of this Agreement by the Borrower or the performance by the Borrower of its obligations hereunder.

(h) The execution and delivery of this Agreement by the Borrower and the performance by the Borrower of its obligations hereunder, will not violate any provision of any applicable law or regulation or any order, judgment, writ, award or decree of any court, arbitrator or governmental authority, domestic or foreign, applicable to the Borrower or any of its property, or the organizational or governing documents of the Borrower or any agreement or instrument to which the Borrower is party or by which it or its property is bound.

(i) The Borrower has taken all action required on its part for control (as defined in sections 8-106, 9-104, 9-105, 9-106, 9-107 and 9-107A of the UCC, section 201 of the federal Electronic Signatures in Global and National Commerce Act and, as the case may be, section 16 of the Uniform Electronic Transactions Act, as applicable) to have been obtained by the Secured Party over all Collateral with respect to which such control may be obtained pursuant to the UCC. No person other than the Secured Party has control or possession of all or any part of the Collateral.

6. Voting, Distributions and Receivables.

(a) The Secured Party agrees that unless an Event of Default shall have occurred and be continuing, the Borrower may, to the extent the Borrower has such right as a holder of the Collateral consisting of securities, other equity interests or indebtedness owed by any obligor, vote and give consents, ratifications and waivers with respect thereto, except to the extent that, in the Secured Party's reasonable judgment, any such vote, consent, ratification or waiver could or would detract from the value thereof as Collateral or which could or would be inconsistent with or result in any violation of any provision of the Secured Promissory Note or this Agreement.

(b) The Secured Party may, or at the request and option of the Secured Party the Borrower shall, notify account debtors and other persons obligated on any of the Collateral of the security interest of the Secured Party in any account, chattel paper,

general intangible, instrument or other Collateral and that payment thereof is to be made directly to the Secured Party.

7. Covenants. The Borrower covenants as follows:

(a) The Borrower will not, without providing at least sixty (60) days' prior written notice to the Secured Party, change its legal name, identity, type of organization, jurisdiction of organization, corporate structure, location of its principal executive office or its principal place of business or its organizational identification number. The Borrower will, prior to any change described in the preceding sentence, take all actions requested by the Secured Party to maintain the perfection and priority of the Secured Party's security interest in the Collateral.

(b) The Collateral, to the extent not delivered to the Secured Party pursuant to Section 4, will be kept at those locations listed Schedule II and the Borrower will not remove the Collateral from such locations without providing at least sixty (60) days' prior written notice to the Secured Party. The Borrower will, prior to any change described in the preceding sentence, take all actions required by the Secured Party to maintain the perfection and priority of the Secured Party's security interest in the Collateral.

(c) The Borrower shall, at its own cost and expense, defend title to the Collateral and the First Priority lien and security interest of the Secured Party therein against the claim of any person claiming against or through the Borrower and shall maintain and preserve such perfected First Priority security interest for so long as this Agreement shall remain in effect.

(d) The Borrower will not sell, offer to sell, dispose of, convey, assign or otherwise transfer, grant any option with respect to, restrict, or grant, create, permit or suffer to exist any mortgage, pledge, lien, security interest, option, right of first offer, encumbrance or other restriction or limitation of any nature whatsoever on, any of the Collateral or any interest therein except with the prior written consent of the Secured Party.

(e) The Borrower will keep the Collateral in good order and repair and will not use the same in violation of law or any policy of insurance thereon. The Borrower will permit the Secured Party, or its designee, to inspect the Collateral at any reasonable time, wherever located.

(f) The Borrower will pay promptly when due all taxes, assessments, governmental charges, and levies upon the Collateral or incurred in connection with the use or operation of the Collateral or incurred in connection with this Agreement.

(g) The Borrower will continue to operate its business in compliance with all applicable provisions of the federal Fair Labor Standards Act, as amended, and with all applicable provisions of federal, state and local statutes and ordinances dealing with the control, shipment, storage or disposal of hazardous materials or substances.

