
Kalaris
Therapeutics

2025 ANNUAL REPORT

400 Connell Drive, Suite 5500
Berkeley Heights, New Jersey 07922
(650) 249-2727

Dear Kalaris Therapeutics, Inc. Stockholders:

2025 was a transformational year for our company, and I want to thank each employee, stockholder, and external vendor partner for their contributions to and support of our mission to develop and commercialize treatments for prevalent retinal diseases with major unmet medical needs. Our lead product candidate, TH103, is a novel investigational therapy engineered by VEGF scientific pioneer Dr. Napoleone Ferrara to address the limitations of current therapies for neovascular and exudative retinal diseases. I also would like to recognize each patient who has enrolled in our clinical trial of TH103 for nAMD, as well as the clinical trial's principal investigators and their teams.

Our merger with AlloVir Inc., which closed in March 2025, has further strengthened our foundation and enabled us to continue to advance the clinical development of TH103. In the third quarter of 2025, we began to enroll patients in our Phase 1b/2 multiple ascending dose trial of TH103 in nAMD, which is designed to inform dose selection for potential Phase 3 development. We also opened our new corporate headquarters in Berkeley Heights, New Jersey and selected KBI Biopharma as our Contract Development and Manufacturing Organization for clinical and commercial drug substance manufacturing.

The year culminated with our announcement of positive initial Phase 1a single ascending dose data for TH103 in December 2025. These data indicated that TH103 was generally well tolerated and exhibited improvements on visual acuity and retinal anatomy outcomes at 1-month post-dosing. In addition, preliminary single dose pharmacokinetic data suggested increased intraocular retention, which may support a longer duration of effect. Also in December 2025, we raised gross proceeds of $50.0 million through an oversubscribed private placement of equity securities, which helped strengthen our balance sheet.

As we advance the development of TH103, we remain committed to our belief that TH103 may provide extended intraocular retention with enhanced VEGF inhibition and has potential to be a best-in class therapeutic for patients with neovascular and exudative retinal diseases. These are exciting times for Kalaris, and on behalf of myself, our Board of Directors, management and the entire Kalaris team, I want to thank you for your continued support.

Very truly yours,

Andrew Oxtoby
President and Chief Executive Officer

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 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: 001-39409

KALARIS THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**83-1971007**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
400 Connell Drive, Suite 5500 Berkeley Heights, New Jersey	**07922**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 249-2727

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	KLRS	The Nasdaq Global 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 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant was $12.6 million based on the closing price of the shares of common stock on The Nasdaq Global Market on June 30, 2025, the last business day of the registrant's most recently completed second quarter. In determining the market value of non-affiliate common stock, shares of the Registrant's common stock beneficially owned by officers, directors and affiliates have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 10, 2026, the Registrant had 22,928,303 shares of common stock, $0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A relating to the 2026 Annual Meeting of Stockholders within 120 days of the end of the registrant's fiscal year ended December 31, 2025. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein.

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On March 18, 2025, AlloVir, Inc., a Delaware corporation and our predecessor company, consummated the previously announced merger (the "Merger") pursuant to the terms of the Agreement and Plan of Merger, dated as of November 7, 2024 (the "Merger Agreement"), by and among AlloVir, Aurora Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of AlloVir ("Merger Sub") and Kalaris Tx, Inc. (formerly Kalaris Therapeutics, Inc.), a Delaware corporation ("Legacy Kalaris"). In connection with the completion of the Merger, we changed our name from "AlloVir, Inc." to "Kalaris Therapeutics, Inc.," and our business became primarily the business conducted by Legacy Kalaris. We are now a clinical stage biopharmaceutical company dedicated to the development and commercialization of treatments for prevalent retinal diseases with major unmet medical needs.

In this Annual Report, unless otherwise stated or the context otherwise requires, references to the "Company," "Kalaris," "we," "us," and "our" refer to Kalaris Therapeutics, Inc. (formerly AlloVir, Inc.) and its consolidated subsidiaries. References to "Legacy Kalaris" refer to Kalaris Tx, Inc. (formerly Kalaris Therapeutics, Inc.) and references to "AlloVir" refer to AlloVir, Inc. prior to completion of the Merger.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K ("Annual Report") contains "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act") that involve substantial risk and uncertainties.

All statements, other than statements of historical fact, contained or incorporated by reference in this Annual Report, including statements regarding the strategy, future operations, future financial position, 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. These statements are based on current expectations and beliefs of our management, as well as assumptions made by, and information currently available to, our management, and are subject to risks and uncertainties. There can be no assurance that future developments affecting us will be those that we have anticipated. Forward-looking statements include, but are not limited to, statements concerning the following:

- our future operations, including research and development activities;
- our nature, strategy and focus;
- the development and commercial potential and potential benefits of our product candidate, including expectations around intellectual property protection;
- anticipated clinical drug development activities and related timelines, including the expected timing for announcement of data and other clinical results;
- the uncertainties associated with our product candidate, as well as risks associated with the clinical development and regulatory approval of our product candidate, including potential delays in the completion of clinical trials;
- expectations regarding the therapeutic benefits, clinical potential and clinical development of TH103;
- risks related to our inability to obtain sufficient additional capital to continue to advance our product candidate;
- uncertainties in obtaining successful clinical results for our product candidate and unexpected costs that may result therefrom;
- risks related to the failure to realize any value from any product candidates being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market;
- the ability to obtain, maintain, and protect intellectual property rights related to our product candidate;
- changes in regulatory requirements and government incentives;
- our competitive position and expectations regarding developments and projections relating to our competitors and any competing therapies that are or become available;
- adverse reactions or changes to business relationships resulting from the completion of our merger (the "Merger") with AlloVir, Inc. ("AlloVir"); and
- the risk of involvement in litigation, including securities class action litigation, that could divert the attention of our management, harm our business and for which we may not have sufficient insurance coverage to cover all costs and damages.

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 this Annual Report under the heading "*Risk Factors*" in Part I, Item 1A. "Risk Factors" that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Moreover, we operate in a competitive and rapidly changing environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties, nor can management assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. You should read this Annual Report 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 are made as of the date of this Annual Report, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

RISK FACTORS SUMMARY

Our business is subject to a number or risks that, if realized, could materially affect our business, prospects, operating results and financial condition. These risks are discussed more fully in the "Risk Factors" section in Part I, Item 1A of this Annual Report. These risks include, but are not limited to, the following:

- We have incurred significant losses since our inception. We expect to continue to incur significant expenses and operating losses for the foreseeable future and may never achieve or maintain profitability.
- We have never generated revenue from product sales and may never achieve or maintain profitability.
- We are heavily dependent on the success of our lead product candidate, TH103, which will require significant clinical testing before we can seek marketing approval and potentially generate commercial sales. If TH103 does not receive marketing approval or is not successfully commercialized, or if there is significant delay in doing so, our business will be harmed.
- We will need substantial additional funding for our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- We have identified material weaknesses in our internal control over financial reporting and we may identify additional material weaknesses in the future or fail to maintain an effective system of internal control over financial reporting, which may result in material misstatements of our financial statements.
- We are early in our development efforts. If we are unable to commercialize TH103 or any product candidate we may develop or experience significant delays in doing so, our business will be materially harmed.
- The results of early-stage clinical trials and preclinical studies may not be predictive of future results. Initial success in clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials.
- If we experience delays or difficulties in the enrollment of patients in our clinical trials for TH103 or any other product candidate we develop, our receipt of necessary marketing approvals could be delayed or prevented.
- Even if TH103 or any other product candidate we may develop receives marketing approval, we may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, and the market opportunity for any of our product candidates, if approved, may be smaller than we estimate.
- We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, which may prevent or delay our ability to seek or obtain marketing approval for or commercialize our product candidates or otherwise harm our business. If we are not able to maintain these third-party relationships or if these arrangements are terminated, we may have to alter our development and commercialization plans and our business could be adversely affected.
- Manufacturing biologics is complex, and we may experience manufacturing problems that result in delays in our development or future commercialization programs.
- If we are unable to obtain and maintain sufficient intellectual property protection for our technology, our product candidates, and product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to our, and our ability to successfully develop and, if approved, commercialize our product candidates may be adversely affected.
- Even if we complete the necessary preclinical studies and clinical trials for our product candidates, the regulatory approval process is expensive, time-consuming and uncertain and we may not receive approvals for the commercialization of some or all of our product candidates in a timely manner, or at all.
- The market price of our common stock has been and is expected to continue to be volatile.
- We incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies.

- We do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and, as a result, it may be difficult for our stockholders to sell shares of our common stock.
- Our executive officers, directors and principal stockholder, Samsara BioCapital, LP ("Samsara LP"), have the ability to control or significantly influence all matters submitted to our stockholders for approval.
- Samsara LP, our principal stockholder, beneficially owns greater than 50% of our outstanding shares of capital stock, which has caused us to be deemed a "controlled company" under the rules of Nasdaq. As a result, we rely on exemptions from certain corporate governance requirements under Nasdaq listing standards afforded to a "controlled company". Such reliance may result in our stockholders not having the same protections afforded to stockholders of companies that are subject to all of the corporate governance standards of Nasdaq.

The summary risk factors described above should be read together with the text of the full risk factors below, in the section entitled "Risk Factors" in Part I, Item 1A and the other information set forth in this Annual Report, including our consolidated financial statements and the related notes, as well as in other documents that we file with the Securities and Exchange Commission. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us, or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations and future growth prospects.

PART I

Item 1. Business.

Overview

We are a clinical stage biopharmaceutical company dedicated to the development and commercialization of treatments for prevalent retinal diseases with major unmet medical needs.

We are developing TH103, a novel, clinical stage anti-vascular endothelial growth factor ("VEGF") drug, specifically engineered to achieve extended intraocular retention with enhanced VEGF inhibition in patients with exudative and/or neovascular retinal diseases. TH103 is a fully humanized recombinant fusion protein, functioning as a "decoy receptor" (a VEGF trap), leveraging salient molecular properties of the human body's native, highest affinity VEGF receptor 1. In head-to-head preclinical studies, TH103 showed more anti-VEGF activity and longer duration of activity compared to aflibercept, the current market-leading anti-VEGF agent, which also functions as a decoy receptor VEGF trap but differs from TH103 in key molecular elements. In December 2025, we reported initial data from our Phase 1a single ascending dose ("SAD") trial of TH103 in treatment-naïve neovascular Age-related Macular Degeneration ("nAMD") patients that showed TH103 was generally well tolerated and exhibited improvements on functional and anatomical outcomes at 1-month post-dosing. Preliminary single dose pharmacokinetic data from the Phase 1a trial also provide evidence that TH103 may offer extended treatment durability after a standard four-dose loading regimen.

We are investigating TH103 as a treatment for patients with nAMD, a leading cause of blindness in the United States and Europe that affects an estimated 1.6 million adults in the United States. Over the past 20 years, anti-VEGF therapeutics have revolutionized the treatment of prevalent exudative and/or neovascular retinal diseases, which represented an estimated $15 billion global branded market in 2024 based on publicly available SEC filings and publicly available regulatory documents reporting 2024 global net revenues for Eylea, Vabysmo, Lucentis and Eylea HD. While clinical trials for these drugs have shown improvements in mean visual acuity, these results often are not reproduced in real-world settings. Many patients find the treatment burden to be challenging because it requires a demanding schedule of clinic visits and years of monitoring and treatments. This onerous treatment burden can lead to a lack of adherence to the frequent visit regimen and a decline in vision after initial gains. Although newer anti-VEGF drugs and a higher-dose version of an existing drug have been approved for treatment, registrational studies for these drugs were not designed to demonstrate a reduction in treatment burden compared to existing therapies, and there remains a significant unmet need for a longer acting anti-VEGF agent.

We are currently conducting a Phase 1b/2 multiple ascending dose ("MAD"), dose-finding study evaluating four monthly loading injections of TH103 in patients with nAMD to assess the safety, tolerability and efficacy of TH103 in patients receiving multiple doses of TH103. The study is designed to help identify the optimal dose and regimen for potential Phase 3 development. We expect to share preliminary data from the ongoing Phase 1b/2 study in the first half of 2027. We also plan to expand the development of TH103 beyond nAMD into other prevalent VEGF-mediated retinal diseases such as diabetic eye disease, and retinal vein occlusion ("RVO") in the future.

TH103 was developed by Dr. Napoleone Ferrara, a Lasker Award-winning scientist known for isolating the genetic sequence for three human VEGF-A isoforms. He also was involved in determining the various isoforms' differential interactions with their related receptor tyrosine kinases, VEGF receptor 1 ("VEGFR-1") and VEGF receptor 2 ("VEGFR-2"). While at Genentech Inc., he supported the discovery and development of approved anti-VEGF therapeutics such as Lucentis ® and Avastin ® for neovascular/exudative retinal diseases and multiple cancers. Millions of patients worldwide have benefited from enhanced function or longevity because of these therapies. Dr. Ferrara is a member of our board of directors and, pursuant to a consulting agreement, provides scientific, technical and medical advice to support our research and development activities.

Our board of directors, management team and investors include co-founders, scientists and leaders and investors from companies that have played pivotal roles in developing retina therapeutics, including Macugen, the first-in-class U.S. Food and Drug Administration ("FDA")-approved anti-VEGF agent launched in ophthalmology. We believe this expertise could also be applicable to other therapeutic areas.

Background

Vascular endothelial growth factor A ("VEGF-A") is the primary signaling molecule that promotes vascular permeability and stimulates the growth of abnormal new blood vessels. This pathologic process is referred to as "neovascularization". Neovascularization plays a central role in retinal diseases characterized by exudation (fluid leakage) and/or neovascularization such as nAMD, diabetic macular edema ("DME"), diabetic retinopathy ("DR"), and RVO. Fluid leakage is visible with high resolution and retinal thickness is quantified by clinicians using optical coherence tomography ("OCT"), a non-invasive imaging modality which is the current standard to guide diagnosis and therapy for neovascular diseases. All four of the currently FDA approved and marketed

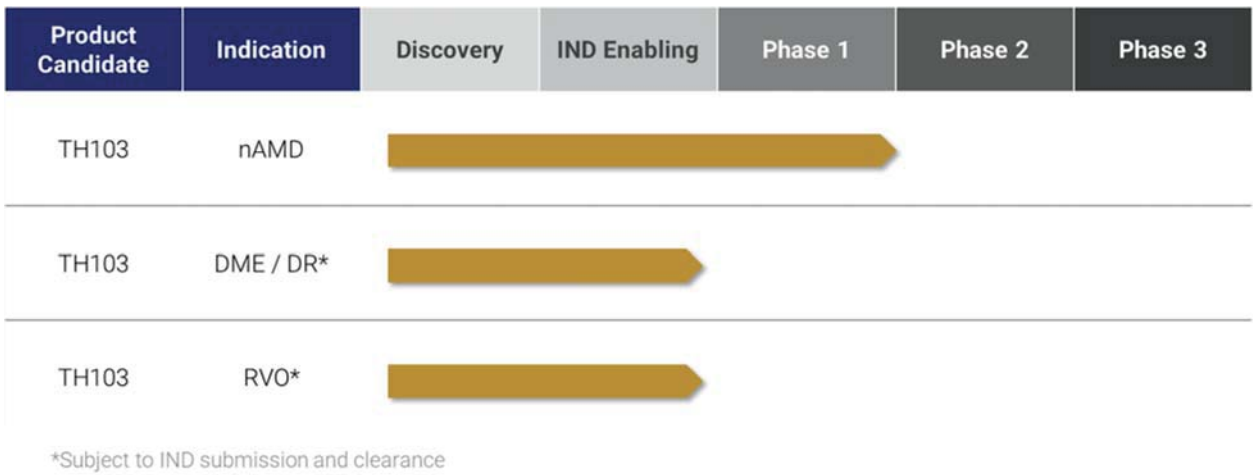
therapeutics for the treatment of these diseases, which are ranibizumab, faricimab, aflibercept, and brolucizumab and sold under the brand names Lucentis®, Vabysmo®, Eylea®, and Beovu ®, respectively, as well as the currently marketed aflibercept biosimilar Pavblu® and off-label, compounded anti-VEGF oncology drug bevacizumab, are biologic anti-VEGF agents. They bind to the ligand VEGF at the extracellular level, inhibiting its subsequent binding to the cognate receptor on the endothelial cells and its downstream signaling and biologic activity. On-label anti-VEGF agents together generated approximately $15 billion in global revenue during 2024 for VEGF-mediated retinal diseases, which estimate is based on publicly available SEC filings and publicly available regulatory documents reporting 2024 global net revenues for Eylea, Vabysmo, Lucentis and Eylea HD.

Anti-VEGF agents for the management of retinal diseases are typically administered by intravitreal injection, an in-office procedure routinely performed by a trained retina specialist and generally well-tolerated by patients. Existing therapies have made great strides in preserving or improving vision for patients with those neovascular eye diseases, but for many patients the onerous treatment burden of frequent clinic visits as often as every one to two months over many years is intractable. To ease this treatment burden on patients and their caregivers, some physicians attempt to extend the dosing interval, and some patients delay or miss appointments, together resulting in suboptimal clinical outcomes compared with those seen in registrational trials for these treatments.

Recently approved agents have attempted to address the treatment burden by including a second target or by increasing the dose of an existing drug. However, registrational trials for these agents were not designed to compare study agent treatment burden to the active control group because the trials required monthly patient visits. Therefore, any potential reduction in treatment burden provided by these agents is difficult to ascertain. Other design features in these registrational trials that presented inherent limitations to data interpretation included: treatment intervals differed between study agent and active control groups, precluding direct interval comparisons; within-trial treatment interval reassignments introduced confounding biases including selection bias and unmasking; and interval reassignments were based on unvalidated clinical criteria. A significant unmet need remains for an anti-VEGF agent that can demonstrate longer acting anti-VEGF activity and provide for extended intervals between patient visits while maintaining optimal vision outcomes.

Our Product Candidate

We are evaluating TH103 in an ongoing Phase 1b/2 clinical trial for nAMD and plan to develop TH103 for other exudative and neovascular retinal diseases. Our development pipeline for TH103 is shown in the image below.

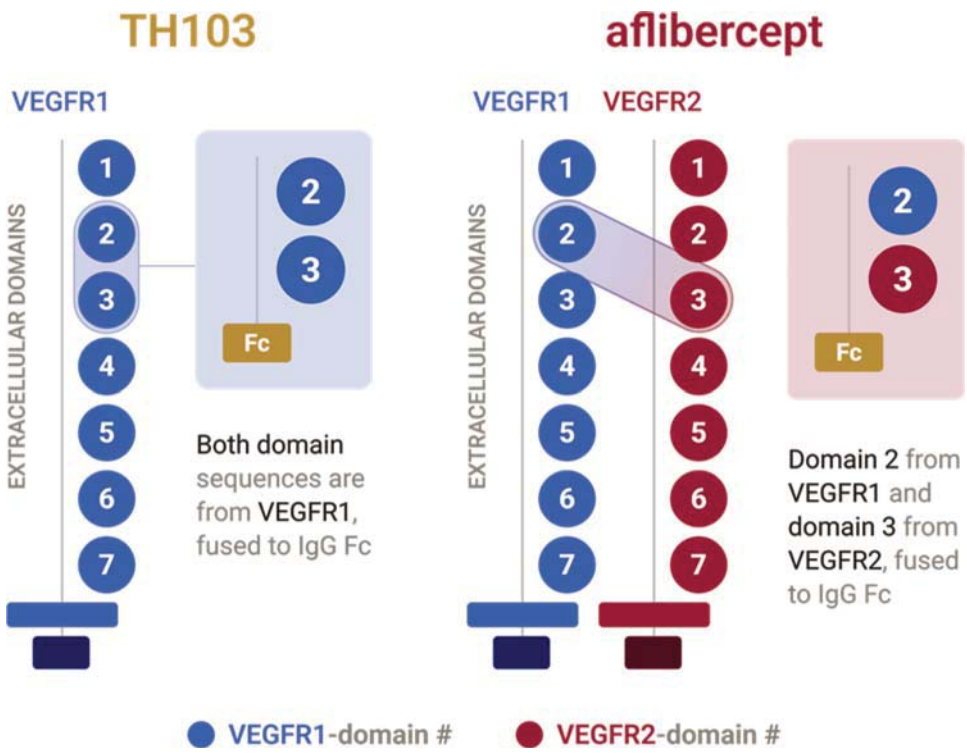


TH103 is a decoy receptor VEGF trap engineered to achieve extended intraocular retention with enhanced VEGF inhibition and has a high affinity for both VEGF and heparan sulfate proteoglycans (“HSPG”). HSPG are macromolecules that are present throughout the eye, including the vitreous and all retinal layers. We believe HSPG macromolecules act as molecular anchors for TH103, potentially extending its intraocular retention and reducing the frequency of anti-VEGF injections.

To achieve high affinity for both VEGF and HSPG, TH103 is engineered by fusing extracellular VEGF receptor binding elements, namely domain 2 (“D2”) and domain 3 (“D3”) of the native VEGFR1 with the constant region (Fc portion) of human Immunoglobulin G1 (“IgG1”), as VEGF-A binds to VEGFR1 with higher affinity than VEGFR2. D2 provides high affinity VEGF binding and D3 enhances VEGF functional affinity and also binds HSPG with high affinity. In contrast, aflibercept, the current market-leading VEGF trap, uses domain 3 from VEGF receptor 2 (“VEGFR2”), which has much lower affinity for HSPG. Therefore, TH103 is designed for extended intraocular retention with enhanced VEGF inhibition, as demonstrated in head-to-head preclinical experiments against aflibercept. The image below compares TH103 and aflibercept’s designs, where VEGFR1 extracellular elements are represented in blue and elements of VEGFR2 are represented in red.

TH103 extracellular domains 2 and 3 of native VEGFR1;

Aflibercept extracellular domains 2 and 3 derived from VEGFR1 and VEGFR2, respectively



Preclinical Studies of TH103

Dr. Ferrara and his team conducted a series of in vitro and in vivo preclinical experiments comparing TH103 to aflibercept. In nAMD, abnormal growth of choroidal blood vessels occurs in the macula, known as choroidal neovascularization ("CNV"), making it important to evaluate TH103's ability to inhibit choroidal cell proliferation in an animal model through its anti-VEGF activity. In an in vitro study of bovine choroidal endothelial cells ("BCEC"), TH103 demonstrated 100% inhibition of proliferation of BCEC at a 1 nanomolar ("nM") concentration (maximum effect, Emax), while aflibercept achieved only 80% inhibition, even at higher tested concentrations.

To determine if these findings translated in vivo, Dr. Ferrara used the standard rodent laser-induced CNV model. In this model, focused laser energy is applied to the mouse retina one day after administration of the study agent to cause thermal retinal damage which induces CNV lesion growth that is measured seven days later. When compared to aflibercept and a control at equimolar concentrations (2.5 µg), TH103 demonstrated an approximately two-fold reduction in the mean CNV area ($p<0.01$ compared with IgG control). Additionally, the reduction in mean CNV with TH103 was numerically greater than that achieved with a 10-fold higher concentration of aflibercept (25 µg).

To determine if anti-VEGF activity was sustained over a longer period, the mouse experiment was repeated with the study agents administered 14 days before the laser application. At day 7 post-laser (21 days after administration of the study agents), TH103 showed a significant reduction in mean CNV growth, whereas aflibercept showed no reduction compared to the control, suggesting that TH103 had longer lasting and increased anti-VEGF activity compared with aflibercept.

Clinical Trials of TH103

Based on the preclinical study results and favorable preclinical toxicology data, we advanced TH103 into clinical development, beginning with a Phase 1a single-ascending dose trial designed to evaluate the safety, tolerability, pharmacokinetics, and anti-VEGF activity of TH103 following one intravitreal injection in treatment-naïve nAMD patients at multiple dose levels starting at 0.5 mg. In December 2025, we announced positive initial Phase 1a data from 13 nAMD patients who completed six months of follow-up, which support the molecular hypothesis and showed strong clinical activity, including a rapid, robust response in best corrected visual acuity ("BCVA") and OCT parameters across dose levels at one month following dosing. These results included a mean 10-letter improvement in best corrected visual acuity ("BCVA"), mean 129 µm improvement in central subfield thickness ("CST"), and ~95% reduction in mean intraretinal fluid volume ("IRF") in the central subfield at one month following dosing.

TH103 was generally well tolerated in the Phase 1a trial, with no dose-limiting toxicities ("DLTs") observed, no TH103-related serious adverse events ("SAEs") observed, and no instances of TH103-related retinal vascular occlusive disease, retinal vasculitis, cataracts, or elevated intraocular pressure observed. Two subjects in the 2.5 mg cohort presented on Day 4 following dosing with transient, mild-moderate intraocular inflammation ("IOI"). While the underlying cause of the observed IOI has not been definitively established, in light of the biologic expression system used for manufacture, we evaluated host cell proteins as a potential contributing factor and implemented additional downstream processing steps that significantly reduced host cell protein levels. Following completion of a new manufacturing batch, six additional subjects were enrolled and treated with new, further purified material at the 2.5 mg dose level and there were no new instances of IOI in these six subjects (≥ 3-month follow-up).

Subsequent to our December 2025 initial data disclosure, we observed a case of moderate IOI, which resolved, in one subject in the Phase 1a trial who received a single administration of 5.0 mg of TH103 with the new material. Further analysis of that manufacturing batch, utilizing advanced analytical methods, quantified remaining host cell protein levels and identified specific constituent sub-host cell proteins. These findings indicated that some sub-host cell proteins had been reduced by a lower proportion than the overall host cell protein level in the manufacturing batch. Based on these results, we have continued to advance additional process refinements in our manufacturing process to further reduce the level of host cell protein in our drug product, and we plan to use additional purification manufacturing processes in preparing the drug product for our ongoing and planned clinical trials. Moreover, we believe we have identified specific process modifications that may eliminate all remaining host cell protein subtypes to below levels of detection and aim to utilize these modifications in future batches of our drug product.

We believe the initial data from our Phase 1a clinical trial provides preliminary evidence that TH103 may offer extended treatment durability. In addition, in pharmacokinetic ("PK") analysis, dose adjusted mean Cmax plasma levels of TH103 were 27 to 51-fold lower compared to current leading anti-VEGF agents on a dose-adjusted basis, consistent with greater intraocular retention and reduced systemic exposure. This pharmacokinetic profile aligns with the molecule's engineered properties and preclinical data demonstrating prolonged intraocular residence time. Furthermore, following only a single TH103 injection, 31% of patients received no additional anti-VEGF treatment during the entire six-month follow-up period. These single-dose findings suggest the potential for extended durability outcomes after a standard four-dose loading regimen.

Based on these positive initial Phase 1a data, we are currently conducting a Phase 1b/2, MAD, dose-finding study to help assess the safety and efficacy of repeat TH103 administration. The trial is designed to enroll and treat approximately 60 to 80 patients with nAMD who receive four initial monthly loading doses of TH103 with the goal of identifying the optimal dose and regimen for potential Phase 3 development. The range of doses being evaluated in our Phase 1b/2 MAD trial is informed by the SAD data from our Phase 1a trial and began with 0.5 mg. Study assessments in the Phase 1/2 MAD trial are expected to include safety and preliminary efficacy with a primary timepoint for analysis at one-month following the loading phase. Patients will then be followed in an extension phase for up to six additional months. During the extension phase, patients will exit the study after disease activity warrants retreatment.

We expect to share preliminary data from the ongoing Phase 1b/2 study in the first half of 2027. Assuming successful completion of the ongoing Phase 1b/2 clinical trial of TH103, and subject to favorable results from such trial and discussions with regulators, we intend to initiate Phase 3 clinical trials of TH103 for nAMD by year-end 2027. Positive data in nAMD could also be leveraged to expand the development of TH103 beyond nAMD into other prevalent VEGF-driven retinal diseases, including diabetic eye disease and RVO, with the goal of delivering longer-lasting therapeutic benefit and improved outcomes for patients worldwide.

Our Board and Management Team

Our management team and board of directors has deep experience developing and commercializing a number of product candidates, including retina therapeutics, and has been involved at other companies in the development of a number of FDA approved anti-VEGF therapies. We are supported by institutional investors with a track record in funding successful retina therapeutic development to FDA approval.

Our management team consists of executives with extensive pharmaceutical industry experience, including specific experience in anti-VEGF therapeutic development. Our Chief Executive Officer is Andrew Oxtoby, who has over two decades of experience in the pharmaceutical and biotech industries and has held a variety of leadership roles across multiple therapeutic areas during his career. Prior to joining Legacy Kalaris in March 2024, Mr. Oxtoby was the Chief Commercial Officer of Chinook Therapeutics, Inc. and has also held multiple executive leadership roles at Aimmune Therapeutics, Inc. and Eli Lilly and Company ("Eli Lilly"). Mr. Oxtoby also serves on our board of directors.

Our Chief Medical Officer, Matthew Feinsod, M.D., is a board-certified ophthalmologist who has played key roles in a number of private and public ophthalmology biotech companies over the past 20 years, including Eyetech Pharmaceuticals Inc. ("Eyetech") and Imagen Biotech Inc., from early-stage candidate development through product commercialization involving therapeutics targeting the retina. Dr. Feinsod also served as a medical officer in the ophthalmology division of the FDA.

Our Chief Financial Officer, Matthew Gall, MBA, most recently served as Chief Financial Officer of iTeos Therapeutics, Inc. ("iTeos"), where he was responsible for business development and overall financial operations and strategy. Prior to iTeos, Mr. Gall held positions of increasing responsibility at Sarepta Therapeutics, Inc., Celgene Corporation, and Gilead Sciences across the finance and business development functions.

The Chair of our board of directors is David Hallal, who was previously the Chairman of the board of directors at Allovir. David Hallal currently serves as Chief Executive Officer and Chairman of the Board at Scholar Rock, Inc. and Executive Chairman of ElevateBio LLC ("ElevateBio") and previously served as Chief Executive Officer of ElevateBio. Prior to ElevateBio, Mr. Hallal spent more than a decade at Alexion Pharmaceuticals, Inc. as Chief Executive Officer, Chief Operating Officer, and Chief Commercial Officer, and has also held commercial leadership positions at biopharmaceutical companies where he launched and expanded the adoption of numerous first-in-class products, amongst others, as the VP of Sales at Eyetech where he helped launch the first ever anti-VEGF therapeutic for retinal diseases.

Also on our board of directors is our scientific founder, Napoleone Ferrara, M.D., distinguished Professor of Pathology at the University of California San Diego and Lasker Award winner who co-discovered and isolated VEGF-A and its isoforms, along with its receptors, and while at Genentech, Inc. ("Genentech"), was an inventor of both Avastin® and Lucentis®.

Anthony Adamis, M.D., the former head of ophthalmology, immunology and infectious disease at Genentech, and a co-founder of Eyetech and Eyebiotech Limited (acquired by Merck & Co., Inc. ("Merck")), is also on our board of directors. Dr. Adamis was a pioneer in demonstrating the role of anti-VEGF in mediating ischemic and exudative diseases in the eye while at Harvard Medical School. At Eyetech, he led the team that developed the first anti-VEGF in ophthalmology, Macugen®, and, while at Genentech, he supervised the development of Lucentis®, Vabysmo® and Susvimo®.

Also on our board of directors are Srinivas Akkaraju, M.D., PhD, and Mike Dybbs, PhD, who are partners at Samsara LP. Dr. Akkaraju is the managing general partner at Samsara LP, and has extensive investing experience in ophthalmology biotechnology companies, including Eyetech, the company behind the development and launch of Macugen, the first anti-VEGF agent to be approved for the treatment of nAMD in 2004. Dr. Akkaraju currently serves on the board of directors of vTv Therapeutics, Inc., Scholar Rock Holding Corporation, Mineralys Therapeutics, Inc., Incentiva SA, and Alumis Inc., and he previously served as director of Chinook Therapeutics, Inc., Syros Pharmaceuticals, Inc., Intercept Pharmaceuticals, Inc., Jiya Acquisition Corp., Seattle Genetics, Inc. (now, Seagen Inc.), and Principia Biopharma, Inc. Dr. Dybbs is a partner at Samsara LP where he has worked since March 2017. Dr. Dybbs has extensive experience in the life sciences industry and currently serves on the board of directors of two publicly traded biotechnology companies, Sutro Biopharma, Inc. and Nkarta, Inc.

Also on our board of directors is Morana Jovan-Embiricos, PhD, who previously served as a member of the board of directors of AlloVir. Ms. Jovan-Embiricos is Founder and Managing Partner at F2 Ventures and has extensive experience in both the public and private biotechnology equity markets through a series of funds launched at F2 since 2003. She also serves on the board of directors of Orna Therapeutics, Inc. and ElevateBio.

Also on our board of directors is Leone Patterson, MBA, who most recently served as Executive Vice President and Chief Business and Financial Officer of Zymeworks Inc. Ms. Patterson has more than 20 years of public company biotech experience and has managed significant growth within international commercial companies working across areas including strategy, finance, operations and governance, and also currently serves on the board of directors of Nkarta, Inc.

Our Strategy

Our objective is to become a leading biopharmaceutical company dedicated to the development and commercialization of treatments for prevalent retinal diseases with major unmet medical needs.

Key components of our strategy to achieve this objective include:

- *Advance the clinical development of TH103 as a potential treatment for nAMD.*

Our product candidate TH103 is being evaluated in an ongoing Phase 1b/2 clinical trial for patients with nAMD. TH103 is a fully humanized, recombinant fusion protein specifically engineered to achieve extended intraocular retention with enhanced VEGF inhibition in patients with neovascular and/or exudative retinal diseases. Our Phase 1b/2 trial is a MAD, dose-finding study intended to assess safety and efficacy in patients with nAMD receiving four initial monthly loading doses of TH103, and to help identify the optimal dose and regimen for potential Phase 3 development. We expect to share preliminary data from the ongoing Phase 1b/2 study in the first half of 2027. Assuming successful completion of the ongoing Phase 1b/2 clinical trial of TH103, and subject to the favorable results from such trial and discussions with regulators, we intend to initiate Phase 3 clinical trials of TH103 for nAMD by year-end 2027.

- *Pursue the development of TH103 as a treatment for other neovascular and/or exudative retinal diseases.*

We are also evaluating the potential development of TH103 to treat additional VEGF-mediated neovascular diseases of the retina including DME, DR, RVO and retinopathy of prematurity ("ROP"). DME and RVO together impact an estimated 40 million people worldwide and patients with DME/DR and RVO face similar treatment challenges as nAMD patients, particularly the treatment burden of frequent clinic visits incurred by aged patients. We believe that TH103 has the potential to significantly reduce this burden and provide meaningful benefits to patients with DME/DR and RVO. We may also evaluate TH103 to treat ROP. ROP is a rare retinal disorder affecting an estimated 14,000 to 16,000 newborns in the United States each year.

- *Commercialize TH103, if approved, and potentially expand into other ophthalmic therapeutics.*

We have retained worldwide development and commercialization rights to TH103. We intend to commercialize TH103, if approved, with our own specialty salesforce. We envision expanded use of our commercial organization to distribute additional retinal and/or ophthalmologic therapeutics that we may market through future discovery, licensing, partnership or acquisition activity.

Our executive team and board of directors have deep expertise in drug development and commercialization, particularly related to ophthalmology and retina therapeutics, and have collectively contributed to the discovery, development and commercialization of multiple approved products across a number of therapeutic areas, including ophthalmology.

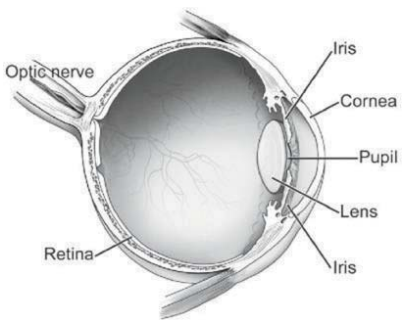
- *Strengthen our development pipeline through discovery, licensing, and/or acquisition activities.*

We intend to opportunistically complement our ongoing development programs by accessing additional product candidates and technologies through internal discovery and development, in-licensing, strategic collaborations and/or acquisitions. We believe that the significant ophthalmic drug development expertise of our management team and board of directors provides us with a differentiated set of capabilities to identify, access and advance product candidates for diseases of the eye and potentially other therapeutic areas.

The Human Retina

Light enters the human eye and is refracted by the cornea and lens before penetrating through the vitreous humor to the neurosensory retina which lines the posterior of the eye. The central region of the retina is the macula, and the central 1mm of the macula is called the fovea which is responsible for color and high acuity central vision. The peripheral retina is responsible for the peripheral field of vision. The retina contains photoreceptors, which are specialized light-sensing cells called rods and cones; these cells convert light into signals that are transmitted to the visual cortex of the brain through the millions of nerve fibers which make up the optic nerve.

The composition of the human eye



Source: National Eye Institute Media Library

Diseases of the Retina

Based on available third-party epidemiologic studies, we expect that the prevalence of retinal diseases, such as age-related macular degeneration ("AMD"), DME/DR and RVO, which are primarily age-related, will continue to grow and that there remains a significant unmet need for these indications despite the availability of approved treatment options. More than three million people in the United States are currently impacted by significant visual impairment or blindness resulting from these retinal diseases, and the branded market for therapeutics used to treat them was estimated, based on publicly available SEC filings and publicly available regulatory documents reporting 2024 global net revenues for Eylea, Vabysmo, Lucentis and Eylea HD, to be $15 billion worldwide in 2024.

Neovascular Age-Related Macular Degeneration

AMD is an eye disease that results in visual distortion and loss of central vision. It generally affects people over 50 years of age and is a leading cause of blindness among older adults. In the United States, approximately 20 million people have AMD, including more than 35% of adults over 80 years of age, and an estimated 1.6 million adults had nAMD in 2024. Worldwide, an estimated 200 million people have AMD, with the patient population expected to increase to 300 million by 2040, largely due to an aging population.

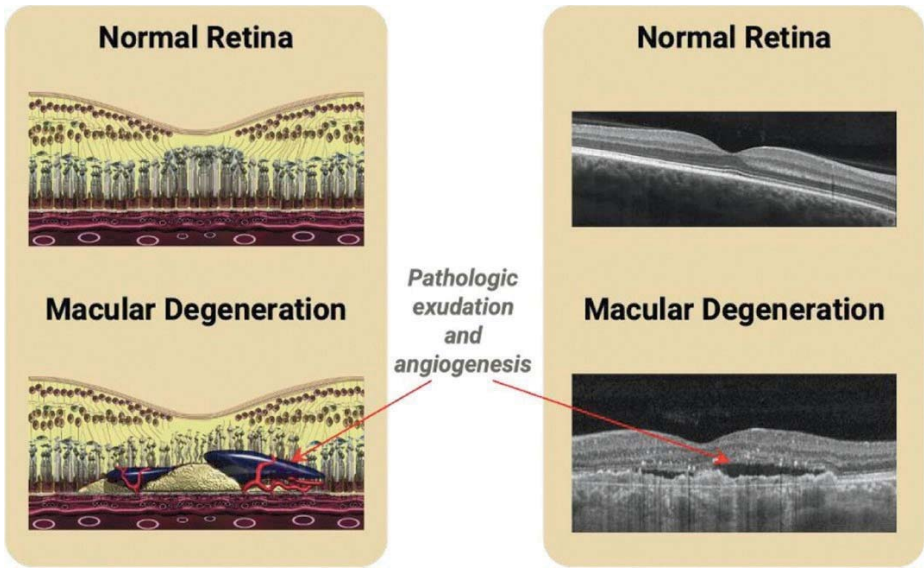
Atrophic, or dry, AMD ("dAMD") accounts for up to 90% of all AMD cases and is usually a slowly progressive condition that involves the accumulation of deposits, known as drusen, which causes a thickening of Bruch's membrane that disrupts the cytoarchitecture of the overlying retinal pigmentation epithelium ("RPE"). This disruption, coupled with oxidative stress and inflammation, is thought to result in compromised RPE function and eventually cell death or dysfunction of the RPE and overlying neurosensory retina. Symptoms of dAMD, which may be unrecognizable to patients in the earlier stages of the disease, advance slowly over several years. Late-stage dAMD, also referred to as geographic atrophy ("GA"), may affect as many as 2 million people in the United States.

nAMD is a severe, advanced form of the disease caused by the aberrant growth of abnormal new blood vessels, known as neovascularization, in the highly vascularized choroid layer under the macula. These aberrant and abnormal vessels leak fluid and bleed into the macula, leading to acute or subacute vision loss, associated retinal cell dysfunction and death, and scar tissue, or "fibrosis". While nAMD makes up only 10% to 15% of all AMD patients, it is responsible for approximately 90% of AMD-related blindness. Left untreated, loss of central vision is irreversible, and patients may be unable to read, drive or perform other activities of daily living, contributing to a significant decline in quality of life. Patients with dAMD at any stage can progress to nAMD.

VEGF and its role in the pathology of nAMD

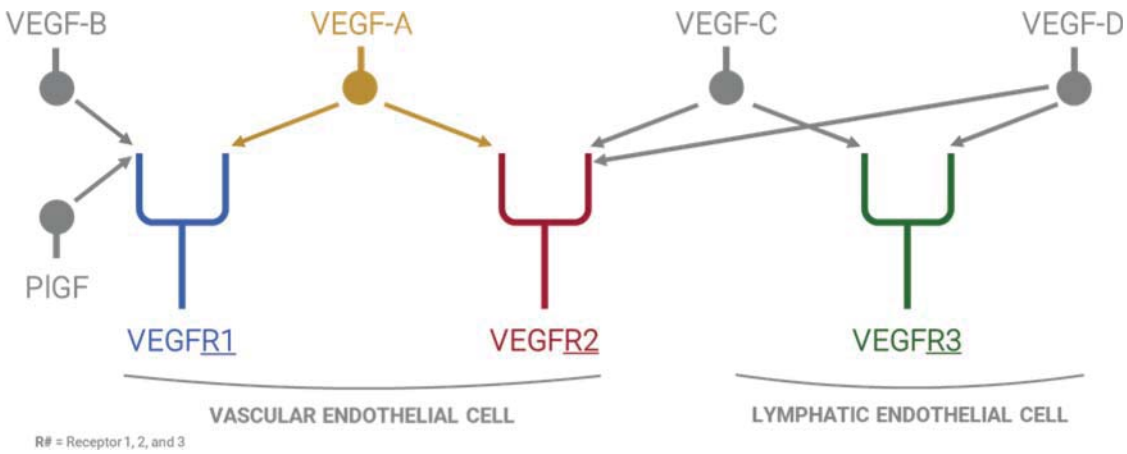
VEGF is the core signaling protein involved in the development of the abnormal growth of blood vessels under the retina in patients with nAMD. Binding of VEGF to its cognate receptors on the endothelial cell surface results in the activation of signaling pathways, which initiates endothelial cell division, migration and proliferation. VEGF also promotes vascular permeability. As such, upregulation of VEGF is implicated in retinal diseases characterized by abnormal vessel growth (neovascularization) and leakage (exudation), such as nAMD, diabetic eye disease and RVO. Pharmaceutical inhibition of VEGF has been proven to result in significant therapeutic benefit in patients with nAMD and for approximately 20 years anti-VEGF agents have been the standard of care for patients with nAMD.

VEGF-A is the primary mediator and the key target for pathologic angiogenesis and exudation (permeability) in retinal disease



In humans, the VEGF superfamily includes five related members, VEGF-A, VEGF-B, VEGF-C, VEGF-D and placental growth factor ("PlGF"). Members of the VEGF superfamily bind to specific receptor tyrosine kinases, VEGFRs, which includes VEGFR1, VEGFR2 and VEGFR3. VEGF-A and VEGF-B both bind to VEGFR1. VEGF-A also binds to VEGFR2. VEGF-C and VEGF-D interact primarily with VEGFR3. VEGFR1 and VEGFR2 are expressed predominantly on vascular endothelial cells, while VEGFR3 is expressed primarily on lymphatic endothelial cells. VEGFR2 is a key signaling receptor for VEGF-A and mediates cellular responses to VEGF-A. VEGFR1, which has a ten-fold higher binding affinity for VEGF-A compared to VEGFR2, triggers endothelial cell and monocyte migration, and is also responsible for the modulation of VEGFR2 signaling activity. The interactions between the different VEGF superfamily members and their corresponding receptors are illustrated in the simplified schematic presented below.

VEGF-A is the growth factor primarily involved in retinal neovascularization and exudation



Similar to other VEGFRs, the extracellular portion of VEGFR1 consists of seven immunoglobulin-like domains. D2 on VEGFR1 is the primary binding element for VEGF and is responsible for ligand specificity while D3 plays an important role in binding affinity and stability. Moreover, D3 of VEGFR1 provides a molecular interface which aligns more closely with VEGF than the corresponding domain on VEGFR2, a distinction which might contribute to its higher VEGF binding functional affinity. In addition, D3 on VEGFR1, though not the corresponding D3 of VEGFR2, is a prominent heparin binding site because of an aggregation of basic charged amino acids. As a result, D3 of VEGFR1 binds to HSPG molecules, which are located on the cell surface or extracellular matrix of various tissues throughout the body including the vitreous and retinal layers.

Currently Approved Therapeutics to Treat nAMD

We are aware of six reference biologic (non-biosimilar) drugs that the FDA has approved for the treatment of exudative and neovascular retinal diseases to date, all of which are designed to inhibit the activity of VEGF. The approved reference biologic drugs include: pegaptanib, a pegylated aptamer under the brand name Macugen®; ranibizumab, a VEGF-targeted antibody fragment approved in 2006 and marketed by F. Hoffmann-La Roche AG ("Roche") as Lucentis®; aflibercept, a fusion protein consisting of extracellular binding domains of VEGFR1 and VEGFR2, initially approved in 2011 and approved at a higher dose in 2023, is commercialized by Regeneron Pharmaceuticals, Inc. under the brand names Eylea® and EyleaHD®; brolucizumab, a single chain antibody fragment approved in 2019 and sold by Novartis AG under the brand name Beovu®; and faricimab, a bispecific antibody targeting both VEGF and angiopoietin-2, approved in 2022 and sold by Roche under the brand name Vabysmo®. In addition, bevacizumab, a full-length monoclonal antibody targeting VEGF sold by Roche under the brand name Avastin® that was initially approved in 2004 to treat colon cancer and subsequently approved to treat multiple additional cancers, is used off-label to treat exudative and neovascular retina diseases. Commercial distribution of pegaptinib has been discontinued in the United States and brolucizumab is used infrequently due to safety concerns. The remaining four approved reference biologic anti-VEGF drugs for the treatment of nAMD generated, based on publicly available SEC filings and publicly available regulatory documents reporting 2024 global net revenues for Eylea, Vabysmo, Lucentis and Eylea HD, an estimated worldwide revenue of $15 billion in 2024 with aflibercept alone generating worldwide sales of approximately $9 billion. In addition to these figures, off-label use of bevacizumab is estimated to represent approximately 25% of the overall total of intravitreal injections for the treatment of neovascular and/or exudative retinal diseases. Lastly, biosimilars for both ranibizumab and aflibercept have more recently entered the U.S. market.

Because nAMD is a heterogenous disease, patients exhibit a range of baseline presentations and responses to anti-VEGF therapy. For example, patients may present at different disease stages (acute, sub-acute and chronic), severities and neovascular types based on lesion location and features. The wide variability of presenting baseline functional and anatomical variables such as visual acuity, lesion characteristics and retinal integrity often limit the ability to predict treatment response.

The recent FDA approvals of anti-VEGF agents faricimab and high-dose (8mg) aflibercept involved registrational clinical trials that studied longer treatment intervals. The FDA labels for these agents describe the range of dosing intervals that were tested and reached non-inferiority with active controls. However, these clinical trials were not designed to provide evidence of superior, clinically meaningful durability or reduction in patient burden compared with already existing agents for several reasons: (1) asymmetric dosing intervals between treatment and active controls precluded direct comparisons; (2) mid-study treatment interval reassignments introduced multiple confounding biases that limit data interpretability; and (3) patients were required to return for monthly monitoring visits in order to identify which patients needed supplemental injections, thereby precluding any assessment of reduced patient burden. Compounding these issues, the criteria upon which supplemental injection decisions were made (i.e., mid-study interval reassignments) were not validated, may not have reflected clinical practice, and varied between trials. Despite the availability of newer treatment options, we believe a significant unmet need remains for an anti-VEGF therapeutic with more durable efficacy to allow for an extended interval of time between visits for a higher percentage of patients.