8. Secured Party Appointed Attorney-in-Fact. The Borrower hereby appoints the Secured Party the Borrower's attorney-in-fact, with full authority in the place and stead of the Borrower and in the name of the Borrower or otherwise, from time to time in the Secured

Party's discretion to take any action and to execute any instrument which the Secured Party may deem necessary or advisable to accomplish the purposes of this Agreement (but the Secured Party shall not be obligated to and shall have no liability to the Borrower or any third party for failure to do so or take action). This appointment, being coupled with an interest, shall be irrevocable. The Borrower hereby ratifies all that said attorneys shall lawfully do or cause to be done by virtue hereof.

9. Secured Party May Perform. If the Borrower fails to perform any obligation contained in this Agreement, the Secured Party may itself perform, or cause performance of, such obligation, and the expenses of the Secured Party incurred in connection therewith shall be payable by the Borrower; ***provided*** that the Secured Party shall not be required to perform or discharge any obligation of the Borrower.

10. Reasonable Care. The Secured Party shall have no duty with respect to the care and preservation of the Collateral beyond the exercise of reasonable care. The Secured Party shall be deemed to have exercised reasonable care in the custody and preservation of the Collateral in its possession if the Collateral is accorded treatment substantially equal to that which the Secured Party accords its own property, it being understood that the Secured Party shall not have any responsibility for (a) ascertaining or taking action with respect to any claims, the nature or sufficiency of any payment or performance by any party under or pursuant to any agreement relating to the Collateral or other matters relative to any Collateral, whether or not the Secured Party has or is deemed to have knowledge of such matters, or (b) taking any necessary steps to preserve rights against any parties with respect to any Collateral. Nothing set forth in this Agreement, nor the exercise by the Secured Party of any of the rights and remedies hereunder, shall relieve the Borrower from the performance of any obligation on the Borrower's part to be performed or observed in respect of any of the Collateral.

11. Remedies Upon Default.

(a) If any Event of Default shall have occurred and be continuing, the Secured Party, without any other notice to or demand upon the Borrower, may assert all rights and remedies of a secured party under the UCC or other applicable law, including, without limitation, the right to take possession of, hold, collect, sell, lease, deliver, grant options to purchase or otherwise retain, liquidate or dispose of all or any portion of the Collateral. If notice prior to disposition of the Collateral or any portion thereof is necessary under applicable law, written notice mailed to the Borrower at its notice address as provided in Section 15 hereof 10 (ten) days prior to the date of such disposition shall constitute reasonable notice, but notice given in any other reasonable manner shall be sufficient. So long as the sale of the Collateral is made in a commercially reasonable manner, the Secured Party may sell such Collateral on such terms and to such purchaser(s) as the Secured Party in its absolute discretion may choose, without assuming any credit risk and without any obligation to advertise or give notice of any kind other than that necessary under applicable law. Without precluding any other methods of sale, the sale of the Collateral or any portion thereof shall have been made in a commercially reasonable manner if conducted in conformity with reasonable commercial practices of creditors disposing of similar property. At any sale of the Collateral, if permitted by applicable law, the Secured Party may be the purchaser, licensee, assignee or recipient of the Collateral or any part thereof and shall be entitled, for the purpose of bidding and making settlement or payment of the purchase price for all or any portion of the Collateral sold, assigned or licensed at such sale, to use and apply any of the Secured Obligations as a credit on account of the

purchase price of the Collateral or any part thereof payable at such sale. To the extent permitted by applicable law, the Borrower waives all claims, damages and demands it may acquire against the Secured Party arising out of the exercise by it of any rights hereunder. The Borrower hereby waives and releases to the fullest extent permitted by law any right or equity of redemption with respect to the Collateral, whether before or after sale hereunder, and all rights, if any, of marshalling the Collateral and any other security for the Secured Obligations or otherwise. At any such sale, unless prohibited by applicable law, the Secured Party or any custodian may bid for and purchase all or any part of the Collateral so sold free from any such right or equity of redemption. Neither the Secured Party nor any custodian shall be liable for failure to collect or realize upon any or all of the Collateral or for any delay in so doing, nor shall it be under any obligation to take any action whatsoever with regard thereto. The Borrower agrees that it would not be commercially unreasonable for the Secured Party to dispose of the Collateral or any portion thereof by utilizing internet sites that provide for the auction of assets of the type included in the Collateral or that have the reasonable capability of doing so, or that match buyers and sellers of assets. The Secured Party shall not be obligated to clean-up or otherwise prepare the Collateral for sale.

(b) If any Event of Default shall have occurred and be continuing, all rights of the Borrower to exercise the voting and other consensual rights it would otherwise be entitled to exercise pursuant to Section 6(a), shall immediately cease, and all such rights shall thereupon become vested in the Secured Party, which shall have the sole right to exercise such voting and other consensual rights.

(c) If any Event of Default shall have occurred and be continuing, any cash held by the Secured Party as Collateral and all cash Proceeds received by the Secured Party in respect of any sale of, collection from, or other realization upon all or any part of the Collateral shall be applied in whole or in part by the Secured Party to the payment of expenses incurred by the Secured Party in connection with the foregoing or incidental to the care or safekeeping of any of the Collateral or in any way relating to the Collateral or the rights of the Secured Party hereunder, including reasonable attorneys' fees, and the balance of such proceeds shall be applied or set off against all or any part of the Secured Obligations in such order as the Secured Party shall elect. Any surplus of such cash or cash Proceeds held by the Secured Party and remaining after payment in full of all the Secured Obligations shall be paid over to the Borrower or to whomsoever may be lawfully entitled to receive such surplus. The Borrower shall remain liable for any deficiency if such cash and the cash Proceeds of any sale or other realization of the Collateral are insufficient to pay the Secured Obligations and the fees and other charges of any attorneys employed by the Secured Party to collect such deficiency.

(d) If the Secured Party shall determine to exercise its rights to sell all or any of the Collateral pursuant to this Section, the Borrower agrees that, upon request of the Secured Party, the Borrower will, at its own expense, do or cause to be done all such acts and things as may be necessary to make such sale of the Collateral or any part thereof valid and binding and in compliance with applicable law.

12. No Waiver and Cumulative Remedies. The Secured Party shall not by any act (except by a written instrument pursuant to Section 14), delay, indulgence, omission or otherwise be deemed to have waived any right or remedy hereunder or to have acquiesced in any Default or Event of Default. All rights and remedies herein provided are cumulative and are not exclusive of any rights or remedies provided by law.

13. Security Interest Absolute. The Borrower hereby waives demand, notice, protest, notice of acceptance of this Agreement, notice of loans made, credit extended, Collateral received or delivered or other action taken in reliance hereon and all other demands and notices of any description. All rights of the Secured Party and liens and security interests hereunder, and all Secured Obligations hereunder, shall be absolute and unconditional irrespective of:

(a) any illegality or lack of validity or enforceability of any Secured Obligation or any related agreement or instrument;

(b) any change in the time, place or manner of payment of, or in any other term of, the Secured Obligations, or any rescission, waiver, amendment or other modification of the Secured Promissory Note and this Agreement or any other agreement, including any increase in the Secured Obligations resulting from any extension of additional credit or otherwise;

(c) any taking, exchange, substitution, release, impairment or non- perfection of any Collateral or any other collateral, or any taking, release, impairment, amendment, waiver or other modification of any guaranty, for all or any of the Secured Obligations;

(d) any manner of sale, disposition or application of proceeds of any Collateral or any other collateral or other assets to all or part of the Secured Obligations;

(e) any default, failure or delay, willful or otherwise, in the performance of the Secured Obligations;

(f) any defense, set-off or counterclaim (other than a defense of payment or performance) that may at any time be available to, or be asserted by, the Borrower against the Secured Party; or

(g) any other circumstance (including, without limitation, any statute of limitations) or manner of administering the Loan or any existence of or reliance on any representation by the Secured Party that might vary the risk of the Borrower or otherwise operate as a defense available to, or a legal or equitable discharge of, the Borrower or any other grantor, guarantor or surety.

14. Amendments. None of the terms or provisions of this Agreement may be amended, modified, supplemented, terminated or waived, and no consent to any departure by the Borrower therefrom shall be effective unless the same shall be in writing and signed by the Secured Party and the Borrower, and then such amendment, modification, supplement, waiver or consent shall be effective only in the specific instance and for the specific purpose for which made or given.