A description of the reference biologic therapeutics currently used to treat nAMD and the FDA-approved range of dosing frequencies are detailed in the table below.

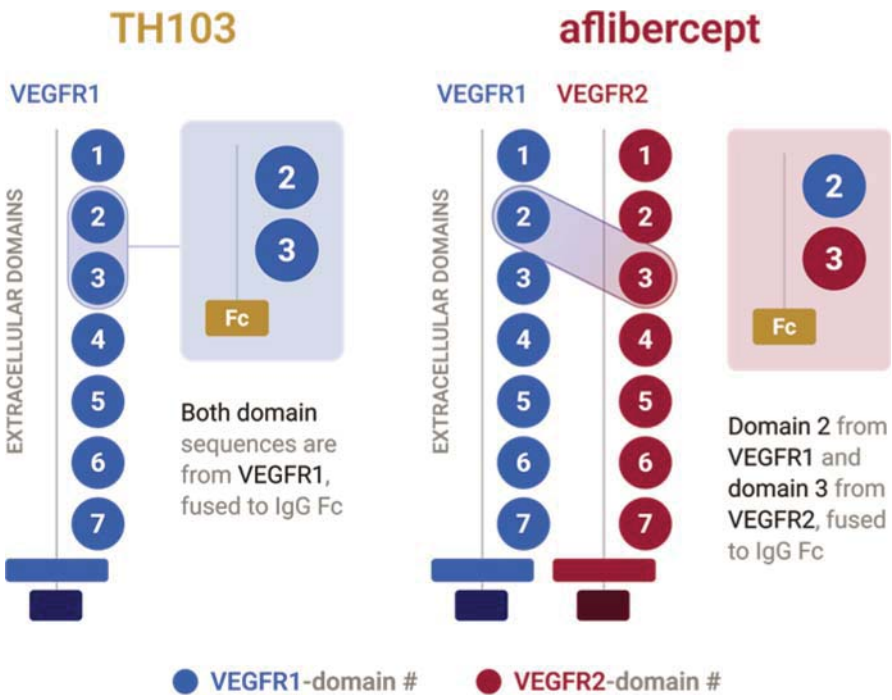
Therapeutic	• ranibizumab	• aflibercept (2 mg)	• faricimab	• aflibercept (8 mg)	• bevacizumab [1]
Brand name	• Lucentis	• Eylea	• Vabysmo	• Eylea HD	• Avastin
Molecular design	• antibody fragment targeting VEGF-A	• Protein fusion VEGF-A/B, PlGF trap	• Bi-specific antibody targeting VEGF-A and angiopoietin-2	• Protein fusion VEGF-A/B, PlGF trap	• full length antibody targeting VEGF-A
FDA-approved dosing frequency[2]	• every 4 weeks	• every 8 weeks	• every 4, 8, 12 or 16 weeks[3]	• every 8 to 16 weeks [3]	
	currently marketed FDA approved therapeutics for nAMD				

(1) Bevacizumab is not FDA-approved for the treatment of nAMD but is used off-label.
(2) Recommended dosing frequency after completion of initial series of induction doses. Treatment intervals based on FDA approved prescribing information.
(3) Dosing schedule as determined by OCT and visual acuity examinations. Faricimab may require dosing every 4 weeks in some patients.

Our Solution: TH103

Our product candidate, TH103, is an intravitreally administered, fully humanized, recombinant anti-VEGF fusion protein that incorporates novel molecular modifications specifically engineered to achieve extended intraocular retention with enhanced VEGF inhibition. Preclinical study results suggest that TH103 may extend treatment durability and reduce treatment burden. Similar to the chimeric fusion protein and leading branded agent, aflibercept, TH103 fuses two VEGF extracellular binding domains to the Fc portion of an IgG1 molecule and is expected to be able to bind VEGF-A, VEGF-B and PlGF. However, in contrast to aflibercept, which utilizes the D2 binding domain of VEGFR1 and the D3 binding domain of VEGFR2, TH103 contains D2 and D3 binding domains of only VEGFR1. We believe this configuration of domains, intended to mimic their orientation on the most potent VEGF binding receptor, VEGFR1, as well as binding to HSPG, which is present in all retinal layers and may confer improved VEGF inhibition and prolonged duration of action for TH103. A comparison of the molecular design of TH103 and aflibercept is presented in the image below.

D2 and D3 extracellular binding domains of VEGFR1 for TH103 and Aflibercept

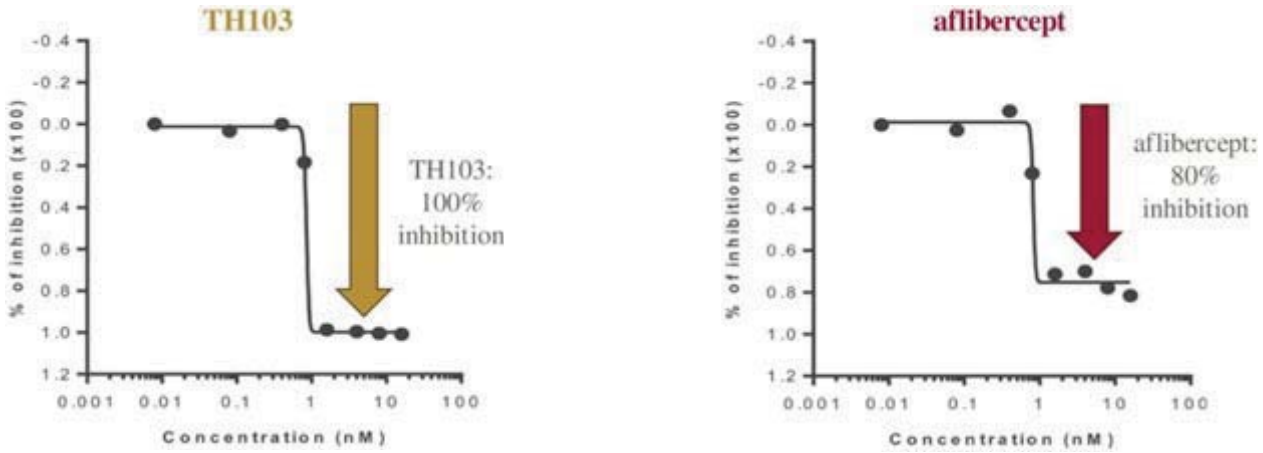


Given its high affinity for HSPG that is present in all retinal layers, inclusion of VEGFR1 D3 has been shown in preclinical experiments to increase TH103 residence time in ocular tissues, such as the vitreous and retina. In contrast, aflibercept contains VEGFR2 D3 for its lower tissue sequestration which improves its pharmacokinetic profile in systemic indications, such as cancer, where it is marketed as Zaltrap® (FDA approved to treat metastatic colorectal cancer) but may limit retinal tissue sequestration.

Preclinical Evaluation of TH103 compared to aflibercept

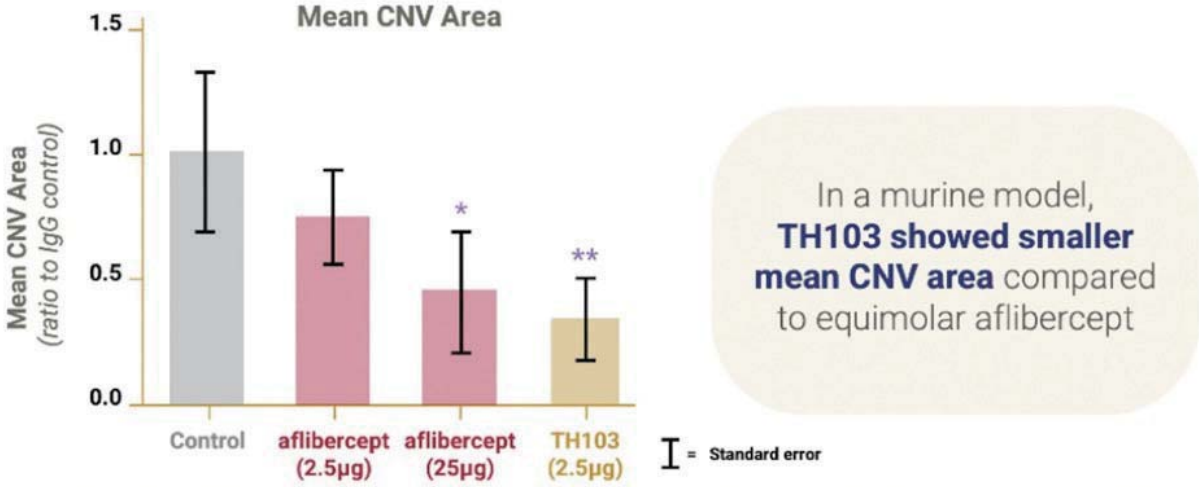
In both in vitro and in vivo preclinical studies comparing the anti-VEGF activity of TH103 and aflibercept, TH103 demonstrated longer lasting and increased anti-VEGF activity. In an in vitro study designed to compare their inhibitory effects, TH103 demonstrated 100% inhibition of VEGF-induced proliferation of bovine choroidal endothelial cells (“BCEC”) at approximately 1 nM, the half-maximal inhibitory concentration of TH103. In contrast, aflibercept only inhibited up to 80% of BCEC proliferation at 1 nM and at all higher concentrations tested. These results are illustrated in the images below.

TH103 demonstrated greater inhibition of VEGF-induced BCEC proliferation as compared to aflibercept.



To translate these data in vivo, a rodent laser-induced choroidal neovascularization ('CNV") experiment was conducted, which is commonly used in evaluating investigational therapies for the treatment of nAMD during preclinical development. TH103 or aflibercept were administered by intravitreal injection to the mouse eye one day prior to laser-induced CNV growth, and CNV area was measured seven days later. As is shown in the image below, in the preclinical study, TH103 demonstrated an approximately two-fold reduction in mean CNV area compared with equimolar concentrations of aflibercept. Moreover, mean CNV reduction achieved with 2.5 µg TH103 compared favorably even with a 10-fold higher concentration of aflibercept (25 µg).

TH103 demonstrated reduced mean CNV area as compared to aflibercept

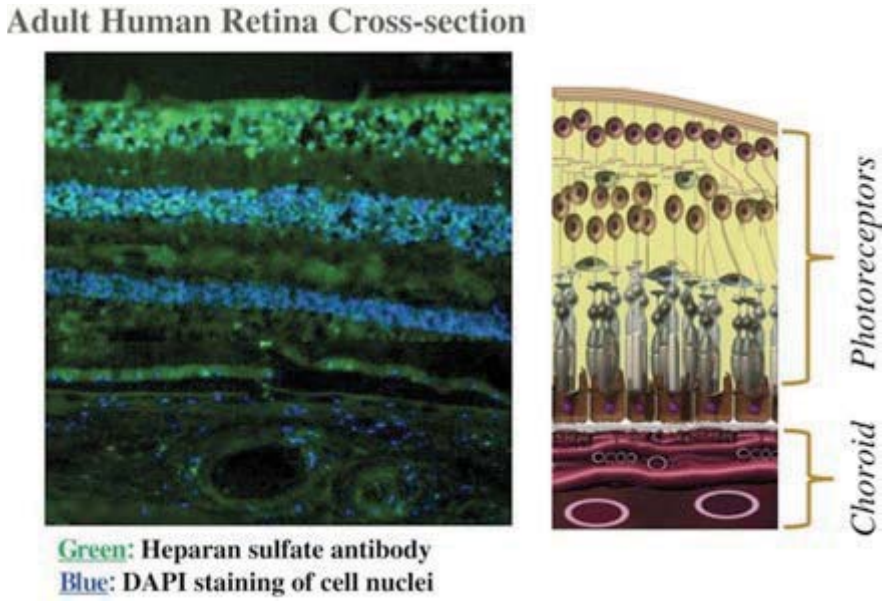


*Note: Data are based on three independent experiments with at least five mice per group; Asterisks denote significant differences (Student's t test) compared to the appropriate IgG control groups (**P < 0.01, *P < 0.05)*

TH103 exhibited high affinity HSPG binding D3 for increased intraocular retention

Based on data we have generated, inclusion of VEGFR1 D3 conferred an approximately 780-fold higher affinity than aflibercept for HSPG, as measured by the equilibrium dissociation constant ("KD"). As depicted in the cross-sectional image of the retina presented below, HSPG are found in all layers of the retina and choroid, including the internal limiting membrane, nerve fiber layer, ganglion cell layer, neurosensory retina, RPE and Bruch's membrane. Importantly in AMD, published third-party preclinical animal data indicated that expression of HSPG is increased and parallels the area of CNV lesions. We believe the high affinity of TH103 for HSPG may prolong retinal tissue sequestration and prolonged anti-VEGF activity.

Heparan sulfate is present across all retinal layers and choroid.

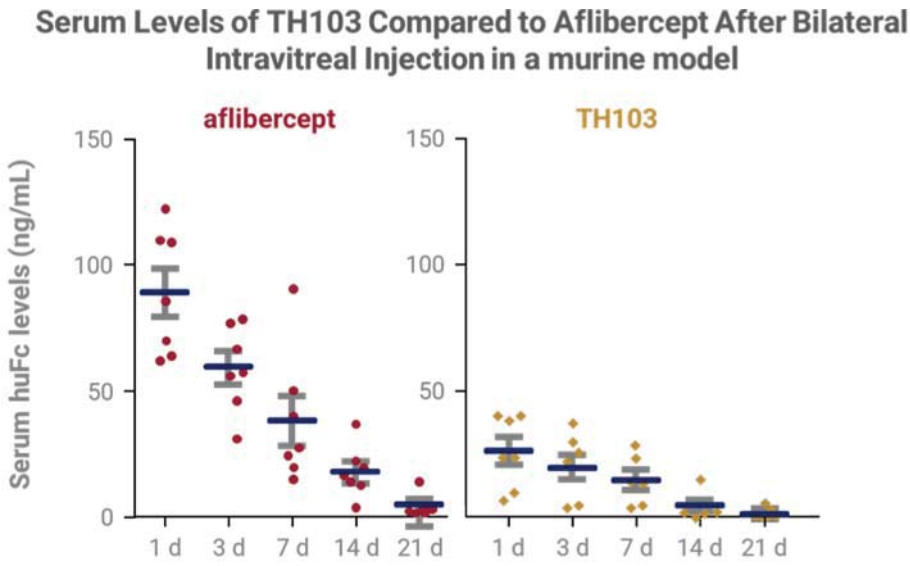


An in vivo rabbit study compared retinal retention of TH103 to aflibercept. As shown in the images below, immunofluorescent staining conducted 14 days after intravitreal administration demonstrated that TH103 had greater retinal retention compared to aflibercept, with darker staining indicating higher levels of TH103 in the retina.

14 days post-injection, TH103 showed darker immunofluorescent staining compared with aflibercept in rabbit retina cross section

The sustained retina retention of TH103 following intravitreal injection is also supported by the pharmacokinetic data shown below. Serum levels of aflibercept and TH103 were measured in mice at 1, 3, 7, 14, and 21 days after intravitreal injection. Each molecule was injected in both eyes in equimolar amounts (2.4 µg). As illustrated in the image below, aflibercept administration resulted in higher serum levels as compared to TH103 at all time points throughout the experiment, suggesting TH103 was retained in the eye for longer than the aflibercept. Overall systemic exposure ("AUC") was lower for TH103 as compared to aflibercept.

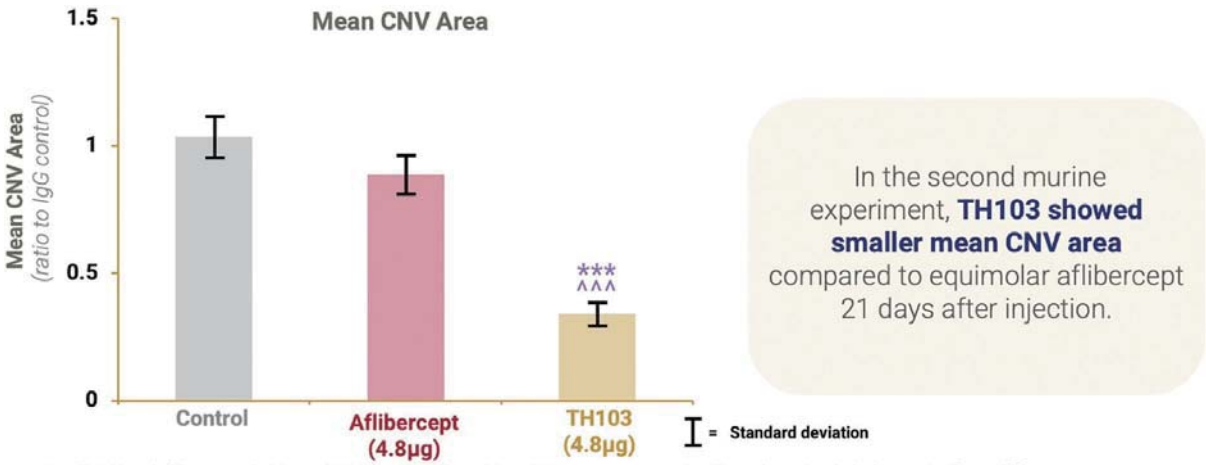
TH103 demonstrated lower serum levels compared to aflibercept following IVT administration in a preclinical in vivo experiment



Serum levels of aflibercept and TH103 in mice at different time points after intravitreal injection. Each molecule was injected in both eyes in equimolar amounts (2.4 µg). After 1, 3, 7, 14, and 21 d, peripheral blood was collected from the tail vein. Human Fc levels were measured by ELISA. Values shown are means ± SEM. n = 8 per point.

To test the hypothesis that TH103 would maintain bioactivity longer than aflibercept, the mouse laser-induced CNV experiment was repeated, administering the doses 14 days (instead of one day) prior to the laser treatment. This allowed for the assessment of treatment effects 21 days post-injection. As shown in the bar graph below, 21 days after administration TH103 demonstrated a statistically significant, greater mean reduction in CNV area ($p<0.001$ compared to aflibercept or control) at the same equimolar concentrations. We believe that these results are indicative of TH103's significantly enhanced binding characteristics in the retina resulting in longer-acting anti-VEGF activity.

TH103 demonstrated increased duration of action in reducing mean CNV area after administration at Day -14 in a preclinical study head-to-head against the market leading agent



*Note: TH103 and aflibercept administered 14 days prior to laser injury; CNV measurement at Day 7 post-laser; Symbols denote significant differences (Student's t test) between TH103 and control (***P < 0.001) and between TH103 and aflibercept (^^^P < 0.001)*

Preclinical safety evaluations

TH103 has undergone single-dose and repeat-dose preclinical toxicity studies in Dutch Belted rabbits and Göttingen minipigs in support of IND clearance and preparation for a single ascending dose, first-in-human clinical trial. Anti-drug antibody ("ADA") generation was observed in most animals and was not unexpected following intravitreal administration of humanized biologic agents in animals due to cross-species reactivity. This phenomenon has also been reported in preclinical toxicology studies of other anti-VEGF biologic therapies.

Single Dose Toxicology Studies

In both the rabbit and minipig studies, there were no observed TH103-related effects on body weight, food consumption, clinical observations, intraocular pressure, electroretinogram ("ERG"), clinical pathology parameters (hematology, coagulation and clinical chemistry), organ weights, or macroscopic examinations. Toxicokinetic parameters indicated that systemic exposure for TH103 increased with increasing dose in an approximately dose proportional manner and in general was extremely low.

In the Dutch-belted rabbit toxicology study, a single intravitreal injection of one of three doses of TH103 (0.6 mg, 1.2 mg and 2.3 mg) was administered in one eye. All treated animals were positive for ADA by day 8 and remained positive through day 29. There was a dose-dependent and time-dependent intraocular inflammation that coincided with ADA levels. The intraocular inflammation improved in most eyes over time. Based on the recoverable nature of inflammation and absence of degenerative findings, the No Observed Adverse Effect Level ("NOAEL") in this study was determined to be 1.2 mg per eye, which is equivalent to approximately 3.2 mg per eye in a human eye based on average vitreous volumes.

In the Göttingen minipig toxicology study, a single intravitreal injection of one of three doses of TH103 (0.9 mg, 2.3 mg and 3.7mg per eye) was administered in both eyes. Similar to the study in rabbits, most treated animals were positive for ADA by day 8 and remained positive through day 29. ADA levels and intraocular inflammation coincided in most animals across all dose levels, but a dose-related response was not observed.

Repeat Dose Toxicology Studies

Göttingen minipigs were administered repeat doses of TH103 by intravitreal injection into both eyes at 4-week intervals for six months (doses of 1.0 mg, 2.1 mg and 3.6 mg per eye) at seven time points through day 169 followed by an 8-week recovery period after the last dose to evaluate the potential reversibility of any finding. There were no observed TH103-related effects on body weight, electrocardiology, ERG, clinical pathology parameters (hematology, coagulation and clinical chemistry) or organ weights. Toxicokinetic parameters indicated that systemic exposure for TH103 generally increased with increasing dose. In general, at all dose levels there was a direct and dose-dependent relationship between intraocular inflammation and ADA levels, with increasing severity from day 22 to day 183. Intraocular inflammation improved in nearly all animals after administration of systemic and topical steroids.

Initial data from Phase 1a clinical trial of TH103

Based on the preclinical study results and favorable preclinical toxicology data, we advanced TH103 into a Phase 1a study intended to evaluate safety, tolerability, pharmacokinetics, and anti-VEGF activity following a single injection of TH103. The Phase 1a trial was an open label, SAD trial, conducted at multiple sites across the U.S. in which a single injection of TH103 was administered to treatment-naïve nAMD patients. Patients returned for frequent follow-up visits during the first month after injection, then were monitored monthly out to six months following injection. Patients could be treated with standard of care aflibercept 2 mg according to a relatively conservative definition for disease activity and retreatment. In December 2025, we announced initial data from a total of 13 patients in the trial who received a 0.05ml injection across 3 doses, 0.5mg (diluted to 0.05ml per dose), 1.5mg (diluted to 0.05ml per dose), and 2.5mg (0.05ml per dose), and completed the entire 6-month study and follow up period.

Baseline characteristics of the patients in our Phase 1a trial of TH103 who reached the completion of the study were relatively balanced across dose groups, as shown in the table below, with the exception of the 2.5 mg cohort, which enrolled a lower mean visual acuity of 49 letters. Also of note was that an atypically high 46% of patients in the trial presented with Type 3, Stage 3 lesions, which in general are more complex than Types 1 and 2 nAMD and can require more frequent treatments to maintain disease control.

Key baseline characteristics of patients in Phase 1a trial of TH103 who have reached study completion

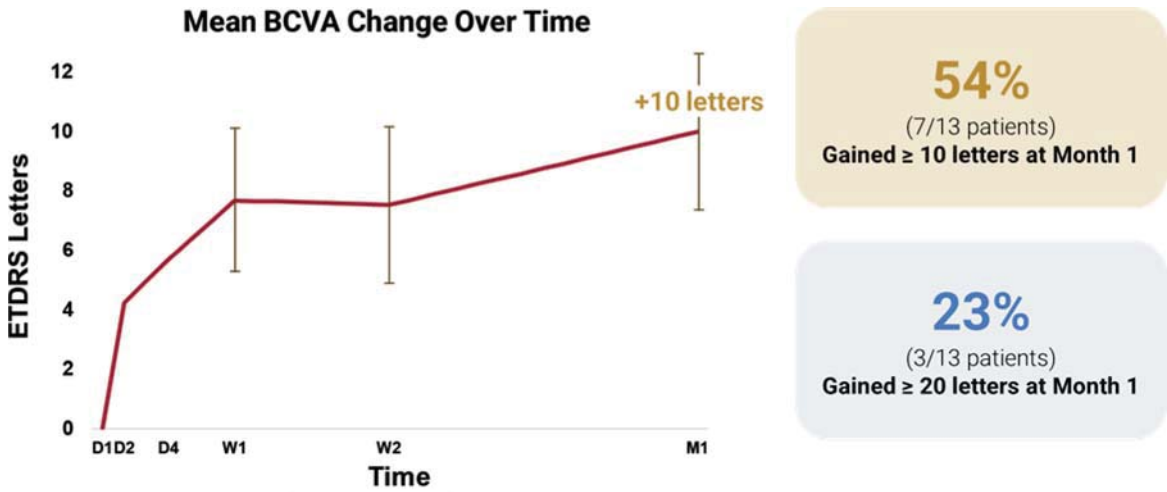
		Study Cohort			
		0.5 mg (n=3)	1.5 mg (n=7)	2.5 mg (n=3)	All Patients (n=13) [1]
Age (mean)		78	77	82	79
Sex (female / male)		3 / 0	5 / 2	1 / 2	9 / 4
BCVA (ETDRS letters, mean, range)		58 (44-71)	59 (35-73)	49 (36-63)	57 (35-73)
Lesion Type	Type 1	1	3	1	5 (38%)
	Type 2	-	1	-	1 (8%)
	Type 3[2]	1	3	2	6 (46%)
	Ungradable	1	-	-	1 (8%)
CST (µm, mean, range)		483 (421-550)	442 (329-611)	485 (440-554)	470 (329-611)

1) Includes all patients who completed the entire 6-month follow-up period, excludes patients dosed with additionally purified material (6 dosed at the 2.5mg dose level and 1 patient dosed at the 5.0mg dose level subsequent to the December 2025 disclosure)
2) Also called retinal angiomatous proliferation, or RAP; all Type 3 lesions were determined to be Stage 3

In December 2025, we announced initial Phase 1a data which support the molecular hypothesis and showed strong clinical activity, including improvements in best corrected visual acuity ("BCVA") and OCT parameters across dose levels at Month 1.

These results included a mean 10-letter best corrected visual acuity ("BCVA") improvement after a single TH103 injection at Month 1, as shown in the image below. Notably, over half of the patients in our Phase 1a study gained 10 or more letters, and almost a quarter gained 20 or more letters, with no obvious difference in response across dose levels.

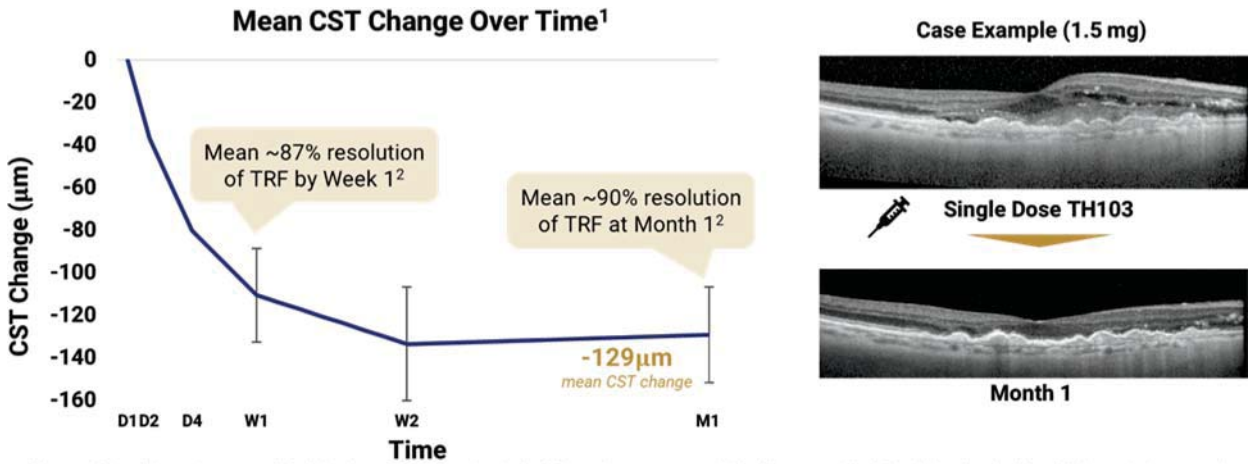
Mean 10 letter gain in BCVA letter score after a single TH103 injection at Month 1



ETDRS = Early Treatment Diabetic Retinopathy Study
Note: n = 13 at all timepoints except Month 1, where n =12; one patient in the 0.5 mg cohort was treated with aflibercept at Week 2 and therefore the Month 1 data point is censored. Patients dosed at 2.5 mg with additionally purified material (n=6) are excluded from efficacy & PK analyses due to limited follow-up.; Brackets indicate standard error.

These results also included rapid, robust improvement in mean central subfield thickness ("CST") and total retinal fluid (TRF) volume at Week 1 and Month 1, as shown in the graphic below. On CST, TH103-treated patients improved at Month 1 by 129 µm on average. To further characterize this improvement, automated fluid measurement software was applied specifically to quantify the abnormal retinal fluid in the central subfield, demonstrating an 87% resolution in mean total retinal fluid at Week 1 and a 90% resolution at Month 1.

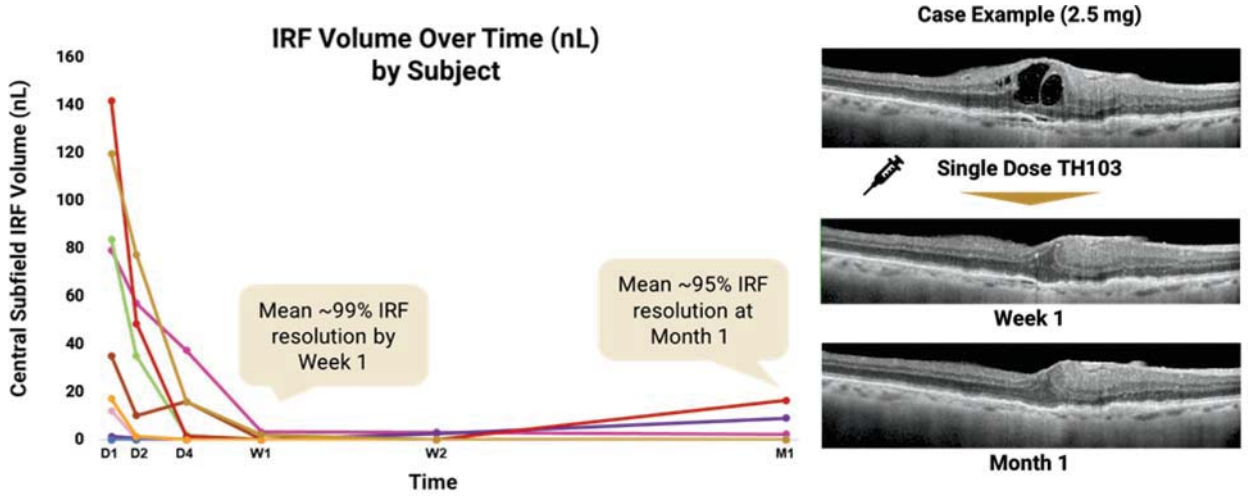
Rapid, robust improvement in CST and total retinal fluid (TRF) volume at Week 1 and Month 1



Note: n = 13 at all timepoints except Month 1, where n =12; one patient in the 0.5 mg cohort was treated with aflibercept at Week 2 and therefore the Month 1 data point is censored. Patients dosed at 2.5 mg with further purified material (n=6) are excluded from efficacy & PK analyses due to limited follow-up; Brackets indicate standard error.
Sources: 1) As measured by independent reading center; 2) Data from automated fluid measurement software, Notal Vision Inc.; percentage change in mean central subfield TRF volume (subretinal fluid + intraretinal fluid in the central subfield, measured in nanoliters) from Day 1 to Week 1 & Month 1

That same fluid measurement technology was applied to further understand TH103's potency on the damaging intraretinal fluid ("IRF"). The below by-patient plot of IRF illustrates the completeness of the TH103 response, as well as the rapid rate of intraretinal fluid resolution, with a mean 99% resolution as early as 1 week after injection that was maintained as a mean 95% reduction in IRF at Month 1. Together, these efficacy data demonstrate a robust and rapid improvement in both visual acuity and lesion morphology, consistent with the original TH103 hypothesis.

Rapid and consistent resolution of intraretinal fluid (IRF) volume observed across doses



Note: Measurement of intraretinal fluid volume (nL) in the central subfield, depicting individual patients (n = 12; one patient in the 0.5 mg cohort was treated with aflibercept 2mg at Week 2 and excluded from the analysis); 3 patients had zero measured IRF throughout depicted timeframe and appear as overlapping lines on the x-axis; Patients dosed at 2.5 mg with additionally purified material (n=6) are excluded from efficacy & PK analyses due to limited follow-up.
Source: Data from automated fluid measurement software, Notal Vision Inc.; percentage change in mean central subfield IRF volume (nL) from Day 1 to Week 1 / Month 1 (n = 12)

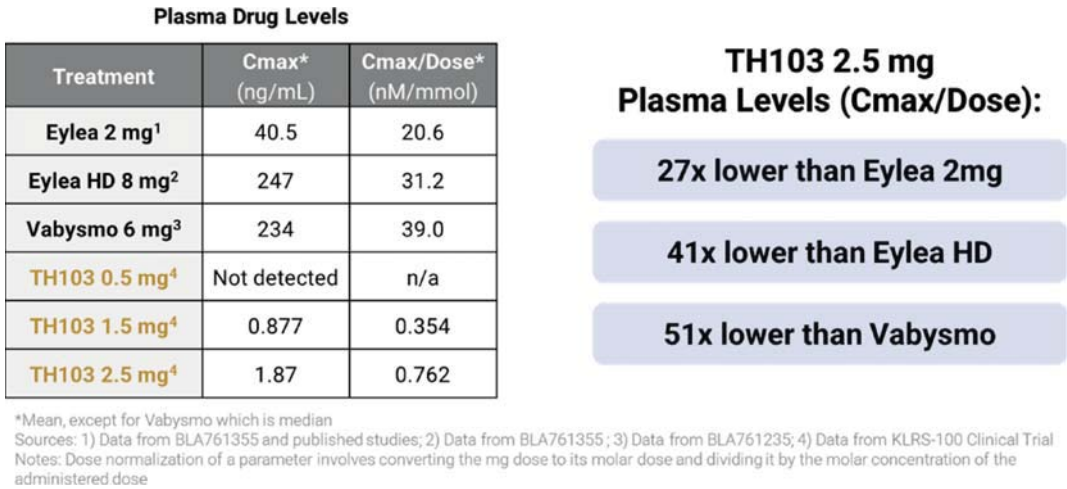
In the safety analysis, which was a primary objective of the study, TH103 was also shown to be generally well tolerated, including no dose-limiting toxicities ("DLTs"), no TH103-related serious adverse events ("SAEs"), and no instances of TH103-related retinal vascular occlusive disease, retinal vasculitis, cataracts, or elevated intraocular pressure observed, which support exploration of

further dose escalation. Two subjects in the 2.5mg cohort presented on Day 4 with transient, mild-moderate IOI. While the underlying cause of the observed IOI has not been definitively established, in light of the biologic expression system used for manufacture, we evaluated host cell proteins as a potential contributing factor and implemented additional downstream processing steps that significantly reduced host cell protein levels. Following completion of a new manufacturing batch, six additional subjects were enrolled and treated with this further purified material at the 2.5 mg dose level and there were no new instances of IOI in these 6 patients (≥ 3-month follow-up).

Subsequent to our December 2025 initial data disclosure, we observed a case of moderate IOI, which resolved, in one subject in the Phase 1a trial who received a single administration of 5.0 mg of TH103 with the new material. Further analysis of that manufacturing batch, utilizing advanced analytical methods, quantified remaining host cell protein levels and identified specific constituent sub-host cell proteins. These findings indicated that some sub-host cell proteins had been reduced by a lower proportion than the overall host cell protein level in the manufacturing batch. Based on these results, we have continued to advance additional process refinements in our manufacturing process to further reduce the level of host cell protein in our drug product, and we plan to use additional purification manufacturing processes in preparing the drug product for our ongoing and planned clinical trials. Moreover, we believe we have identified specific process modifications that may eliminate all remaining host cell protein subtypes to below levels of detection and aim to utilize these modifications in future batches of our drug product.

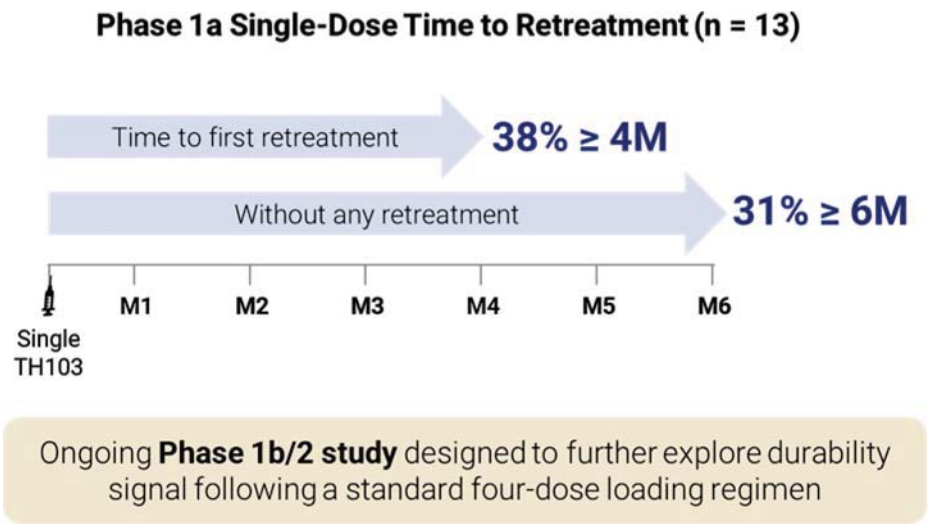
Additionally, the Phase 1a data provided evidence that TH103 may offer extended treatment durability. In the pharmacokinetic ("PK") analysis summarized in the graphic below, plasma levels of TH103 mean Cmax were 27 to 51-fold lower compared to current leading anti-VEGF agents on a dose-adjusted basis, consistent with greater intraocular retention and reduced systemic exposure. This pharmacokinetic profile aligns with the molecule's engineered properties and preclinical data demonstrating greater intraocular retention.

Initial SAD plasma PK data is consistent with greater TH103 intraocular retention



In addition, while this single-injection Phase 1a study was not designed to study durability, 38% of patients went at least 4 months before receiving additional anti-VEGF treatment, and 31% of patients never met the re-treatment criteria during the entire six-month follow-up period after one TH103 administration, as shown in the image below. These single-dose findings suggest the potential for extended durability outcomes after TH103 is administered in a standard four-dose loading regimen.

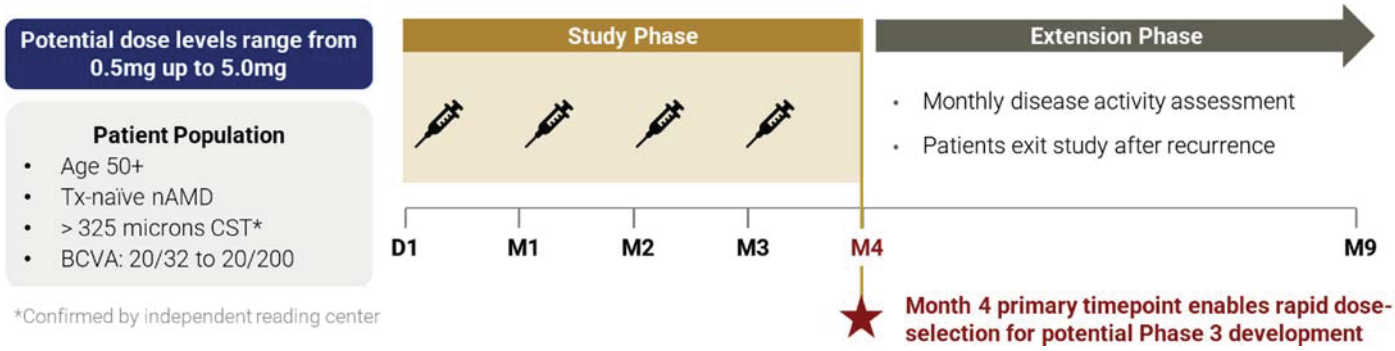
Single-dose durability signal suggests potential for stronger durability outcomes after standard four-dose loading regimen



Our ongoing Phase 1b/2 clinical trial of TH103

We are currently conducting an ongoing Phase 1b/2 MAD, dose-finding study intended to assess safety and efficacy of repeat TH103 administration. The trial is designed to enroll and treat approximately 60 to 80 patients with nAMD who receive four initial monthly loading doses of TH103 with the goal of identifying the optimal dose and regimen for potential Phase 3 development, which is depicted in the image below. The range of doses being evaluated in our Phase 1b/2 MAD trial is informed by the SAD data from our Phase 1a trial and began with 0.5 mg. Study assessments are expected to include safety and preliminary efficacy with a primary timepoint for analysis at one-month following the fourth loading dose. Patients will then be followed in an extension phase for up to six additional months. During the extension phase, patients will exit the study after disease activity warrants retreatment. We expect to share preliminary data from the ongoing Phase 1b/2 study in the first half of 2027.

Ongoing Phase 1b/2 Trial in nAMD; Preliminary Data Expected First Half of 2027



Updates Following December 2025 Phase 1a Trial Initial Data Disclosure

As of the date of this Annual Report, we have dosed a total of 17 patients in our ongoing Phase 1b/2 MAD trial, including six patients who have received four injections of 0.5 mg of TH103 with no reported IOI, six patients who have received one injection of 1.5 mg of TH103 with no reported IOI, two patients who have received two injections of 1.5mg with no reported IOI and two patients who have received three injections of 1.5 mg of TH103 with one reported case of IOI after one patient's third injection that was asymptomatic and resolving, presenting with improved BCVA/CST from baseline and moderate anterior vitreous cell and mild arteriolar abnormalities (without leak or occlusion). One other patient who received a single administration of 0.5 mg of TH103 has also exited the study for reasons unrelated to study drug.

While the underlying cause of the observed IOIs in our Phase 1a clinical trial and Phase 1b/2 clinical trial of TH103 has not been definitively established, in light of the biologic expression system used for manufacture, we evaluated host cell proteins as a potential contributing factor and have continued to advance additional process refinements in our manufacturing process to reduce the level of host cell protein in our drug product. We believe that our continued progress in reducing host cell protein levels in our

manufactured drug product and the corresponding higher levels of the total dose amount of TH103 we have been able to administer to patients before IOI is observed reflects our continued progress in refining our manufacturing process. Further analysis of the manufacturing batch most recently administered in our Phase 1b/2 clinical trial, utilizing advanced analytical methods, quantified remaining host cell protein levels and identified specific constituent sub-host cell proteins. These findings indicated that some sub-host cell proteins had been reduced by a lower proportion than the overall host cell protein level in the manufacturing batch. Ongoing process refinements are focused on significant reductions of all remaining sub-host cell protein, and new material with further reduced levels of constituent host cell proteins is expected to be available in the second quarter of 2026.

Anticipated future clinical trials of TH103 as a treatment for nAMD.

Assuming successful completion of the ongoing Phase 1b/2 clinical trial of TH103, and subject to the favorable results from such trial and discussions with regulators, we intend to initiate Phase 3 clinical trials of TH103 for nAMD by year-end 2027.

Potential Indication Expansion Opportunities for TH103

In addition to nAMD, we believe TH103 may also offer therapeutic benefit to patients with other VEGF-mediated retinal diseases marked by exudation and/or neovascularization, such as DME/DR, RVO and ROP. We believe that the preclinical studies conducted to date for the development of TH103 for nAMD and the results, if favorable, from our ongoing Phase 1b/2 clinical trial of TH103 for nAMD will support IND submissions to the FDA for these additional intraocular indications. Descriptions of these diseases and the limitations of currently used therapeutics are presented below.

Diabetic Macular Edema / Diabetic Retinopathy

DR is a condition in which the small blood vessels of the retina are damaged as a result of a sustained elevation of blood glucose levels. The earlier stages of DR involve the emergence of microaneurysms in the blood vessels and the formation of lipid deposits. In more advanced stages, patients with DR may experience the abnormal proliferation of the weakened blood vessels throughout the retina, resulting in fluid leakage and vision disruption. An estimated 9.6 million people in the United States have DR and 1.8 million have vision threatening disease. A majority of people who have had diabetes for 20 or more years also have DR. DME, a complication associated with DR, is caused by leakage of fluid into the macula from the retinal microvasculature, which can result in significant visual decline and contribute to the risk of blindness. It is a leading cause of blindness among the U.S. adult population, with an estimated 1.4 million people living with the disease in the United States Worldwide, the market for DME/DR treatments is estimated to currently exceed $12 billion.

Limitations of current treatments for DME/DR

In both DME and DR, initial disease onset often goes unnoticed, which contributes to a large undiagnosed population. Among those diagnosed, recommended treatment for patients with early-stage disease or mild visual impairment is observation only largely to avoid the associated treatment burden. For patients with more advanced disease, the standard of care includes laser treatment, intravitreal injections of steroids or anti-VEGF therapies. However, many patients fail to display a sustained response to therapy, necessitating repeat injections to maintain therapeutic effectiveness. In consequence, these patients experience clinic visit burden and related compliance challenges similar to those with nAMD.

Retinal Vein Occlusion

RVO occurs when there is a partial or complete blockage of the central retinal vein, or more commonly, a peripheral retinal vein that drains blood from the retina. The occlusion increases venous pressure and causes intraretinal hemorrhages, edema, and ischemia, triggering a complex cascade of molecular events that upregulate VEGF and other proinflammatory mediators. While there is no cure for RVO, treatment focuses on managing the complications that lead to vision loss. Macular edema and neovascularization, which occur in approximately 25% of RVO cases, are common complications. RVO is estimated to affect about 16 million people worldwide.

Limitations of current treatments for RVO

The introduction of anti-VEGF therapies has significantly improved patient outcomes in the treatment of RVO. However, a primary challenge in managing RVO-similar to nAMD and DME-is the chronic nature of the disease, which requires ongoing monitoring and repeated intravitreal injections to maintain visual function. Adherence to clinic visit regimens can be difficult, leading to suboptimal outcomes.

Retinopathy of Prematurity

ROP, which involves the abnormal growth of blood vessels in the retina of newborns, affects between 14,000 and 16,000 infants each year in the United States. Infants born prior to 31 weeks gestation or at a birth weight of approximately 3 pounds or less are at highest risk for developing ROP. Resolution of the condition occurs without further medical intervention in 90% of cases, though an estimated 1,100 to 1,500 infants are born with a more severe form of the disorder that requires treatment. ROP causes legal blindness in as many as 600 children annually.

Limitations of current treatments for ROP

Standard of care treatment for ROP involves the intravitreal administration of anti-VEGF therapeutics. However, significant systemic exposure to these agents may have detrimental neurodevelopmental effects in newborns. The increased binding affinity of TH103 to HSPG, which results in significantly lower systemic levels compared to aflibercept, may prove particularly useful in treating ROP as it may reduce potential risks to infants associated with systemic anti-VEGF exposure.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely on third-party contract manufacturers for the manufacture of our product candidate for our ongoing and planned clinical trials, and, if we receive marketing approval, we intend to rely on such third parties for commercial manufacture. Our principal contract manufacturers are STC Biologics, Inc. and Sharp Sterile Manufacturing (formerly, Berkshire Sterile Manufacturing Inc.). Additionally, KBI Biopharma, based in North Carolina, is our Contract Development and Manufacturing Organization ("CDMO") for future clinical and commercial supply manufacturing of TH103 drug substance. We are also currently in the process of selecting our CDMO partner for future clinical and commercial supply manufacturing of TH103 drug product.

We believe that our contract manufacturers are capable of producing sufficient quantities of our product candidate to support our ongoing and planned clinical trials. We also believe that there are a number of alternative third-party manufacturers that have similar capabilities that would be capable of providing sufficient quantities of our product candidate for our ongoing and planned clinical trials. However, should our contract manufacturers not be able to provide sufficient quantities of our product candidate for our ongoing and planned clinical trials, we would be required to seek alternative contract manufacturers to provide our product candidate, likely resulting in delays of our ongoing and planned clinical trials.

TH103 is produced through well-established biological manufacturing processes. TH103 is produced in Chinese hamster ovary K1 cells by recombinant DNA technology using a conventional fusion protein manufacturing process. We believe our existing supply of TH103 is sufficient to satisfy our near-term development requirements.

In addition, we rely on third parties to package, label, store and distribute TH103, and we intend to rely on third parties for our commercial products if marketing approval is obtained. We expect this strategy will enable us to maintain a more efficient infrastructure, avoiding dependence on our own manufacturing facility and equipment, while simultaneously enabling us to focus our expertise and resources on the clinical development and future commercialization activities.