15. Addresses For Notices. All notices and other communications provided for in this Agreement shall be in writing and shall be personally delivered to an officer or a responsible employee of the Secured Party or the Borrower, as the case may be, or sent by facsimile or other direct electronic means, charges prepaid, as follows (or as to either Party at such other address as shall be designated by such Party in a written notice to each other Party):

In the case of the Borrower:	Minglemint Solutions LLC 5361 Winter Dr. Tobyhanna, PA 18466-8126 Attention: Menachem Wagner Email: menachemwagner@gmail.com
In the case of the Secured Party:	Kala Bio, Inc. 1167 Massachusetts Avenue Arlington, MA 02476 Attention: Avi Minkowitz Email: aviminksmail@gmail.com

16. Continuing Security Interest; Further Actions. This Agreement shall create a continuing First Priority lien and security interest in the Collateral and shall (a) subject to Section 17, remain in full force and effect until payment and performance in full of the Secured Obligations, (b) be binding upon the Borrower, its successors and assigns, and (c) inure to the benefit of the Secured Party and its successors, transferees and assigns; *provided* that the Borrower may not assign or otherwise transfer any of its rights or obligations under this Agreement without the prior written consent of the Secured Party. Without limiting the generality of the foregoing clause (c), any assignee of the Secured Party's interest in any agreement or document which includes all or any of the Secured Obligations shall, upon assignment, become vested with all the benefits granted to the Secured Party herein with respect to such Secured Obligations.

17. Termination; Release. On the date on which all Secured Obligations have been paid and performed in full, the Secured Party will, at the request and sole expense of the Borrower, (a) duly assign, transfer and deliver to or at the direction of the Borrower (without recourse and without any representation or warranty) such of the Collateral as may then remain in the possession of the Secured Party, together with any monies at the time held by the Secured Party hereunder, and (b) execute and deliver to the Borrower a proper instrument or instruments acknowledging the satisfaction and termination of this Agreement.

18. Governing Law. This Agreement and any claim, controversy, dispute or cause of action (whether in contract or tort or otherwise) based upon, arising out of or relating to this Agreement and the transactions contemplated hereby and thereby shall be governed by, and construed in accordance with, the laws of the State of Pennsylvania and applicable federal laws, except to the extent perfection and the effect of perfection or non-perfection of the security interest granted hereunder, in respect of any particular Collateral, are governed by the laws of a jurisdiction other than the State of Pennsylvania.

19. WAIVER OF JURY TRIAL. EACH PARTY HERETO ACKNOWLEDGES THAT THE RIGHT TO TRIAL BY JURY IS A CONSTITUTIONAL ONE, BUT THAT IT MAY BE WAIVED. EACH PARTY HERETO, AFTER CONSULTING OR HAVING HAD THE OPPORTUNITY TO CONSULT, WITH COUNSEL OF THEIR CHOICE, KNOWINGLY, VOLUNTARILY AND INTENTIONALLY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY

JURY IN ANY LITIGATION BASED UPON OR ARISING OUT OF THIS AGREEMENT OR ANY OF THE TRANSACTIONS CONTEMPLATED HEREBY. THESE PROVISIONS SHALL NOT BE DEEMED TO HAVE BEEN MODIFIED IN ANY RESPECT OR RELINQUISHED BY ANY PARTY HERETO, EXCEPT BY A WRITTEN INSTRUMENT EXECUTED BY EACH PARTY HERETO.

20. Severability. If any provision of this Agreement is held by a court of competent jurisdiction to be illegal, invalid or unenforceable under present or future laws, such provision shall be fully severable, shall not impair or invalidate the remainder of this Agreement and the effect thereof shall be confined to the provision held to be illegal, invalid or unenforceable.

21. No Obligation. Nothing contained herein shall be construed as an obligation on the part of the Secured Party to extend or continue to extend credit to the Borrower.