Competition

The biopharmaceutical industry, and in particular the market for products treating retinal diseases, is characterized by intense investment and competition aimed at rapidly advancing new technologies. Our product candidates are expected to face substantial competition from multiple sources, including large and specialty pharmaceutical and biotechnology companies, academic research 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 emerge in the future within the field of ophthalmology and, furthermore, within the treatment of retinal neovascular and/or exudative diseases. Many of the companies against which we are competing or against which we may compete in the future, either alone or in combination with their respective strategic partners, have significantly greater financial, technical and human resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, the regulatory approval process, and marketing than we do.

In addition to the current standard of care treatments for patients with nAMD, numerous commercial and academic pre-clinical studies and clinical trials are being undertaken by a large number of parties to assess novel technologies and product candidates. Large pharmaceutical companies that have commercialized or are developing treatments for nAMD include Roche, Novartis AG ("Novartis"), Regeneron Pharmaceuticals, Inc. ("Regeneron"), AbbVie Inc. ("AbbVie") and Eli Lilly. Roche has received FDA approval for faricimab, ranibizumab and bevacizumab, though bevacizumab is not approved specifically for nAMD; Novartis has received FDA approval for brolucizumab; and Regeneron has received FDA approval for aflibercept and aflibercept HD. AbbVie is currently collaborating with RegenexBio Inc. ("RegenexBio") to develop ABBV-RGX-314 as a potential gene therapy treatment for

nAMD. Merck is developing both MK-3000, a tri-specific antibody, and MK-MK-8748, a bi-functional Fc-fusion protein, in DME and nAMD. In December 2025, Eli Lilly completed the acquisition of Adverum Biotechnologies, Inc. and its portfolio of investigational gene therapy products, including ixoberogene soroparvovec, for which it previously reported results from a Phase 2 clinical trial.

Several companies have received FDA approval for biosimilars to treat nAMD, including: Samsung Bioepis Co., Ltd. and Biogen Inc., which received approval for Byooviz (ranibizumab-nuna), a ranibizumab biosimilar, in September 2021 and Opuviz (aflibercept-yszy) in May 2024; Coherus BioSciences, Inc., which obtained approval for Cimerli (ranibizumab-eqrn), a ranibizumab biosimilar, in August 2022; Formycon AG, which received approval for Ahzantive (aflibercept-mrbb) in June 2024; Sandoz Group AG, which received approval for Enzeevu (aflibercept-abzv) in August 2024; Mylan Laboratories Inc. and Biocon Biologics Limited, which received approval for Yesafili (afliberceptjbvf), an aflibercept biosimilar, in May 2024; and Amgen Inc. ("Amgen"), which received approval for Pavblu (aflibercept-ayyh) in August 2024. Amgen launched and began commercial distribution for Pavblu in the fourth quarter of 2024 and additional aflibercept biosimilars are expected to enter the market in the next twelve to twenty-four months. Outlook Therapeutics, Inc. is also developing bevacizumab-vikg, an investigational ophthalmic formulation of bevacizumab as a potential treatment for nAMD. These biosimilars may provide new, cost-effective options for the treatment of nAMD, as well as other retinal conditions mediated by VEGF.

Emerging biopharmaceutical companies advancing therapeutic candidates through clinical trials to treat nAMD include 4D Molecular Therapeutics, Inc. ("4D Molecular Therapeutics"), RegenexBio, Eyepoint Pharmaceuticals, Inc. ("Eyepoint Pharmaceuticals"), Ocular Therapeutix, Inc. ("Ocular Therapeutix"), Kodiak Sciences, Inc. ("Kodiak"), and Ollin Biosciences, Inc. ("Ollin"), among others. 4D Molecular Therapeutics and RegenexBio are each advancing anti-VEGF gene therapy candidates to treat nAMD. 4D Molecular Therapeutics' drug candidate is in an ongoing Phase 3 trial for nAMD and a Phase 1 trial for DME and RegenexBio's drug candidate is in a pivotal clinical trial for nAMD and a Phase 2 trial for a potential DR treatment. Eyepoint Pharmaceuticals is developing a sustained release, small molecule tyrosine kinase inhibitor, which is currently under evaluation in two ongoing Phase 3 trials for nAMD and two ongoing Phase 3 trials for DME. Ocular Therapeutix is currently conducting two Phase 3 trials of axitinib intravitreal implant, a small molecule tyrosine kinase inhibitor to treat nAMD, which is also being evaluated in a Phase 3 trial for DR. Kodiak is investigating multiple therapeutics in retinal diseases, including tarcocimab, an investigational anti-VEGF monoclonal antibody, and KSI-501, a bi-specific Anti-IL-6/VEGF trap, which are being evaluated in a Phase 3 trial in nAMD. Ollin is investigating OLN324, a VEGF/Ang2 bispecific antibody, in a Phase 2 trial in DME and nAMD and has indicated the goal of commencing Phase 3 trials in 2026. Several other companies are also developing therapies for nAMD, DME, and other retinal diseases in various earlier stages of clinical development.

We also compete with third parties for retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. We may pursue the in-license or acquisition of rights to complementary technologies and product candidates on an opportunistic basis. The acquisition and licensing of technologies and product candidates is a competitive area, and a number of more established companies also have similar strategies to in-license or acquire technologies and product candidates that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to in-license or acquire the relevant technology or product candidate on terms that would allow us to make an appropriate return on our investment.

Mergers and acquisition activity in the pharmaceutical, biopharmaceutical and biotechnology sector is likely to result in greater resource concentration among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through sizeable collaborative arrangements with established companies. These competitors also compete with us in recruiting and retain qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our business.

Our commercial opportunity could be reduced or eliminated if one or more of our competitors develop and commercialize products that are safer, more effective, better tolerated, or of greater convenience or economic benefit than our proposed product offering. Our competitors also may be in a position to obtain FDA or other regulatory approval for their products more rapidly, resulting in a stronger or dominant market position before we are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be product safety, efficacy, convenience and treatment cost.

Intellectual Property

The proprietary nature of, and protection for, our product candidates and their methods of use are an important part of our strategy to develop and commercialize novel medicines, as described in more detail below. We have obtained patents and filed patent applications in the United States and other countries relating to certain of our proprietary technology, inventions, improvements, and product candidates, and we are pursuing additional patent protection for them. We strive to protect the proprietary technologies that we believe are important to our business, including pursuing and maintaining patent protection intended to cover TH103, its methods of use, related technologies, and other inventions that are important to our business. In addition to patent protection, we also rely on trade secret to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. We will also seek to rely on regulatory protection afforded through inclusion in expedited development and review, data exclusivity, market exclusivity and patent term extensions where available.

As of December 31, 2025, we own or have an exclusive license to multiple patent families. These families include 35 issued/allowed patents (6 issued U.S. patents and 29 issued/allowed foreign patents) and 27 other pending applications (5 pending U.S. applications and 22 foreign patent applications).

As of December 31, 2025, we have an exclusive license to two patent families licensed from the Regents of the University of California ("UCSD"). The first patent family includes issued patents in Australia, China, Canada, Europe (validations in UK, Germany, France, Austria, Belgium, Switzerland, Denmark, Spain, Finland, Ireland, Italy, Luxembourg, Netherlands, Sweden, Iceland, and Norway), Colombia, Eurasia, Israel, Japan, Macau, New Zealand, and the United States and pending applications in Australia, Europe, China, Brazil, Colombia, Eurasia, Hong Kong, India, Israel, Japan, South Korea, Mexico, Singapore, and United States. Counting each European validation separately, this patent family gives us rights to twenty-eight (28) ex-U.S. issued/allowed patents in Europe, Australia, North America, South America, and Asia relating to TH103 that are expected to expire in 2039 (excluding patent term extension). The second patent family includes three granted U.S. cases and is also pending in Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, Israel, South Korea, Mexico, New Zealand, and the United States. This second family includes three (3) issued U.S. patents (expected to expire in 2040 excluding patent term extension) with claims covering the TH103 composition of matter and corresponding methods for treating VEGF-related conditions in the eye.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of TH103, future product candidates, and the methods used to develop and manufacture them, as well as successfully defending any such patents against third-party challenges, preserving the confidentiality of our trade secrets, and operating without infringing on the proprietary rights of others. Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidates will depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our product candidates, discovery programs and processes.

The terms of individual patents depend upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office ("USPTO") in examining and granting a patent or may be shortened if a patent is terminally disclaimed over an earlier filed patent. In the United States, the term of a patent that covers an FDA-approved drug may also be eligible for extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the subject drug candidate is under regulatory review. 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 an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions to extend the term of a patent that covers an approved drug are available in Europe and other foreign jurisdictions. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any issued patents we may obtain in any jurisdiction where such patent term extensions are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment that such extensions should be granted, and if granted, the length of such extensions.

In certain foreign jurisdictions similar extensions as compensation for regulatory delays are also available. The actual protection afforded by a patent varies on a claim by claim and country by country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extensions or adjustments, the availability of legal remedies in a particular country and the validity and enforceability of the patent. In particular, up to a five-year extension may be available in the Europe and Japan. We plan to seek such extensions as appropriate.

In addition to patent protection, we also rely on trade secret protection for our proprietary information that is not amenable to, or that we do not consider appropriate for, patent protection, including, for example, aspects of our manufacturing processes for TH103. However, trade secrets can be difficult to protect. Although we take steps to protect our proprietary information, including restriction to our premises and our confidential information, as well as entering into agreements with our employees, consultants, advisors, and potential collaborators, such individuals may breach such agreements and disclose our proprietary information including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In addition, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information.

License Agreement with The Regents of the University of California

In April 2021, we entered into a license agreement with UCSD, which was amended in June 2022 (the "UCSD license agreement"). Pursuant to the UCSD license agreement, UCSD granted us (1) an exclusive, worldwide license, with specified rights to sublicense, under UCSD's interest in specified patent rights related to VEGF inhibitors (the "patent rights") to make, have made, use, sell, offer for sale, and import products (the "licensed products") that are covered by the patent rights or that incorporate or are developed using certain technical information (the "technology"), and (2) a nonexclusive, worldwide license, with specified rights to sublicense, to use the technology. The patent rights and technology incorporate inventions made in the course of research conducted by Dr. Napoleone Ferrara and his associates at the University of California, San Diego (the "inventions"). The foregoing licenses are subject to rights retained by UCSD to use the inventions for educational and research purposes, publish or disseminate information about the Inventions, and allow other nonprofit institutions to use, publish or disseminate information about the Inventions for educational and research purposes. Under the UCSD license agreement, we are obligated to use commercially reasonable efforts to develop, seek and obtain regulatory approval for, sell, and fill the market demand for at least one licensed product in the United States or another specified major market, as well as to annually spend an amount in the low hundreds of thousands of dollars for the development of licensed products, until the earlier of (1) receipt of regulatory approval of a licensed product or (2) abandonment of development of the licensed product due to efficacy or safety, and to carry out a specified development plan within specified time periods. We are also obligated to use certain diligence benchmarks within specified deadlines.

We are required to pay UCSD a nominal annual license maintenance fee, which may be credited against royalties due for the calendar year. We are also required to pay UCSD milestone payments upon achievement of specified clinical and regulatory milestone events for each indication, in an amount not to exceed $4.6 million in the aggregate, and low single digit tiered royalties on annual net sales, which may be subject to reduction if we are required to pay royalties to third parties for patent rights that cover the licensed products. Our obligation to pay royalties continues on a licensed product-by-licensed product and country-by-country basis until expiration of the last to expire patent rights in such country. In addition, we must pay to UCSD a percentage of non-royalty sublicensing income we receive from sublicensees. We are obligated to pay an "assignment fee" upon a specified change of control of us based on the valuation of the change of control transaction. We also paid UCSD an upfront fee of $150,000 in connection with our entry into the UCSD license agreement and were obligated to issue shares of common stock of Legacy Kalaris equal to a percentage in the mid-single digits of outstanding equity securities of Legacy Kalaris on a fully diluted basis as of the date a specified funding threshold of Legacy Kalais was attained, as consideration for the licenses granted by UCSD. In June 2022, after the closing of Legacy Kalaris' Series A financing, Legacy Kalaris issued 680,725 shares of its common stock to UCSD. Under the UCSD license agreement, UCSD was also granted a participation right in certain future securities offerings of Legacy Kalaris, which was exercisable for a maximum of two years following the effective date of the UCSD license agreement and which has terminated. We are also responsible for reimbursement of all expenses for the preparation, filing, prosecution, and maintenance of patents under the patent rights. To date, we have paid an aggregate of $0.1 million in milestone payments to UCSD under the UCSD license agreement.

The UCSD license agreement remains in effect until the expiration or abandonment of the last licensed patent or patent application. UCSD may terminate the UCSD license agreement for our material breach, subject to a specified cure period, or in the event we become the subject of a specified insolvency event. We may terminate the UCSD license agreement for convenience upon sixty days prior notice.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union ("EU"), extensively regulate, among other things, the research, development, testing, manufacture, pricing, reimbursement, sales, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products, including biological products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources and may have a significant impact on our business.

Licensure and Regulation of Biologics in the United States

In the United States, our product candidates are regulated as biological products, or biologics, under the Public Health Service Act ("PHSA") and the Federal Food, Drug and Cosmetic Act ("FDCA") and its implementing regulations and guidance. 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. The failure of a sponsor to comply with the applicable United States requirements at any time during the product development process, including preclinical testing, clinical testing, the approval process, or post-approval process, may subject a sponsor to delays in the conduct of the study, regulatory review, and approval, and/or administrative or judicial sanctions.

A sponsor seeking approval to market and distribute a new biologic in the United States generally must satisfactorily complete each of the following steps:

- preclinical laboratory tests, animal studies, and formulation studies all performed in accordance with the FDA's Good Laboratory Practice ("GLP") regulations and standards and other applicable regulations;
- completion of the manufacture, under current Good Manufacturing Practices ("cGMP") conditions, of the drug substance and product that the sponsor intends to use in human clinical trials along with required analytical and stability testing;
- design of clinical protocol and submission to the FDA of an investigational new drug application ("IND") for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board ("IRB") representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety, potency, and purity of the product candidate for each proposed indication, in accordance with current Good Clinical Practices ("GCP");
- preparation and submission to the FDA of a biologics license application ("BLA"), for a biologic product requesting marketing for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product in clinical development and proposed labelling;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with cGMP requirements and to assure that the chemistry, methods, and controls ("CMC") are adequate to preserve the product's identity, strength, quality, and purity;
- satisfactory completion of any FDA audits of the preclinical studies and clinical trial sites to assure compliance with GLP, as applicable, and GCP, and the integrity of clinical data in support of the BLA;
- payment of substantial application and program fees pursuant to the Prescription Drug User Fee Act ("PDUFA");
- approval of a BLA licensing the biologic product for marketing 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 ("REMS") and any post-approval studies or other post-marketing commitments required by the FDA.

Preclinical Studies

Before testing any biologic product candidate in humans, the product candidate must undergo preclinical testing. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate the potential for efficacy and toxicity in animals. These studies are generally referred to as IND-enabling studies. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements, including GLP regulations and standards and the United States Department of Agriculture's Animal Welfare Act, if applicable. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application.

With passage of the FDA's Modernization Act 2.0 in December 2022, Congress eliminated provisions in both the FDCA and the PHSA that required animal testing in support of a BLA. While animal testing may still be conducted, the FDA was authorized to rely on alternative non-clinical tests, including cell-based assays, microphysiological systems, or bioprinted or computer models. In April 2025, the FDA released a roadmap to replace animal testing in preclinical safety studies with scientifically validated new approach methodologies.

Investigational New Drug Application

An IND is a request for FDA authorization to administer an investigational product candidate to humans. Such authorization must be secured prior to interstate shipment and administration of any new biologic that is not the subject of an approved BLA. In support of a request for an IND, sponsors must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND.

The FDA requires a 30-day waiting period after the filing of each IND before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects and patients will be exposed to unreasonable health risks. The FDA's primary objectives in reviewing an IND are to assure the safety and rights of patients and to help assure that the quality of the investigation will be adequate to permit an evaluation of the biological product's safety, purity and potency. At any time during this 30-day period, or thereafter, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold or partial clinical hold. Occasionally, clinical holds are imposed due to manufacturing issues that may present safety issues for the clinical study subjects.

A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical protocol or protocols under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols or parts of the protocols may do so. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise demonstrating to the satisfaction of the FDA that the investigation can proceed.

In addition to the foregoing IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the trial at least annually. The IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to trial subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Finally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data monitoring committee ("DMC"). This group provides authorization for whether a trial may move forward at designated check points based on access that only the group maintains to available data from the trial. Suspension or termination of development during any phase of clinical trials can occur if it is determined that the participants or patients are being exposed to an unacceptable health risk or for other reasons.

Expanded Access

Expanded access, sometimes called "compassionate use," is the use of investigational products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. The rules and regulations related to expanded access are intended to improve access to investigational products for patients who may benefit from investigational therapies. FDA regulations allow access to investigational products under an IND by the company or the treating physician for treatment purposes on a case-by-case basis for: individual patients (single-patient IND applications for treatment in emergency settings and non-emergency settings); intermediate-size patient populations; and larger populations for use of the investigational product under a treatment protocol or treatment IND application.

When considering an IND application for expanded access to an investigational product with the purpose of treating a patient or a group of patients, the sponsor and treating physicians or investigators will determine suitability when all of the following criteria apply: patient(s) have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; the potential patient benefit justifies the potential risks of the treatment and the potential risks are not unreasonable in the context or condition to be treated; and the expanded use of the investigational drug for the requested treatment will not interfere initiation, conduct, or completion of clinical investigations that could support marketing approval of the product or otherwise compromise the potential development of the product.

There is no obligation for a sponsor to make its products available for expanded access; however, as required by the 21st Century Cures Act (the "Cures Act"), passed in 2016, if a sponsor has a policy regarding how it evaluates and responds to expanded access requests, sponsors are required to make such policies publicly available upon the earlier of initiation of a Phase 2 or Phase 3 clinical trial, or 15 days after the investigational biologic receives designation as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy.

In addition to and separate from expanded access, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a manufacturer to make its investigational products available to eligible patients as a result of the Right to Try Act.

Human Clinical Trials

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written trial protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

The clinical investigation of an investigational biological product is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The three phases of an investigation are as follows:

- Phase 1. Phase 1 studies include the initial introduction of an investigational biological product into humans. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational biological product in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness.
- Phase 2. Phase 2 includes the controlled clinical trials conducted to preliminarily or further evaluate the effectiveness of the investigational biological product for a particular indication(s) in patients with the disease or condition under trial, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the biological product. Phase 2 clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population.
- Phase 3. Phase 3 clinical trials are generally controlled clinical trials conducted in an expanded patient population generally at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the biological product has been obtained, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational biological product, and to provide an adequate basis for product approval.

A clinical trial may combine the elements of more than one phase and the FDA often requires more than one Phase 3 trial to support marketing approval of a product candidate. A company's designation of a clinical trial as being of a particular phase is not necessarily indicative that the study will be sufficient to satisfy the FDA requirements of that phase because this determination cannot be made until the protocol and data have been submitted to and reviewed by the FDA. Generally, pivotal trials are Phase 3 trials, but they may be Phase 2 trials if the design provides a well-controlled and reliable assessment of clinical benefit, particularly in an area of unmet medical need.

In some cases, the FDA may approve a BLA for a product but require the sponsor to conduct additional clinical trials to further assess the product's safety and effectiveness after approval. Such trials are typically referred to as post-approval clinical trials. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of biologics approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any post-approval clinical trial requirement or to request a change in the product labeling. The failure to exercise due diligence with regard to conducting post-approval clinical trials could result in withdrawal of approval for products.

In December 2022, with the passage of Food and Drug Omnibus Reform Act ("FDORA"), Congress required sponsors to develop and submit a Diversity Action Plan ("DAP") for each Phase 3 clinical trial or any other "pivotal study" of a new biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Specifically, action plans must include the sponsor's goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for DAPs. Unlike most guidance documents issued by the FDA, the DAP guidance when finalized will have the force of law because FDORA specifically dictates that the form and manner for submission of DAPs are specified in FDA guidance.

In response to an Executive Order issued by President Trump on January 21, 2025 on diversity, equity and inclusion programs, the FDA removed this draft guidance from its website. Subsequently, in July 2025, pursuant to a court order, the FDA restored the draft DAP guidance to its website with a statement that "information on this page may be modified and/or removed in the future

subject to the terms of the court's order and implemented consistent with applicable law." 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 NDAs.

In September 2025, the FDA issued final guidance with updated recommendations for GCPs aimed at modernizing the design and conduct of clinical trials. The updates are intended to help pave the way for more efficient clinical trials to facilitate the development of medical products. The final guidance is adopted from the International Council for Harmonisation's ("ICH") recently updated E6(R3) final guideline that was developed to enable the incorporation of rapidly developing technological and methodological innovations into the clinical trial enterprise. That guideline was finalized by the ICH on January 6, 2025. In addition, the FDA issued draft guidance outlining recommendations for the implementation of decentralized clinical trials.

In October 2025, the FDA issued final guidance that focuses on patient-focused drug development. The guidance outlines how stakeholders, such as patients, caregivers, researchers and medical product developers, can submit patient experience data in support of the development and approval of drug products. To that end, the guidance provides an overview of clinical outcome assessments in clinical trials, and the role that clinical outcome assessments may play in in evaluating the clinical benefit of a medical product.

Sponsors of clinical trials are required to register and disclose certain clinical trial information on a public registry (clinicaltrials.gov) maintained by the National Institute of Health. In particular, information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Although the FDA has historically not enforced these reporting requirements, the FDA has, as of January 31, 2026, issued eight notices of non-compliance. While these notices of non-compliance did not result in civil monetary penalties, the failure to submit clinical trial information to clinicaltrials.gov is a prohibited act under the FDCA with violations subject to potential civil monetary penalties of up to $10,000 for each day the violation continues. Violations may also result in injunctions and/or criminal prosecution or disqualification from federal grants.

Clinical Studies Outside the United States

In connection with a clinical development program, a sponsor may conduct trials at sites outside the United States. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived. When a foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain regulatory requirements of the FDA in order to use the study as support for an IND or application for marketing approval. Specifically, the studies must be conducted in accordance with GCP, including undergoing review and receiving approval by an independent ethics committee ("IEC"), and seeking and receiving informed consent from subjects. GCP requirements encompass both ethical and data integrity standards for clinical studies. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical studies, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign studies are conducted in a manner comparable to that required for IND studies.

The acceptance by the FDA of study data from clinical trials conducted outside the United States in support of United States approval may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted.

FDA Meetings and Interactions

Following the clearance of an IND and the commencement of clinical trials, the sponsor will continue to have interactions with the FDA. Progress reports detailing the results of clinical trials must be submitted annually within 60 days of the anniversary dates that the IND went into effect and more frequently if serious adverse events occur. These reports must include a development safety update report ("DSUR"). In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other trials or animal or *in vitro* testing that suggest a significant risk in humans exposed to the product; and any clinically important increase in the occurrence of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

In addition, sponsors are given opportunities to meet with the FDA at certain points in the clinical development program. Meetings at other times may also be requested. There are five types of meetings that occur between sponsors and the FDA. Type A meetings are those that are necessary for an otherwise stalled product development program to proceed or to address an important safety issue. Type B meetings include pre-IND and pre-BLA meetings, as well as end of phase meetings such as EOP2 meetings. A Type C meeting is any meeting other than a Type A or Type B meeting regarding the development and review of a product, including for example meetings to facilitate early consultations on the use of a biomarker as a new surrogate endpoint that has never been previously used as the primary basis for product approval in the proposed context of use. A Type D meeting is focused on a narrow set of issues, which should be limited to no more than two focused topics and should not require input from more than three disciplines or divisions. Finally, INTERACT meetings are intended for novel products and development programs that present unique challenges in the early development of an investigational product.

The FDA has indicated that its responses, as conveyed in meeting minutes and advice letters, only constitute mere recommendations and/or advice made to a sponsor and, as such, sponsors are not bound by such recommendations and/or advice. Nonetheless, from a practical perspective, a sponsor's failure to follow the FDA's recommendations for design of a clinical program may put the program at significant risk of failure.

Pediatric Studies

Under the Pediatric Research Equity Act of 2003 ("PREA"), a BLA or supplement thereto must contain data that are adequate to assess the safety, potency and purity of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the sponsor plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The sponsor, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the sponsor may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the sponsor, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. 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 completed. The FDA is required to send a PREA Non-Compliance letter to sponsors who have failed to submit their pediatric assessments under PREA, have failed to seek or obtain a deferral or deferral extension or have failed to request approval for a required pediatric formulation. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation, although the FDA has taken steps to limit what it considers abuse of this statutory exemption in PREA. The FDA also maintains a list of diseases that are exempt from PREA requirements due to low prevalence of disease in the pediatric population. In May 2023, the FDA issued new draft guidance that further describes the pediatric study requirements under PREA.

Compliance with cGMP Requirements

The FDA's regulations require that pharmaceutical products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. Manufacturers and others involved in the manufacture and distribution of products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process.

Any product manufactured by or imported from a facility that has not registered, whether foreign or domestic, is deemed misbranded under the FDCA. Establishments may be subject to periodic unannounced inspections by government authorities to ensure compliance with cGMPs and other laws. Inspections must follow a "risk-based schedule" that may result in certain establishments being inspected more frequently. Manufacturers may also have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being deemed to be adulterated. Changes to the manufacturing process, specifications or container closure system for an approved product are strictly regulated and often require prior FDA approval before being implemented. The FDA's regulations also require, among other things, the investigation and correction of any deviations from cGMP and the imposition of reporting and documentation requirements upon the sponsor and any third-party manufacturers involved in producing the approved product.

The PREVENT Pandemics Act, which was enacted in December 2022, clarifies that foreign manufacturing establishments are subject to registration and listing requirements even if a 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.

In May 2025, the FDA disclosed plans to expand its use of unannounced inspections of foreign manufacturing facilities that produce drugs and biologics distributed in the United States. Subsequently, in August 2025, the FDA introduced a "PreCheck" program with the intention of supporting companies as they build new facilities in the United States. The PreCheck program provides manufacturers with more frequent FDA communication at critical development stages, including facility design, construction, and pre-production. These FDA initiatives flow from an Executive Order issued by President Trump on May 5, 2025, calling for actions to reduce regulatory barriers to pharmaceutical manufacturing in the United States.

Submission and Filing of a BLA

The results of product candidate development, preclinical testing, and clinical trials, including negative or ambiguous results as well as positive findings, are submitted to the FDA as part of a BLA requesting a license to market the product. The BLA must contain extensive manufacturing information and detailed information on the composition of the product and proposed labeling as well as payment of a user fee.

The FDA has traditionally required at least two adequate and well-controlled clinical investigations to establish effectiveness of a new product. In February 2026, however, FDA leadership published an editorial in the New England Journal of Medicine stating 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. 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.

Under federal law, the submission of most BLAs is subject to an application user fee, which for federal fiscal year 2026 is $4,682,003 for an application requiring clinical data. The sponsor of a licensed BLA is also subject to an annual program fee, which for federal fiscal year 2026 is $442,213. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for products with orphan designation and a waiver for certain small businesses. The terms and requirements of PDUFA are reauthorized in five year cycles with the next cycle currently being negotiated to cover federal fiscal years 2028 to 2032. The new legislation must be enacted by October 1, 2027, or the FDA will lose its authority to collect user fees which fund a substantial portion of the drug review process.

Following submission of a BLA, the FDA has 60 days to conduct a preliminary review of the application, and it must inform the sponsor within that period of time whether the BLA is sufficiently complete to permit substantive review. In the event that FDA determines that an application does not satisfy this standard, it will issue a Refuse to File ("RTF") determination to the sponsor. Typically, an RTF will be based on administrative incompleteness, such as clear omission of information or sections of required information. In October 2025, the FDA issued internal guidance clarifying that "materially incomplete or inadequately organized" applications that would not permit timely, efficient and complete review will be the subject of an RTF. The internal guidance also provides that the agency will issue an RTF for an application that relies on a single adequate and well-controlled investigation to support approval if prior communications with the FDA determined the need for more than one clinical study and any justification for a single investigation is inadequate. The FDA may request additional information and studies, and the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing.

The FDA reviews the application to determine, among other things, whether the proposed biologic is safe, potent and pure for its intended use. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months from the filing date in which to complete its initial review of a standard application that is a new molecular entity, and six months from the filing date for an application with priority review. The review process may be extended by the FDA for three additional months to consider new information or in the case of a clarification provided by the sponsor to address an outstanding deficiency identified by the FDA following the original submission. Despite these review goals, it is not uncommon for FDA review of an application to extend beyond the PDUFA goal date.

The FDA seeks to meet these timelines for review of an application but its ability to do so may be affected by a variety of factors. While the costs associated with review of an application are typically covered by the PDUFA user fee program, other activities, including government budget and funding levels, the ability to hire and retain key personnel and statutory, regulatory and policy changes, may impact the FDA's review and approval of marketing applications. Average review times at the agency have fluctuated in recent years, as a result. For example, during the past decade, the U.S. government has shut down several times and certain regulatory agencies, including the FDA, have had to furlough critical employees and stop critical activities. Further, there is substantial uncertainty as to how measures currently being implemented by the new Trump Administration across the government will impact the FDA and other federal agencies with jurisdiction over biologics.

In connection with its review of an application, the FDA will typically submit information requests to the applicant and set deadlines for responses thereto. The FDA will also conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether the manufacturing processes and facilities comply with cGMPs. The FDA will not approve the product

unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. The FDA also may inspect the sponsor and one or more clinical trial sites to assure compliance with IND and GCP requirements and the integrity of the clinical data submitted to the FDA. The FDA may conduct inspections of facilities involved in the preparation, conduct, or analysis of clinical and non-clinical studies submitted to the FDA as well as other persons holding study records or involved in the study process.

Moreover, the FDA will review a sponsor's financial relationship with the principal investigators who conducted the clinical trials in support of the BLA. That is because, under certain circumstances, principal investigators at a clinical trial site may also serve as scientific advisors or consultants to a sponsor and receive compensation in connection with such services. Depending on the level of that compensation and any other financial interest a principal investigator may have in a sponsor, the sponsor may be required to report these relationships to the FDA. The FDA will then evaluate that financial relationship and determine whether it creates a conflict of interest or otherwise affects the interpretation of the trial or the integrity of the data generated at the principal investigator's clinical trial site. If so, the FDA may exclude data from the clinical trial site in connection with its determination of safety and efficacy of the investigational product.

The FDA may also refer the application to an advisory committee for review, evaluation, and recommendation as to whether the application should be approved. In particular, the FDA may refer applications for novel biologic products or biologic products that present difficult questions of safety or efficacy to an advisory committee. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates, and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA's Decision on a BLA

Under the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure, and potent, and the facility where the product will be manufactured meets standards, including cGMP requirements, designed to ensure that it continues to be safe, pure, and potent. Specifically, the FDA must determine that the expected benefits of the proposed product outweigh its potential risks to patients. This "benefit-risk" assessment is informed by the extensive body of evidence about the proposed product in the BLA. The FDA will also consider the severity of the underlying condition and how well patients' medical needs are addressed by currently available therapies; uncertainty about how the premarket clinical trial evidence will extrapolate to real-world use of the product in the post-market setting; and whether risk management tools are necessary to manage specific risks. On the basis of its evaluation of the application and accompanying information, the FDA may issue a complete response letter ("CRL") or an approval letter.

If the application is not approved, the FDA will issue a CRL, which will contain the conditions that must be met in order to secure final approval of the application, and when possible, will outline recommended actions the sponsor might take to obtain approval of the application. Sponsors that receive a CRL may submit to the FDA information that represents a complete response to the issues identified by the FDA, withdraw the application or request a hearing. The FDA will not approve an application until issues identified in the CRL have been addressed. If a CRL is issued, the sponsor will have one year to respond to the deficiencies identified by the FDA, at which time the FDA can deem the application withdrawn or, in its discretion, grant the sponsor an additional six-month extension to respond.

For those seeking to challenge the FDA's CRL decision, the FDA has indicated that sponsors may request a formal hearing on the CRL, or they may file a request for reconsideration or a request for a formal dispute resolution. While CRLs were previously treated by the FDA as confidential and were only disclosed in action packages for approved products, the FDA announced in September 2025 that it will now release CRLs promptly after they are issued to sponsors. Since that announcement, the FDA has posted a number of CRLs on its website.

An approval letter, on the other hand, authorizes commercial marketing of the product with specific prescribing information for specific indications. The FDA may limit the approved indication(s) for use of the product. It may also require that contraindications, warnings, or precautions be included in the product labeling. In addition, the FDA may call for post-approval studies, including Phase 4 clinical trials, to further assess the product's efficacy and/or safety after approval. The FDA may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use ("ETASU").

The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Regulation

If regulatory approval for marketing of a product or new indication for an existing product is obtained, the sponsor will be required to comply with all regular post-approval regulatory requirements as well as any post-approval requirements that the FDA have imposed as part of the approval process. The sponsor will be required to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling requirements. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP regulations, which impose certain procedural and documentation requirements upon manufacturers. Accordingly, the sponsor and its third-party manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with cGMP regulations and other regulatory requirements.

A product may also be subject to official lot release, meaning that the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official lot release, the manufacturer must submit samples of each lot, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot, to the FDA. The FDA may in addition perform certain confirmatory tests on lots of some products before releasing the lots for distribution. Finally, the FDA will conduct laboratory research related to the safety, purity, potency, and effectiveness of pharmaceutical products.

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

Although physicians may prescribe legally available products for unapproved uses or patient populations (i.e., "off-label uses"), manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. 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 biologic. If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services ("HHS"), as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products.

It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in nonpromotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information. 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.

Reference Product Exclusivity

The Biologics Price Competition and Innovation Act of 2009 (the "BPCIA") established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "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 proposed biosimilar product in terms of safety, purity, and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the FDA must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, 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 created certain exclusivity periods for biosimilars approved as interchangeable products.

There have been recent government proposals to reduce the 12-year reference product exclusivity period, but none has been enacted to date. At the same time, since passage of the BPCIA, many states have passed laws or amendments to laws, which address pharmacy practices involving biosimilar products. Further, the FDA may revise the standards governing approval of biosimilars so as to bring such products to the market more quickly. For example, in October 2025, the FDA issued draft guidance which proposes to eliminate the need for sponsors of biosimilar products to conduct comparative human clinical efficacy studies, allowing them to rely instead on analytical testing to demonstrate product differences from a reference product.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent exclusivity in the United States and for biologics, if granted, provides for the attachment of an additional six months of regulatory exclusivity to the term of any existing regulatory exclusivity, including orphan exclusivity. This six-month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity that cover the product are extended by six months.

Patent Term Restoration and Extension

In the United States, a patent claiming a new biologic 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 clearing clinical studies and the submission date of the BLA, plus the time between the submission date of the BLA 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 USPTO reviews and approves the application for any patent term extension in consultation with the FDA.

Healthcare Compliance

In the United States, biopharmaceutical manufacturers and their products are subject to extensive regulation at the federal and state level, such as laws intended to prevent fraud and abuse in the healthcare industry. Healthcare providers and third-party payors play a primary role in the recommendation and prescription of pharmaceutical products that are granted marketing approval. Arrangements with providers, consultants, third-party payors, and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, reporting of payments to healthcare providers and patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal

and state healthcare laws and regulations, including certain laws and regulations applicable only if we have marketed products, include the following:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully offering, soliciting, receiving, or providing remuneration, directly or indirectly, to induce either the referral of an individual for, or the purchase, order, or arranging for or recommending the purchase or order of a good or service for which payment may be made under federal healthcare programs 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 false claims, false statements, and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid. 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 civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- federal Open Payments (or federal "sunshine" law), which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with certain healthcare providers and teaching hospitals to the Centers for Medicate & Medicaid Services ("CMS") within the HHS for re-disclosure to the public, as well as ownership and investment interests held by physicians (as defined by statute) and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous state laws and regulations, including: state anti-kickback and false claims laws; state laws requiring pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers or require pharmaceutical companies to report information related to payments to health care providers or marketing expenditures; and state laws governing privacy, security and breaches 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; and
- laws and regulations prohibiting bribery and corruption such as the FCPA, which, among other things, prohibits United States companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations or foreign government-owned or affiliated entities, candidates for foreign public office, and foreign political parties or officials thereof.

Violations of these laws are punishable by criminal and/or civil sanctions, including, in some instances, exclusion from participation in federal and state health care programs, such as Medicare and Medicaid. Ensuring compliance is time consuming and costly. Similar healthcare laws and regulations exist in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of personal information.

Federal and State Data Privacy and Security Laws

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 regulates standardization of data content, codes, and formats used in healthcare transactions and standardization of identifiers for health plans and providers. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and their regulations, including the omnibus final rule published on January 25, 2013, 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. In addition to federal privacy regulations, there are a number of state laws governing confidentiality and security of health information that are applicable to our business. 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. Accordingly, state attorneys general (along with private plaintiffs) have brought civil actions seeking injunctions and damages resulting from alleged violations of HIPAA's privacy and security rules. New laws and regulations governing privacy and security may be adopted in the future as well.

In addition to potential enforcement by HHS, we are also potentially subject to privacy enforcement from the Federal Trade Commission (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 FTC 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 agency 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 Department of Justice recently finalized a rule implementing Executive Order 14117, which creates similar restrictions related to the transfer of sensitive United States 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.

Additionally, California recently enacted legislation that has been dubbed the first "GDPR-like" law in the United States. Known as the California Consumer Privacy Act ("CCPA"), it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA went into effect on January 1, 2020, and requires covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. The CCPA could impact our business activities depending on how it is interpreted and exemplifies the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data and protected health information.

In November 2020, California voters passed a ballot initiative for the California Privacy Rights Act (the "CPRA"), which 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, 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 before the end of 2026. 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 have passed comprehensive privacy laws during the 2024 legislative sessions that went into effect in 2025. Other states will be considering similar 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, the State of Washington passed the My Health My Data Act in 2023 which specifically regulated health information that is not otherwise regulated by the 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.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our current or future business activities, including certain clinical research, sales, and marketing practices 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.

Coverage, Pricing, and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may seek regulatory approval by the FDA or other government authorities. In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use any product candidates we may develop unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such product candidates. Even if any product candidates we may develop are approved, sales of such product candidates will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers, and managed care organizations, provide coverage, and establish adequate reimbursement levels for, such product candidates. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable marketing approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover any product candidates we may develop could reduce physician utilization of such product candidates once approved and have a material adverse effect on our sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Third-party reimbursement and coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. In addition, any companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to any companion diagnostics.

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of pharmaceuticals have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

A primary trend in the United States healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for medical products, government control and other changes to the healthcare system in the United States.

In March 2010, the United States Congress enacted the ACA, which, among other things, includes changes to the coverage and payment for products under government healthcare programs. Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2012 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which will remain in effect through 2031 pursuant to the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act").

The American Taxpayer Relief Act of 2012, which was enacted in January 2013, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers, and cancer treatment centers, 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 such product candidate is prescribed or used. Indeed, under current legislation, the actual reductions in Medicare payments may vary up to 4%.

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. For example, with enactment of the Tax Cuts and Jobs Act of 2017, which was signed by President Trump on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. On June 17, 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. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

Pharmaceutical Prices

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been 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 addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program ("SIP") to import certain prescription products from Canada into the United States. That regulation was challenged in a lawsuit by 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 number of states have submitted SIP proposals to the FDA with the goal of obtaining authority to import drugs from Canada, subject to conditions. On January 5, 2024, the FDA approved Florida's plan for Canadian product importation. That state now has authority to import certain products 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 product selected for importation, which must be approved by the FDA. The state will also need to relabel the products 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 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 final rule would eliminate the current safe harbor for Medicare drug rebates and create new safe harbors for beneficiary point-of-sale discounts and pharmacy benefit manager service fees. It originally was set to go into effect on January 1, 2022, but with passage of the Inflation Reduction Act of 2022 ("IRA"), it has been delayed by Congress to January 1, 2032.

On August 16, 2022, the IRA was signed into law by President Biden. The new legislation 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. Among other things, the IRA requires manufacturers of certain products to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap and it replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). In addition, 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 issuance of its 2025 Physician Fee Schedule final regulation, CMS finalized its rules governing the IRA inflation rebate programs. The IRA permits the Secretary of the Department of 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 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 products paid for by Medicare Part D starting in 2026, followed by 15 Medicare Part D products in 2027, 15 Medicare Part B or Part D products in 2028, and 20 Medicare Part B or Part D products in 2029 and beyond. This provision applies to products that have been approved for at least 9 years and biologics that have been licensed for 13 years. Drugs and biologics that have been approved for a single rare disease or condition were originally categorically excluded from price negotiation but, with passage of the One Big Beautiful Bill Act on July 3, 2025, Congress extended this exemption to drugs and biologics with multiple orphan drug designations.

Further, the legislation subjects 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 legislation also requires manufacturers to pay rebates for products in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out-of-pocket costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year.

The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023 with the negotiated prices for ten selected drug products becoming effective on January 1, 2026. The second cycle of negotiations with participating drug companies occurred during 2025, and the negotiated prices for this second set of 15 drugs will become effective on January 1, 2027. The second cycle of negotiations with participating drug companies occurred during 2025, and the negotiated prices for this second set of 15 drugs will be effective starting January 1, 2027. On January 27, 2026, CMS published the list of 15 drugs selected for the third cycle of negotiations. These negotiated prices will become effective on January 1, 2028.

On June 6, 2023, Merck & Co. filed a lawsuit against the 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, a number of other parties also filed lawsuits in various courts with similar constitutional claims against the HHS and CMS. We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results.

Since adoption of the IRA, the Trump Administration has taken a number of actions to reduce the costs of pharmaceutical products. For example, on April 15, 2025, President Trump issued an Executive Order which directs HHS to take steps to reduce the prices of pharmaceutical products. Further, on May 12, 2025, President Trump issued an additional Executive Order calling on pharmaceutical manufacturers to voluntarily reduce the prices of medicines in the United States. The Executive Order provides that if such actions do not lower the costs of pharmaceuticals, the Secretary of HHS would pursue other actions, including proposing a rulemaking that imposes most-favored-nation ("MFN") pricing in the United States. Thereafter, on July 31, 2025, President Trump issued letters to 17 pharmaceutical companies reiterating the requirements of the May 12, 2025, Executive Order and demanding that such companies extend MFN pricing to Medicaid patients. Virtually all of these pharmaceutical companies have entered into agreements with the administration to provide for lower prices on certain pharmaceuticals. On February 5, 2026, President Trump launched TrumpRx.gov, a website that directs individuals to pharmaceutical manufacturer websites that are offering price discounts based on the administration's pricing agreements with pharmaceutical manufacturers.

Separately, on December 23, 2025, CMS, through its Center for Medicare and Medicaid Innovation, proposed two five-year pilot programs to implement a "reference pricing" regime for drugs paid for under Medicare for 25% of covered beneficiaries. The programs are referred to as the Global Benchmark for Efficient Drug Pricing (GLOBE) Model for Medicare Part B drugs, and the Guarding U.S. Medicare Against Rising Drug Costs for Medicare Part D drugs. Under the proposed pilot programs, a manufacturer would owe rebates to Medicare if prices for their drugs exceeded the prices paid by other economically comparable reference countries, defined in the proposed regulations as Organization for Economic Co-operation and Development ("OECD"), with a gross domestic product ("GDP") of $400 billion and a per capita GDP that is at least 60% of the U.S. per capita GDP (an initial list of 19 reference countries is included in the proposed rule). These pilot programs are proposed to go into effect beginning October 1, 2026.

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. A number of states, for example, require pharmaceutical manufacturers and other entities in the supply chain, including health carriers, pharmacy benefit managers, wholesale distributors, to disclose information about pricing of pharmaceuticals. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products, and which suppliers will be included in their prescription product and other healthcare 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 may be 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.

Approval and Regulation of Medicinal Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety, and efficacy, and governing, among other things, clinical trials, marketing authorization, commercial sales, and distribution of products. Whether or not it obtains FDA approval for a product, a sponsor will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the European Union generally follows the same lines as in the United States. It entails satisfactory completion of preclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication. It also requires the submission to the relevant competent authorities of a marketing authorization application ("MAA") and granting of a marketing authorization by these authorities before the product can be marketed and sold in the European Union.

Preclinical Studies

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of good laboratory practice (GLP) as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products - e.g., radio-pharmaceutical precursors for radio-labeling purposes). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical Trials

On January 31, 2022, the new Clinical Trials Regulation (EU) No 536/2014 ("CTR") became effective in the EU and replaced the prior Clinical Trials Directive 2001/20/EC. The new regulation aims at simplifying and streamlining the authorization, conduct and transparency of clinical trials in the EU. Under the new coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial to be conducted in more than one Member State of the European Union ("European Union Member State") will only be required to submit a single application for approval. The submission will be made through the Clinical Trials Information System, a clinical trials portal overseen by the European Medicines Agency ("EMA") and available to clinical trial sponsors, competent authorities of the EU Member States and the public.

The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the "EU Portal and Database"; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the appointed reporting Member State, whose assessment report is submitted for review by the sponsor and all other competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted or concerned member states. Part II is assessed separately by each concerned member state. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned member state. However, overall related timelines will be defined by the Clinical Trials Regulation.

As of January 31, 2025, all clinical trials (including those which are ongoing) are subject to the provisions of the CTR. The failure to transition ongoing clinical trials to the CTR can result in corrective measures under Article 77 of the CTR, including revocation of the authorization of the clinical trial or suspension of the clinical trial as well as criminal sanctions and fines under national law of EU Member States.

As in the United States, sponsors conducting certain clinical studies in the EU must submit and make public clinical trial information through the Clinical Trials Information System (CTIS), which has replaced EudraCT under the CTR.

Marketing Authorization

To obtain a marketing authorization for a product under the European Union regulatory system, a sponsor must submit an MAA, either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in European Union Member States (decentralized procedure, national procedure, or mutual recognition procedure). A marketing authorization may be granted only to a sponsor established in the European Union. Regulation (EC) No 1901/2006 provides that prior to obtaining a marketing authorization in the European Union, a sponsor must demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan ("PIP") covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, class waiver, or a deferral for one or more of the measures included in the PIP.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union Member States. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional. Manufacturers must demonstrate the quality, safety, and efficacy of their products to the EMA, which provides an opinion regarding the MAA. The European Commission grants or refuses marketing authorization in light of the opinion delivered by the EMA.

The Committee for Medicinal Products for Human Use ("CHMP"), was established at the EMA and plays a vital role in the authorization of medicines in the European Union. The CHMP provides scientific advice to sponsors investigating and developing new medicines, prepares scientific guidelines and regulatory guidance to help sponsors prepare MAAs, and cooperates with international partners on the harmonization of regulatory requirements. With respect to MAAs filed under the centralized procedure, the CHMP is responsible for conducting an initial assessment of a product candidate and the data supporting approval of the MAA. On the basis of its review, the CHMP provides a scientific opinion on whether or not an MA should be granted for a product candidate.

Conditional Marketing Authorization

In particular circumstances, EU legislation (Article 14-a Regulation (EC) No 726/2004 (as amended by Regulation (EU) 2019/5 and Regulation (EC) No 507/2006 on Conditional Marketing Authorizations for Medicinal Products for Human Use) enables sponsors to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization ("MA"). Such conditional approvals may be granted for product candidates (including medicines designated as orphan medicinal products) if (1) the product candidate is intended for the treatment, prevention or medical diagnosis of seriously debilitating or life-threatening diseases; (2) the product candidate is intended to meet unmet medical needs of patients; (3) a marketing authorization may be granted prior to submission of comprehensive clinical data provided that the benefit of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required; (4) the risk-benefit balance of the product candidate is positive, and (5) it is likely that the sponsor will be in a position to provide the required comprehensive clinical trial data. A conditional MA may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new clinical trials and with respect to the collection of pharmacovigilance data. Conditional MAs are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional MA.

Exceptional Circumstances

An MA may also be granted "under exceptional circumstances" when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. This may arise in particular when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This MA is close to the conditional MA as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a MA. However, unlike the conditional MA, the applicant does not have to provide the missing data and will never have to. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA is withdrawn in case the risk-benefit ratio is no longer favorable. Under these procedures, before granting the MA, the EMA or the competent authorities of the member states make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety, and efficacy. Except conditional MAs, MAs have an initial duration of five years. After these five years, the authorization may be renewed on the basis of a reevaluation of the risk-benefit balance.