22. Cumulative Rights. All rights and remedies of the Secured Party hereunder are cumulative of each other and of every other right or remedy which a secured party may otherwise have at law or in equity, and the exercise of one or more of such rights or remedies shall not prejudice or impair the concurrent or subsequent exercise of any other rights or remedies. Further, except as specifically noted as a waiver herein, no provision of this Agreement is intended by the Parties to waive any rights, benefits or protection afforded to a secured party under Pennsylvania law or other applicable law.

23. Descriptive Headings. The headings in this Agreement are for convenience only and shall in no way enlarge, limit or define the scope or meaning of the various and several provisions hereof.

24. No Contra Proferentem. This Agreement has been reviewed by each Party's professional advisors, and revised during the course of negotiations between the Parties. Each Party acknowledges that this Agreement is the product of their joint efforts, that it expresses their intentions, and that, if there is any ambiguity in any of its provisions, no rule of interpretation favoring one Party over another based on authorship will apply.

25. Counterparts. This Agreement and any amendments, waivers, consents or supplements hereto may be executed in counterparts (and by different Parties hereto in different counterparts), each of which shall constitute an original, but all taken together shall constitute a single contract. Delivery of an executed counterpart of a signature page to this Agreement by facsimile or in electronic (i.e., "pdf" or "tif") format shall be effective as delivery of a manually executed counterpart of this Agreement. This Agreement constitutes the entire contract among the Parties with respect to the subject matter hereof and supersede all previous agreements and understandings, oral or written, with respect thereto.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first above written.

MINGLEMINT SOLUTIONS LLC, as Borrower

By /s/ Menachem Wagner
Name: Menachem Wagner
Title: Manager

KALA BIO, INC., as Secured Party

By /s/ Avi Minkowitz
Name: Avi Minkowitz
Title: CEO

SCHEDULE I

COMMERCIAL TORT CLAIMS

SCHEDULE II

LOCATION OF COLLATERAL

5361 Winter Dr., Tobyhanna, PA 18466-8126

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement Nos. 333-270263, 333-281006, 333-284480 and 333-293323 on Form S-3 and Nos. 333-219403, 333-224083, 333-230206, 333-236402, 333-239426, 333-253503, 333-263948, 333-269114, 333-272834, 333-278363 and 333-284117 on Form S-8 of our report dated April 15, 2026, relating to the consolidated balance sheets of KALA BIO, Inc. as of December 31, 2025, and the related consolidated statements of operations and comprehensive loss, consolidated statements of changes in stockholders' equity, and consolidated statements of cash flows for the year ended December 31, 2025, which appear in this Annual Report on Form 10-K for the fiscal year ended December 31, 2025.

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/s/ HTL International, LLC

Houston, TX

April 15, 2026

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-270263, 333-281006, 333-284480 and 333-293323 on Form S-3 and Registration Statement Nos. 333-219403, 333-224083, 333-230206, 333-236402, 333-239426, 333-253503, 333-263948, 333-269114, 333-272834, 333-278363 and 333-284117 on Form S-8 of our report dated March 31, 2025, relating to the financial statements of KALA BIO, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
April 15, 2026

Exhibit 31.1

CERTIFICATIONS

I, Avi Minkowitz, certify that:

1. I have reviewed this Annual Report on Form 10-K of KALA BIO, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 15, 2026

/s/ Avi Minkowitz
Avi Minkowitz
Chief Executive Officer and Chief Financial Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Avi Minkowitz, certify that:

1. I have reviewed this Annual Report on Form 10-K of KALA BIO, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 15, 2026

/s/ Avi Minkowitz
Avi Minkowitz
Chief Executive Officer and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of KALA BIO, Inc. (the "Company") for the year ended December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Avi Minkowitz, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge on the date hereof:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 15, 2026

/s/ Avi Minkowitz
Avi Minkowitz
Chief Executive Officer and Chief Financial Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of KALA BIO, Inc. (the "Company") for the year ended December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Avi Minkowitz, Chief Executive Officer and Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge on the date hereof:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 15, 2026

/s/ Avi Minkowitz
Avi Minkowitz
Chief Executive Officer and Chief Financial Officer
(Principal Financial Officer)