Pediatric Studies

Prior to obtaining a marketing authorization in the European Union, sponsors have to demonstrate compliance with all measures included in an EMA-approved PIP covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver or a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are set forth in Regulation (EC) No 1901/2006, which is referred to as the Pediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The Pediatric Committee of the EMA ("PDCO") may grant deferrals for some medicines,

allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine in children is not needed or is not appropriate because (a) the product is likely to be ineffective or unsafe in part or all of the pediatric population; (b) the disease or condition occurs only in adult population; or (c) the product does not represent a significant therapeutic benefit over existing treatments for pediatric population. Before a marketing authorization application can be filed, or an existing marketing authorization can be amended, the EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP.

Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a reevaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To that end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the drug on the European Union market (in the case of the centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid.

Regulatory Requirements after Marketing Authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include compliance with the European Union's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. In addition, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's good manufacturing practice requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities, and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union under Directive 2001/83EC, as amended.

Regulatory exclusivity

In the European Union, new products authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic sponsors from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic marketing authorization in the European Union during a period of eight years from the date on which the reference product was first authorized in the European Union. The market exclusivity period prevents a successful generic sponsor from commercializing its product in the European Union until ten years have elapsed from the initial authorization of the reference product in the European Union. The ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

In November 2020, the European Commission launched a review of the European Union's pharmaceutical legislation, including its provisions governing regulatory exclusivity. The European Commission's proposal for revision of several legislative measures was published in April 2023 and includes, among other things, provisions that would potentially reduce the duration of regulatory exclusivity protection. On December 11, 2025, the European Parliament and Council reached a provisional political agreement on the legislation, which is expected to be adopted by mid-2026. Key changes include updating regulatory exclusivity to a new system with eight years of data exclusivity and a reduced market exclusivity period to one year, which can be extended if specific conditions are fulfilled up to a maximum of 11 years. This measure, and others, are expected to be adopted by mid-2026 and, following a transition period of 24 months, will likely take effect in mid-2028.

Orphan Drug Designation and Exclusivity

Regulation (EC) No 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (1) a life‑threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Union when

the application is made, or (2) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment. For either of these conditions, the sponsor must 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 drug will be of significant benefit to those affected by that condition.

An orphan drug designation provides a number of benefits, including fee reductions, regulatory assistance, and the possibility to apply for a centralized European Union marketing authorization. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. During this market exclusivity period, neither the EMA nor the European Commission or the member states can accept an application or grant a marketing authorization for a "similar medicinal product." A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation because, for example, the product is sufficiently profitable not to justify market exclusivity.

Pediatric exclusivity

If a sponsor obtains a marketing authorization in all European Union Member States, or a marketing authorization granted in the centralized procedure by the European Commission, and the trial results for the pediatric population are included in the product information, even when negative, the medicine is then eligible for an additional six-month period of qualifying patent protection through extension of the term of the Supplementary Protection Certificate ("SPC"), or alternatively a one year extension of the regulatory market exclusivity from ten to eleven years, as selected by the marketing authorization holder. *Patent Term Extensions in the European Union and Other Jurisdictions*

The European Union also provides for patent term extension through Supplementary Protection Certificates ("SPCs"). The rules and requirements for obtaining an SPC are similar to those in the United States. An SPC may extend the term of a patent for up to five years after its originally scheduled expiration date and can provide up to a maximum of fifteen years of marketing exclusivity for a drug. In certain circumstances, these periods may be extended for six additional months if pediatric exclusivity is obtained, which is described in detail below. Although SPCs are available throughout the European Union, sponsors must apply on a country-by-country basis. Similar patent term extension rights exist in certain other foreign jurisdictions outside the European Union.

General Data Protection Regulation

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the European Union General Data Protection Regulation ("GDPR"), which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR will be a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance.

In July 2020, the Court of Justice of the European Union (the "CJEU") invalidated the EU-U.S. Privacy Shield framework, one of the mechanisms used to legitimize the transfer of personal data from the European Economic Area ("EEA") to the United States. The CJEU decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the United States. Following the July 2020 Court of Justice of the EU judgement invalidating the so-called EU-U.S. Privacy Shield, the EC adopted an adequacy decision for the EU-U.S. Data Privacy Framework in July 2023. This adequacy decision permits U.S. companies who self-certify under the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the EU to the United States. However, some privacy advocacy groups have already suggested that they will be challenging the EU-U.S. Data Privacy Framework, and there is currently one pending litigation against the EU-U.S. Data Privacy Framework before the Court of Justice of the EU (CJEU), C-703/25 P – Latombe v Commission. 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 so-called standard contractual clauses and other data transfer mechanisms.

Following the CJEU decision, in October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which would serve as a replacement to the EU-US Privacy Shield. The European Union initiated the process to adopt an adequacy decision for the EU-U.S. Data Privacy Framework in December 2022, and the European Commission adopted the adequacy decision in July 2023. The adequacy decision permits United States 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.

Reimbursement and Pricing

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its Member States to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Member States may approve a specific price for a product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage health care expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the Europe Union. The downward pressure on health care costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various Member States, and parallel trade, i.e., arbitrage between low-priced and high-priced Member States, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

Healthcare Reform

In the European Union, similar political, economic, and regulatory developments to those in the United States may affect our ability to profitably commercialize our product candidates, if approved. In many countries, including those of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of a marketing approval for a product. To obtain reimbursement or pricing approval in some countries, pharmaceutical firms may be required to conduct a clinical trial that compares the cost-effectiveness of the product to other available therapies. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could restrict or regulate post-approval activities and affect the ability of pharmaceutical companies to commercialize their products. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

Potential reductions in prices and changes in reimbursement levels could be the result of different factors, including reference pricing used by various European Union member states, and parallel distribution and parallel trade can further reduce prices. It could also result from the application of external reference pricing mechanisms, which consist of arbitrage between low-priced and high-priced member states). There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any product candidates, if approved in those countries.

A health technology assessment ("HTA") of medicinal products in the European Union is an essential element of the pricing and reimbursement decision-making process in a number of European Union member states. The outcome of HTA has a direct impact on the pricing and reimbursement status granted to the medicinal product. A negative HTA by a leading and recognized HTA body concerning a medicinal product could undermine the prospects to obtain reimbursement for such product not only in the European Union member state in which the negative assessment was issued, but also in other European Union member states.

In 2011, Directive 2011/24/EU was adopted at the European Union level. This Directive establishes a voluntary network of national authorities or bodies responsible for HTA in the individual European Union member states. The network facilitates and supports the exchange of scientific information concerning HTAs. Further to this, on December 13, 2021, Regulation No 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. The Regulation intends to boost cooperation among European Union member states in assessing health technologies, including new medicinal products as well as certain high-risk medical devices, and provide the basis for cooperation at the European Union level for joint clinical assessments in these areas. It will permit European Union member states to use common HTA tools, methodologies, and procedures across the European Union, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual European Union member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

Review, Approval and Regulation of Medical Products in the United Kingdom

As of January 1, 2025, the Medicines and Healthcare Products Regulatory Agency (the "MHRA"), became responsible for approving all medicinal products destined for the United Kingdom market (Great Britain and Northern Ireland). The MHRA relies on the Human Medicines Regulations 2012 (SI 2012/1916) (as amended, the "HMR"), as the basis for regulating medicines. The HMR has incorporated into the domestic law the body of European Union law instruments governing medicinal products that existed prior to the United Kingdom's withdrawal from the European Union. On April 28, 2025, the U.K. Parliament adopted amendments to improve and strengthen the clinical trials regulatory regime in the United Kingdom. These revisions will take effect on April 28, 2026, and were needed to replace the prior requirements in the United Kingdom that were based on the repealed Clinical Trials Directive 2001/20/EC, which has been replaced by the Clinical Trials Regulation (EU) No 536/2014.As of January 1, 2024 on, an international recognition procedure ("IRP"), applies in the United Kingdom which is designed to facilitate approval of pharmaceutical products in the United Kingdom. The IRP is open to sponsors that have already received an authorization for the same product from one of the MHRA's specified Reference Regulators ("RRs"). The RRs notably include EMA and regulators in the EEA member states for approvals in the EU centralized procedure and mutual recognition procedure as well as the FDA (for product approvals granted in the U.S.). The RR assessment must have undergone a full and standalone review. RR assessments based on reliance or recognition cannot be used to support an IRP application. A CHMP positive opinion is an RR authorization for the purposes of IRP.

Following the withdrawal of the United Kingdom from the European Union, the U.K. Data Protection Act applies to the processing of personal data that takes place in the United Kingdom and includes parallel obligations to those set forth by GDPR. The United Kingdom government has determined that it considers all EU Member States and EEA member states to be adequate for the purposes of data protection, ensuring that data flows from the United Kingdom to the EU/EEA remain unaffected. Further, the European Commission decided in June 2021 that the level of data protection in the United Kingdom is "essentially adequate" for purposes of data transfer from the European Union to the United Kingdom. On December 19, 2025, the European Commission renewed this decision until December 27, 2031. The United Kingdom and the United States have also agreed to a U.S.- U.K. "Data Bridge," which functions similarly to the EU-U.S. Data Privacy Framework and provides an additional legal mechanism for companies to transfer personal data from the United Kingdom to the United States.

Employees and Human Capital Resources

As of December 31, 2025, we had twenty employees, all of whom were full-time and eleven of whom were engaged in research and development activities. Two of our employees hold Ph.D. or M.D. degrees. None of our employees are represented by a labor union or covered under a collective bargaining agreement. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Corporate Information

We were formed on August 16, 2013 as a Delaware limited liability company under the name AdCyte LLC and on July 29, 2014 we changed our name to ViraCyte LLC. On September 17, 2018, we converted from a Delaware LLC to a Delaware corporation and changed our name to ViraCyte, Inc. On May 22, 2019, we changed our name to AlloVir, Inc. On March 18, 2025, we consummated the previously announced Merger, pursuant to the terms of the Agreement and Plan of Merger, dated as of November 7, 2024, by and among us, Merger Sub and Legacy Kalaris. At the effective time of the Merger (the "Effective Time"), Merger Sub merged with and into Legacy Kalaris, with Legacy Kalaris continuing as our wholly-owned subsidiary and the surviving corporation of the Merger and, after giving effect to the Merger, Legacy Kalaris became our wholly-owned subsidiary. Immediately following the Effective Time, we changed our name to "Kalaris Therapeutics, Inc."

Our principal executive offices are located at 400 Connell Drive, Suite 5500, Berkeley Heights, NJ 07922, and our telephone number is (650) 249-2727. Our website address is www.kalaristx.com. 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 Securities and Exchange Commission (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 & Press," 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, including our financial statements and the related notes included in this Annual Report, 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. In addition, references to past events are provided by way of example only and are not intended to be a complete listing or a representation as to whether or not such factors have occurred in the past or their likelihood of occurring in the future.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception. We expect to continue to incur significant expenses and operating losses for the foreseeable future, and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses. Our net losses were $43.4 million and $69.2 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had cash, cash equivalents and short-term marketable securities of $118.0 million and an accumulated deficit of $160.0 million.

We do not have any products approved for sale and have not generated any revenue from product sales or otherwise. To date, we have funded our operations primarily from sales of redeemable convertible preferred stock, issuances of convertible promissory notes and a SAFE, cash and cash equivalents of AlloVir received in the Merger and proceeds from sales of our common stock and pre-funded warrants in a private placement for aggregate gross proceeds of approximately $50.0 million in December 2025 (the "2025 Private Placement"). We have devoted substantially all of our resources to organizing and staffing, business planning, raising capital, acquiring our technology, establishing our intellectual property portfolio and performing research and development of our product candidate. We are in the early stages of development of our lead product candidate, TH103. We received investigational new drug ("IND") clearance for TH103 for the treatment of patients with neovascular, or wet, age-related macular degeneration ("nAMD"), in June 2024 and, in August 2024, we treated the first patient in our Phase 1a open-label clinical trial to investigate the safety, tolerability, dose range and pharmacokinetic profile or intravitreal injection of TH103 in patients with nAMD. We announced positive initial data from our Phase 1a SAD trial of TH103 in December 2025. We are also conducting a Phase 1b/2 multiple ascending dose, dose-finding study intended to assess safety and efficacy in patients with nAMD receiving four initial monthly loading doses of TH103, which is intended to build upon our ongoing Phase 1a clinical trial and to inform the optimal dose and regimen for potential Phase 3 development. The Phase 1b/2 dose-finding trial is designed to evaluate multiple dose levels of TH103 in approximately 60 to 80 nAMD patients.

We expect to continue to incur significant expenses and operating losses for the foreseeable future, including costs associated with operating as a public company. We anticipate that our expenses will increase substantially if and as we:

- conduct our ongoing Phase 1a and Phase 1b/2 clinical trials of TH103 in patients with nAMD;
- continue to progress the development of TH103 in future preclinical studies and clinical trials;
- advance any future product candidate that we may develop into preclinical and clinical development;
- maintain, expand, enforce and protect our intellectual property portfolio;
- seek regulatory and marketing approvals for TH103 and any other product candidate that successfully completes clinical trials;
- seek to identify and maintain additional collaborations and license agreements, and the success of those collaborations and license agreements;
- make any payments under our existing or future strategic collaboration agreements, licensing agreements or sponsored research agreements, including with the University of California, San Diego ("UCSD");
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval;
- generate revenue from commercial sales of product candidates that may receive marketing approval;
- hire additional clinical, regulatory, manufacturing, quality control, development and scientific personnel;
- in-license or acquire additional technologies or product candidates;

- establish a commercial manufacturing source and secure supply chain capacity sufficient to provide commercial quantities of any product candidates we may develop for which we obtain regulatory approval; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts and our operations as a public company.

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 or maintain profitability.

Our expenses could increase beyond our expectations, if, among other things:

- we are required by regulatory authorities in the United States, Europe, or other jurisdictions to perform trials or studies in addition to, or different than, those that we currently expect;
- there are any delays in establishing appropriate manufacturing arrangements for or completing the development of TH103 or any other product candidate we may develop; or
- there are any third-party challenges to our intellectual property or we need to defend against any intellectual property-related claim.

Even if we obtain marketing approval for and are successful in commercializing one or more product candidates, we expect to incur substantial additional product development and other expenditures to develop and market additional product candidates or to expand the approved indications of any marketed product. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

We have never generated revenue from product sales and may never achieve or maintain profitability.

We initiated clinical development of our lead product candidate, TH103, in June 2024, and expect that it will be many years, if ever, before we have a product candidate ready for commercialization. To become and remain profitable, we must succeed in completing development of, obtaining marketing approval for and eventually commercializing, one or more products that generate significant revenue. The ability to achieve this success will require us to be effective in a range of challenging activities, including:

- completing preclinical and clinical trials;
- identifying additional product candidates;
- obtaining marketing approval for these product candidates;
- manufacturing, marketing and selling any products for which we may obtain marketing approval; and
- achieving market acceptance of products for which we may obtain marketing approval as viable treatment options.

We may never succeed in these activities and, even if we do, we may never generate revenues that are significant enough to achieve profitability. Even if we 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 depress the value of our company and could impair our ability to raise capital, expand our business, maintain our product development efforts, diversify our pipeline or even continue our operations.

We are heavily dependent on the success of our lead product candidate, TH103, which will require significant clinical testing before we can seek marketing approval and potentially generate commercial sales. If TH103 does not receive marketing approval or is not successfully commercialized, or if there is significant delay in doing so, our business will be harmed.

We only recently initiated our first clinical trial, have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures for the foreseeable future will be devoted to TH103. Our business currently depends heavily on the successful development, marketing approval and commercialization of TH103. We cannot be certain that TH103 will achieve success in ongoing or future clinical trials, receive marketing approval or be successfully commercialized.

If we were required to discontinue development of TH103, or if TH103 does not receive marketing approval for one or more of the indications we pursue, fails to achieve significant market acceptance, or fails to receive adequate reimbursement, we may be delayed by many years in our ability to achieve profitability, if ever, and may not be able to generate sufficient revenue to continue our business.

We will need substantial additional funding for our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect to devote substantial financial resources to our ongoing and planned activities, particularly as we conduct our ongoing clinical trials of TH103; prepare for future preclinical studies and clinical trials of TH103; prepare for, initiate and conduct preclinical studies and clinical trials of other product candidates we may develop; and potentially seek marketing approval for any of the product candidates we may develop. We expect our expenses to increase substantially over time in connection with our ongoing and planned activities, particularly as we advance our preclinical activities and our ongoing and planned clinical trials. In addition, if we obtain marketing approval for TH103 or any other product candidate we may develop, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise additional capital or obtain adequate funds when needed or on acceptable terms, we may be required to delay, limit, reduce or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and distract from our product development efforts.

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

- the progress, costs and results of our ongoing Phase 1a and Phase 1b/2 clinical trials of TH103 and future preclinical studies and clinical trials of TH103;
- the scope, progress, costs and results of preclinical and clinical development for any product candidates we may develop;
- the success of any collaborations with third parties;
- our ability to scale up our manufacturing processes and capabilities to support clinical trials of TH103 and other product candidates we may develop;
- the costs, timing and outcome of regulatory review of TH103 and other product candidates we may develop;
- potential changes in the regulatory environment and enforcement rules;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the payment of license fees and other costs of our technology license arrangements;
- the costs and timing of future commercialization activities, including product manufacturing, sales, marketing and distribution, for TH103 and other product candidates we may develop for which we may receive marketing approval;
- our ability to obtain and maintain acceptance of any approved products by patients, the medical community and third-party payors;
- the amount and timing of revenue, if any, received from commercial sales of TH103 and any other product candidates we may develop for which we receive marketing approval;
- potential changes in pharmaceutical pricing and reimbursement infrastructure;
- the availability of raw materials for use in production of our product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property-related claims; and
- the extent to which we in-license or acquire additional technologies or product candidates.

As of December 31, 2025, we had cash, cash equivalents and short-term marketable securities of $118.0 million. Based on our current operating plans, our management expects that our cash, cash equivalents and short-term marketable securities as of December 31, 2025 will be sufficient to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2027. However, we have based these estimates on assumptions that may prove to be wrong, and our operating plans may change as a result of many factors currently unknown to us. In addition, changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. As a result, we could deplete our capital resources sooner than we currently expect. In addition, because the successful development of TH103 or other product candidates that we may pursue is highly uncertain, at this time we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the development of any product candidate.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. We will not generate commercial revenues unless and until we can achieve sales of products, which we do not anticipate for a number of years, if at all. Accordingly, we will need to obtain substantial additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all, and we may be impacted by the economic climate and market conditions. For example, market volatility resulting from general United States or global economic or market conditions, including related to any health epidemics, pandemics or other contagious outbreaks could also adversely impact our ability to access capital as and when needed. Alternatively, we may seek 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.

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 significant revenues from product sales, we expect to finance our operations through a combination of public or private equity offerings or debt financings, or potentially other capital sources, such as collaboration or licensing arrangements with third parties or other strategic transactions. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders'. Any debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our assets, making capital expenditures, declaring dividends or encumbering our assets to secure future indebtedness.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, 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 or other arrangements when needed or on terms acceptable to us, we would be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Legacy Kalaris was incorporated and commenced operations in 2019. We are a clinical stage company with a limited operating history. Our operations to date have been limited to organizing and staffing, business planning, raising capital, acquiring our technology, establishing our intellectual property portfolio and performing research and development of our product candidate. Our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in their early-stages of operations. We have not yet demonstrated our ability to successfully develop any product candidate, obtain marketing approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing, obtaining marketing approval for and commercializing products.

In addition, as our business grows, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown obstacles. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. As we continue to build our business, 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.

We have identified material weaknesses in our internal control over financial reporting and we may identify additional material weaknesses in the future or fail to maintain an effective system of internal control over financial reporting, which may result in material misstatements of our financial statements.

We have identified material weaknesses in our internal control over financial reporting as of December 31, 2024 which remain unremediated as of December 31, 2025. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements would not be prevented or detected on a timely basis.

We did not fully maintain components of the Committee of Sponsoring Organizations of the Treadway Commission framework, including elements of the control environment, risk assessment, monitoring activities, information and communication, and control activities components, relating to: (i) our commitment to attract, develop, and retain competent individuals; (ii) identifying, assessing, and communicating appropriate objectives, (iii) identifying and analyzing risks to achieve these objectives; (iv) selecting, developing, and performing ongoing evaluations to ascertain whether the components of internal controls are present and functioning; (v) communicating accurate information internally and externally, including providing information pursuant to objectives, responsibilities, and functions of internal control; (vi) selecting and developing control activities that contribute to the mitigation of risks and support achievement of objectives and (vii) deploying control activities through policies that establish what is expected and procedures that put policies into action.

These material weaknesses could result in a misstatement of substantially all of our accounts or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected. We have begun taking measures, and plan to continue to take measures, to remediate these material weaknesses. We actively recruited additional accounting personnel with appropriate experience, certification, education and training. For example, following the closing of the Merger, AlloVir's Chief Accounting Officer serves as our Chief Accounting Officer, and AlloVir's Controller serves as our Controller. In addition, in April 2025, we appointed a new member to our board of directors, who was also appointed as chair of the audit committee of the board of directors and was deemed to be an audit committee financial expert by our board of directors. Additionally, in October 2025, we hired our Chief Financial Officer. We are in the process of implementing additional measures and risk assessment procedures designed to improve our disclosure controls and procedures and internal control over financial reporting to address the underlying causes of these material weaknesses, including the implementation of appropriate segregation of duties, formalization of accounting policies and controls, and implementation of accounting systems to automate manual processes. We have engaged financial consultants to assist with the implementation of internal controls over financial reporting. To the extent that we are not able to hire and retain such individuals or are unable to successfully design and implement such controls, the material weaknesses identified may not be remediated and management may be required to record additional adjustments to our financial statements in the future or otherwise not be able to produce timely or accurate financial statements. The material weaknesses will not be considered remediated until management completes the design and implementation of the measures described above, the controls operate for a sufficient period of time, and management has concluded, through testing, that these controls are effective. These remediation measures will be time-consuming and require financial and operational resources. If our management concludes that our internal control over financial reporting is not effective, such a determination could adversely affect investor confidence in us and the valuation of our common stock.

While we are implementing measures to remediate the material weaknesses, we cannot predict the success of such measures or the outcome of our assessment of these measures at this time. We can give no assurance that these measures will remediate the deficiencies in internal control over financial reporting or that additional material weaknesses or significant deficiencies in our internal control over financial reporting will not be identified in the future. Our failure to implement and maintain effective internal control over financial reporting could result in errors in our financial statements that may lead to a restatement of our financial statements or cause us to fail to meet our reporting obligations.

Our ability to use our net operating loss carryforwards ("NOLs") and research and development tax credit carryforwards to offset future taxable income may be subject to certain limitations.

We have a history of cumulative losses and we anticipate that we will continue to incur significant losses in the foreseeable future. As a result, we do not know whether or when we will generate taxable income necessary to utilize our NOLs or research and development tax credit carryforwards. As of December 31, 2025, Kalaris had federal and state NOLs of $83.9 million and $27.4 million, respectively, and federal and state research and development tax credit carryforwards totaling $1.7 million and $0.9 million, respectively.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended and corresponding provisions of state law, a corporation that undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, is subject to limitations on its ability to utilize its pre-change NOLs and research and development tax credit carryforwards to offset future taxable income. Legacy Kalaris experienced an ownership change in March 2022 related to a redeemable convertible preferred stock financing. Net operating loss of $3.6 million generated prior to the 2022 change in ownership will be permanently limited for California tax purposes. Net federal operating losses are not limited as they can be carried forward indefinitely. We may experience ownership changes in the future (which may be outside our control). As a result, if and to the extent we earn net taxable income, our ability to use our pre-change NOLs and research and development tax credit carryforwards to offset such taxable income may be subject to limitations.

Risks Related to Research and Development of Our Product Candidates

We are early in our development efforts. If we are unable to commercialize TH103 or any product candidate we may develop or experience significant delays in doing so, our business will be materially harmed.

We are early in our development efforts. We received IND clearance for TH103 for the treatment of patients with nAMD in June 2024 and, in August 2024, we treated the first patient in our Phase 1a clinical trial of TH103 for patients with nAMD. In December 2025, we announced positive initial data from our Phase 1a SAD trial of TH103. Our ability to generate revenues from product sales, which we do not expect will occur for many years, if ever, will depend heavily on the successful development, marketing approval and eventual commercialization of TH103 or one or more other product candidates, which may never occur. The success of TH103 and any other product candidate we may develop will depend on many factors, including the following:

- successfully completing preclinical studies;
- successfully enrolling patients in our clinical trials of TH103 and completing the clinical trials;
- successfully initiating and completing future clinical trials;
- scaling up manufacturing processes and capabilities to support clinical trials of TH103 and any other product candidate we may develop;
- applying for and receiving marketing approvals from applicable regulatory authorities;
- obtaining and maintaining intellectual property protection and regulatory exclusivity for TH103 and any other product candidates we may develop;
- making arrangements with third-party manufacturers, or establishing commercial manufacturing capabilities, for both clinical and commercial supplies of our product candidates;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of TH103 and any other product candidate we may develop, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;
- maintaining, enforcing, defending and protecting our rights in our intellectual property portfolio;
- not infringing, misappropriating or otherwise violating others' intellectual property or proprietary rights; and
- maintaining a continued acceptable safety profile of our products following receipt of any marketing approvals.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize TH103 and any other product candidate we may develop, which would materially harm our business. As a company, we have limited experience in clinical development. Any predictions about the future success or viability of TH103 or any product candidates we may develop in the future may not be as accurate as they could be if we had a history of conducting clinical trials.

Drug development involves a lengthy and expensive process, with an uncertain outcome. The results of preclinical studies and early clinical trials may not be predictive of future results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of TH103 or any other product candidate we may develop.

The risk of failure for TH103 and any other product candidate we may develop is high. It is impossible to predict when or if TH103 or any other product candidate we may develop will prove effective or safe in humans or will receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of a product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of such product candidate in humans. Clinical trials may fail to demonstrate that TH103 or any of our other product candidates are safe for humans and effective for indicated uses. Even if the clinical trials are successful, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application for marketing approval.

Before we can commence clinical trials for any product candidate we may develop other than TH103, we must complete extensive preclinical testing and studies, manufacturing process development studies, and analytical development studies that support our planned INDs and other applications to regulatory authorities in the United States or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the outcome of our preclinical testing and studies will ultimately support the further development of our current or future product candidates or whether regulatory authorities will accept our proposed clinical programs. In addition, before we can commence clinical trials of TH103 for Diabetic Macular Edema, diabetic retinopathy, and Retinal Vein Occlusion, or any other intraocular indication, we must submit and clear INDs for the applicable indications in the United States or similar applications in other jurisdictions. As a result, we may not be able to submit applications to initiate clinical development of product candidates on the timelines we expect, if at all, and the submission of these applications may not result in regulatory authorities allowing clinical trials to begin. Furthermore, product candidates are subject to continued preclinical safety studies, which may be conducted concurrently with our clinical testing. The outcomes of these safety studies may delay the launch of or enrollment in future clinical trials and could impact our ability to continue to conduct our clinical trials.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to the outcome. We cannot guarantee that any of our clinical trials will be conducted as planned or completed on schedule, or at all. A failure of one or more clinical trials can occur at any stage of testing, which may result from a multitude of factors, including, among other things, flaws in study design, dose selection issues, placebo effects, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Furthermore, the failure of TH103 or any other product candidate we may develop to demonstrate safety and efficacy in any clinical trial could negatively impact the perception of our other product candidates or cause regulatory authorities to require additional testing before approving any of our product candidates.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize any product candidates, including:

- regulators or institutional review boards (“IRBs”) may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or at all;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- regulators may determine that the planned design of our clinical trials is flawed or inadequate;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- we may be unable to establish clinical endpoints that applicable regulatory authorities consider clinically meaningful;
- preclinical testing may produce results based on which we may decide, or regulators may require us, to conduct additional preclinical studies before we proceed with certain clinical trials, limit the scope of our clinical trials, halt ongoing clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may decide, or regulators or IRBs may require us, to suspend or terminate clinical trials of our product candidates for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- regulators or IRBs may require us to perform additional or unanticipated clinical trials to obtain approval or we may be subject to additional post-marketing testing requirements to maintain marketing approval;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate;
- the cost of clinical trials of our product candidates may be greater than we anticipate;

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our clinical investigators, regulators or IRBs to suspend or terminate the trials;
- regulators may withdraw their approval of a product or impose restrictions on our distribution; and
- business interruptions resulting from any health epidemics, pandemics or other contagious outbreaks may result in adverse effects on our business and operations.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive, if there are safety concerns or if we determine that the observed safety or efficacy profile would not be competitive in the marketplace, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval;
- not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in preclinical studies or clinical trials or in obtaining marketing or other regulatory approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. We may also determine to change the design or protocol of one or more of our clinical trials, including to add additional patients or arms, which could result in increased costs and expenses or delays. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

We may conduct clinical trials at sites outside the United States. The Food and Drug Administration (the "FDA") may not accept data from trials conducted in such locations, and the conduct of trials outside the United States could subject us to additional delays and expense.

We may conduct one or more clinical trials at trial sites that are located outside the United States. The acceptance by the FDA or other regulatory authorities of study data from clinical trials conducted outside their jurisdiction may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (1) the data are applicable to the United States population and United States medical practice; (2) the trials were performed by clinical investigators of recognized competence and pursuant to Good Clinical Practices ("GCP") regulations; and (3) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in TH103 or any other product candidate we may develop not receiving approval for commercialization in the applicable jurisdiction.

Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;
- diminished protection of intellectual property in some countries; and
- interruptions or delays in our trials resulting from geopolitical events, such as war or terrorism.

The results of early-stage clinical trials and preclinical studies may not be predictive of future results. Initial success in clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and preliminary or interim results of a clinical trial do not necessarily predict final results. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. In particular, the small number of patients in our ongoing or future early clinical trials may make the results of these trials less predictive of the outcome of later clinical trials. For example, even if successful, the results of our Phase 1b/2 clinical trial of TH103 may not be predictive of the results of further clinical trials of TH103 or any other product candidate we may develop. Our product candidates may also fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Our current or future clinical trials may not ultimately be successful or support further clinical development of any of our product candidates and we cannot assure you that any clinical trials that we may conduct will demonstrate consistent or adequate efficacy and safety to support marketing approval. There is a high failure rate for product candidates proceeding through clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials, and we cannot be certain that we will not face similar setbacks. Any such setbacks in our clinical development could materially harm our business and results of operations.

Interim and preliminary results from our clinical trials that we announce or publish from time to time may change as more participant data becomes available and are subject to audit and verification procedures, which could result in material changes in the final data.

From time to time, we may announce or publish interim or preliminary results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as participant enrollment continues and more participant data become available. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all data. Preliminary or interim results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could be material and could significantly harm our reputation and business prospects.

If we experience delays or difficulties in the enrollment of patients in our clinical trials for TH103 or any other product candidate we develop, our receipt of necessary marketing approvals could be delayed or prevented.

Identifying and qualifying patients to participate in our Phase 1a and Phase 1b/2 clinical trials for TH103 and any other product candidate we may develop is critical to our success. Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients who remain in the trial until its conclusion. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside of the United States. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as TH103, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. We cannot predict how successful we will be at enrolling subjects in future clinical trials. Patient enrollment is affected by a variety of other factors, including:

- the prevalence and severity of the disease under investigation;

- the eligibility criteria for the trial in question;
- the perceived risks and benefits of the product candidate under trial;
- the requirements of the trial protocols;
- the availability of existing FDA approved or off-label treatments for the indications for which we are conducting clinical trials;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain patient consents;
- the proximity and availability of clinical trial sites for prospective patients;
- the conduct of clinical trials by competitors for product candidates that treat the same indications or address the same patient populations as our product candidates;
- the cost to, or lack of adequate compensation for, prospective patients; and
- the impact of any health epidemics, pandemics or other contagious outbreaks

Our inability to locate and enroll a sufficient number of patients for our clinical trials would result in significant delays, could require us to abandon one or more clinical trials altogether and could delay or prevent our receipt of necessary marketing approvals. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which could cause the value of our business to decline and limit our ability to obtain additional financing.

If dose limiting toxicities, serious adverse events, undesirable side effects or unexpected characteristics are identified during the development of TH103 or any other product candidate we may develop, we may need to abandon or limit our further clinical development of those product candidates.

If TH103 or any other product candidate we may develop is associated with dose limiting toxicities, serious adverse events or undesirable side effects in clinical trials or have characteristics that are unexpected in clinical trials or preclinical testing, we may need to abandon development of such product candidate or limit development to more narrow uses or subpopulations in which the dose limiting toxicities, serious adverse events, undesirable side effects or unexpected characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. We have observed cases of intraocular inflammation ("IOI") in our Phase 1a and Phase 1b/2 clinical trials of TH103. While these cases were generally mild-to-moderate, were not considered dose-limiting, resolved or were resolving following the administration of topical and/or oral steroids, and were believed to be related to retained impurities that are a byproduct of our biologic manufacturing process, if we are unable to refine our manufacturing process or otherwise reduce the cases of IOI experienced by patients who receive TH103, the clinical development and commercial potential of TH103 may be adversely impacted. In pharmaceutical development, many compounds that initially showed promise in early-stage or clinical testing are later found to cause side effects that delay or prevent further development of the compound or decrease the size of the patient population for whom the compound could ultimately be prescribed.

Additionally, if the results of our clinical trials reveal undesirable side effects, we, regulatory authorities or the IRBs at the institutions in which our trials are conducted could suspend or terminate our clinical trials, regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications or we could be forced to materially modify the design of our clinical trials. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical trials or result in potential liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. If we elect or are forced to suspend or terminate any clinical trial of our product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate revenues from sales of such product candidate will be delayed or eliminated. Any of these occurrences could materially harm our business.

If TH103 or any other product candidate we may develop receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the drug could be compromised.

We are currently conducting a Phase 1b/2 clinical trials of TH103 for nAMD. Clinical trials will be conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of TH103 that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If TH103 or any other product candidate we may develop receives marketing approval, and we, or others, later discover that they are less effective than previously believed, or cause undesirable side effects, a number of potentially significant negative consequences could result, including:

- withdrawal or limitation by regulatory authorities of approvals of such product;
- seizure of the product by regulatory authorities;
- recall of the product;
- restrictions on the marketing of the product or the manufacturing process for any component thereof;
- requirement by regulatory authorities of additional warnings on the label;
- requirement that we implement a risk evaluation and mitigation strategy or create a medication guide outlining the risks of such side effects for distribution to patients;
- commitment to expensive post-marketing studies as a prerequisite of approval by regulatory authorities of such product;
- the product may become less competitive;
- initiation of regulatory investigations and government enforcement actions;
- initiation of legal action against us to hold it liable for harm caused to patients; and
- harm to our reputation and resulting harm to physician or patient acceptance of our products.

In particular, we are developing TH103 to be a best-in-class anti-vascular endothelial growth factor ("VEGF") therapeutic for common retinal neovascular and exudative diseases. Even if TH103 were to receive marketing approval for any such indication, it may fail to demonstrate longer acting and increased VEGF activity that results in improved real-world outcomes for patients. Any of these events could prevent us from achieving or maintaining market acceptance of a particular product candidate, if approved, and could significantly harm our business, financial condition, and results of operations.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on product candidates that we identify for specific indications. As a result, we may forego or delay the pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. We may curtail, pause, delay or cease development of product candidates at any stage of preclinical or clinical development based on a variety of factors, including our judgments regarding costs or timing of further development, probability of success of clinical development, regulatory requirements, commercial potential, relative benefits and costs and our overall corporate strategy. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on product development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Failure to allocate resources or capitalize on strategies in a successful manner will have an adverse impact on our business.

Risks Related to the Commercialization of Our Product Candidates

Even if TH103 or any other product candidate we may develop receives marketing approval, we may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, and the market opportunity for any of our product candidates, if approved, may be smaller than we estimate.

Even if TH103 or any other product candidate we may develop receives marketing approval, we may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. There is already a large and well-established market for anti-VEGF therapies for retinal diseases, and patients may continue to rely on existing FDA approved

or off-label therapies. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenues from product sales and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages of our product candidates compared to the advantages and relative risks of alternative treatments;
- the effectiveness of sales and marketing efforts;
- our ability to offer our products, if approved, for sale at competitive prices;
- the clinical indications for which the product is approved;
- the cost of treatment in relation to alternative treatments;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- the availability of third-party coverage and adequate reimbursement, and patients' willingness to pay out of pocket for required co-payments or in the absence of third-party coverage or adequate reimbursement;
- product labeling or product insert requirements of the FDA, the European Medical Agency (the "EMA") or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- the prevalence and severity of any side effects;
- support from patient advocacy groups; and
- any restrictions on the use of our products, if approved, together with other medications.

Our assessment of the potential market opportunity for our product candidates is based on industry and market data it obtained from industry publications, research, surveys and studies conducted by third parties and our analysis of these data, research, surveys and studies. 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. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. Our estimates of the potential market opportunities for our product candidates include a number of key assumptions based on our industry knowledge, industry publications and third-party research, surveys and studies, which may be based on a small sample size and fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions. If any of our assumptions or estimates, or these publications, research, surveys or studies prove to be inaccurate, then the actual market for any of our product candidates may be smaller than we expect, and as a result our revenues from product sales may be limited and it may be more difficult for us to achieve or maintain profitability.

If we are unable to establish sales, marketing and distribution capabilities or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience as a company in the sale, marketing or distribution of biopharmaceutical products. To achieve commercial success for any product for which we may obtain marketing approval, we will need to establish a sales, marketing and distribution organization, either ourselves or through collaborations or other arrangements with third parties.

We intend to commercialize TH103, if approved, with our own specialty salesforce. There are risks involved with us establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. These efforts may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. In general, the cost of establishing and maintaining a sales and marketing organization may exceed the cost-effectiveness of doing so.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales, marketing, market access, distribution, customer service, medical affairs and other support personnel;
- our inability to equip sales personnel with effective materials;
- our inability to effectively manage a geographically dispersed sales and marketing team;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement and other acceptance by payors;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do, thus rendering our products non-competitive, obsolete or reducing the size of the market for our products.

The biopharmaceutical industry, and in particular the market for products treating retinal diseases, is characterized by intense investment and competition aimed at rapidly advancing new technologies. Our product candidates are expected to face substantial competition from multiple sources, including large and specialty pharmaceutical and biotechnology companies, academic research 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 emerge in the future within the field of ophthalmology and, furthermore, within the treatment of retinal disease.

We are aware of a number of companies generally pursuing products to treat retinal diseases, including large pharmaceutical companies that have commercialized or are developing treatments for nAMD include Novartis AG ("Novartis"), Regeneron Pharmaceuticals, Inc. ("Regeneron"), AbbVie Inc. ("AbbVie") and F. Hoffmann-La Roche AG ("Roche"). Novartis has received FDA approval for brolucizumab; Regeneron has received FDA approval for aflibercept and aflibercept HD; and Roche has received FDA approval for faricimab, ranibizumab and bevacizumab, though bevacizumab is not approved specifically for nAMD. AbbVie is currently collaborating with RegenexBio Inc. ("RegenexBio") to develop ABBV-RGX-314 as a potential treatment for nAMD. Outlook Therapeutics, Inc. is developing bevacizumab-vikg, an investigational ophthalmic formulation of bevacizumab as a potential treatment for nAMD.

Several companies have received FDA approval for biosimilars to treat nAMD, including: Samsung Bioepis Co., Ltd. and Biogen Inc., which received approval for Byooviz (ranibizumab-nuna), a ranibizumab biosimilar, in September 2021 and Opuviz (aflibercept-yszy) in May 2024; Coherus BioSciences, Inc., which obtained approval for Cimerli (ranibizumab-eqrn), a ranibizumab biosimilar, in August 2022; Formycon AG, which received approval for Ahzantive (aflibercept-mrbb) in June 2024; Sandoz Group AG, which received approval for Enzeevu (aflibercept-abzv) in August 2024; Mylan Laboratories Inc. and Biocon Biologics Limited, which received approval for *Yesafili* (afliberceptjbvf), an aflibercept biosimilar, in May 2024; and Amgen Inc., which received approval for Pavblu (aflibercept-ayyh) in August 2024. As these biosimilars enter the market they may provide new, cost-effective options for the treatment of nAMD, as well as other retinal conditions mediated by VEGF.

Emerging biopharmaceutical companies advancing therapeutic candidates through clinical trials to treat nAMD include 4D Molecular Therapeutics, Inc. ("4D Molecular Therapeutics"), Adverum Biotechnologies, Inc. ("Adverum"), RegenexBio, Eyepoint Pharmaceuticals, Inc. ("Eyepoint Pharmaceuticals") and Ocular Therapeutix, Inc. ("Ocular Therapeutix") among others. 4D Molecular Therapeutics, Adverum and RegenexBio are each advancing anti-VEGF gene therapy candidates to treat nAMD. 4D Molecular Therapeutics' product candidate is in an ongoing Phase 3 trial for nAMD and a Phase 1 trial for DME, Adverum's product candidate is in an ongoing Phase 3 trial and RegenexBio's product candidate is in a pivotal clinical trial for nAMD and a Phase 2 trial for a potential DR treatment. Eyepoint Pharmaceuticals is developing a sustained release, small molecule pan-VEGF inhibitor, which is currently under evaluation in ongoing Phase 3 trials for nAMD and two ongoing Phase 3 trials for DME. Ocular Therapeutix is currently conducting Phase 3 trials of axitinib intravitreal implant, a small molecule tyrosine kinase inhibitor to treat nAMD, which is also being evaluated in a Phase 1/2 trial for DR.

Many of the companies against which we are competing or against which we may compete in the future, either alone or in combination with their respective strategic partners, have significantly greater financial, technical and human resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, the regulatory approval process, and marketing than we do. These same competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our development programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other marketing approval for their products more rapidly than we may obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic and/or biosimilar products. There are biosimilar products currently on the market for certain of the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If our product candidates are approved, we expect that they will be priced at a significant premium over competitive generic products.

Technology in the biopharmaceutical industry has undergone rapid and significant change, and we expect that it will continue to do so. Any products or processes that we develop may become obsolete or uneconomical before we recover any expenses incurred in connection with their development.

Mergers and acquisition activity in the pharmaceutical, biopharmaceutical and biotechnology sector is likely to result in greater resource concentration among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through sizeable collaborative arrangements with established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our business.

We have pursued and may in the future pursue the in-license or acquisition of rights to complementary technologies and product candidates on an opportunistic basis. However, we may be unable to in-license or acquire any additional technologies or product candidates from third parties. The acquisition and licensing of technologies and product candidates is a competitive area, and a number of more established companies also have similar strategies to in-license or acquire technologies and product candidates that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to it. We also may be unable to in-license or acquire the relevant technology or product candidate on terms that would allow us to make an appropriate return on our investment.

Clinical trial and product liability lawsuits against us could divert our resources and could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of clinical trial and product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. While we currently have no products that have been approved for commercial sale, the ongoing, planned and future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies or others selling such products. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trials;

- withdrawal of marketing approval, recall, restriction on the approval or a "black box" warning or contraindication for an approved drug;
- withdrawal of clinical trial participants;
- significant costs to defend any related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- injury to our reputation and significant negative media attention;
- reduced resources of our management to pursue our business strategy;
- distraction of management's attention from our primary business; and
- the inability to commercialize any products that we may develop.

We may need to increase our insurance coverage as we expands our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful clinical trial or product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Risks Related to Our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, which may prevent or delay our ability to seek or obtain marketing approval for or commercialize our product candidates or otherwise harm our business. If we are not able to maintain these third-party relationships or if these arrangements are terminated, we may have to alter our development and commercialization plans and our business could be adversely affected.

We rely, and expect to continue to rely, on third-party clinical research organizations, in addition to other third parties such as research collaboratives, clinical data management organizations, medical institutions and clinical investigators, to conduct our Phase 1a and Phase 1b/2 clinical trials of TH103 and any other clinical trials we conduct. We currently have no plans to independently conduct clinical trials of TH103 or any other product candidate that we may develop. These contract research organizations ("CROs") and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. These third-party arrangements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, our product development activities might be delayed.

Our reliance on these third parties for product development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with good clinical practices ("GCPs") for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities in Europe and other jurisdictions have similar requirements. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We are also required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully develop and commercialize our product candidates. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned, and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit to the FDA. Any such delay or rejection could prevent us from commercializing our product candidates.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding more CROs, investigators and other third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays can occur, which could materially impact our ability to meet our desired clinical development timelines. Although we plan to carefully manage our relationships with our CROs, investigators and other third parties, we may nonetheless encounter challenges or delays in the future, which could have a material and adverse impact on our business, financial condition and prospects.

Manufacturing biologics is complex, and we may experience manufacturing problems that result in delays in our development or future commercialization programs.

The manufacturing of biologics is complex and difficult and we may experience production issues or interruptions for TH103 or any other product candidate it may develop, including raw material or starting material variability in terms of quality, cell line viability, productivity or stability issues, shortages of any kind, shipping, distribution, storage and supply chain failures, growth media contamination, equipment malfunctions, operator errors, facility contamination, labor problems, natural disasters, disruption in utility services, terrorist activities, or acts of god that are beyond our control or the control of our contract development and manufacturing organizations ("CDMOs").

Given the nature of biologics manufacturing, there is a risk of contamination during manufacturing. Any contamination could materially harm our or our CDMOs' ability to produce TH103 or any other product candidate it may develop on schedule and could harm our results of operations and cause reputational damage. Some of the raw materials that we require in our manufacturing process are derived from biologic sources. Such raw materials may be difficult to procure and may be subject to contamination or recall.

Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims, insufficient inventory or potentially delay progression of our clinical development of TH103 and any other product candidate it may develop. For example, we have observed cases of IOI in our Phase 1a and Phase 1b/2 clinical trials of TH103 that are believed to be related to retained host cell protein impurities that are a byproduct of our biologic manufacturing process. Although we believe we have made progress in reducing the level of host cell protein in our manufactured drug product and were already at levels acceptable to the FDA for an investigational product, we may never succeed in our goal of reducing host cell protein to below levels of detection or in reducing host cell protein to a level that does not result in cases of IOI at clinically relevant dose levels. Moreover, our efforts to improve our manufacturing process to remove host cell proteins has in the past, and may in the future, cause delays in our clinical development program. We have also experienced performance failures at our third-party manufacturers that have resulted in lower drug product production yields than expected, as well as delays.

If we successfully develop TH103 and any other product candidate, we may encounter problems achieving adequate quantities and quality that meet FDA, EMA or other comparable applicable foreign standards or specifications with consistent and acceptable production yields and costs. The ability to scale our manufacturing and maintain the manufacturing process at the same levels of quality and efficiency is yet to be tested. If we or our third-party CDMOs are unable to scale our manufacturing at the same levels of quality and efficiency, we may not be able to supply the required number of doses for clinical trials or commercial supply. A material shortage, contamination or manufacturing failure in the manufacture of TH103 and any other product candidate we may develop or other adverse impact or disruption in the commercial manufacturing or the production of clinical material could materially harm our development timelines and our business, financial condition, results of operations and prospects.

We rely on third-party CDMOs for the manufacture of both drug substance and finished drug product of our product candidates for preclinical and clinical testing and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third-party CDMOs for both drug substance and finished drug product, as well as for commercial manufacture of any of our product candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;

- the potential failure to manufacture our product candidate or product according to our specifications;
- the potential failure to manufacture our product candidate or product according to our schedule or at all;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

We or our third-party manufacturers may encounter shortages in the manufacturing of supplies, raw materials or active pharmaceutical ingredients necessary to produce our product candidates in the quantities needed for our clinical trials or, if our product candidates are approved, in sufficient quantities for commercialization or to meet an increase in demand, as a result of capacity constraints or delays or disruptions in the market for the raw materials or active pharmaceutical ingredients, including shortages caused by the purchase of such raw materials or active pharmaceutical ingredients by our competitors or others. We and our third-party manufacturers' failure to obtain the raw materials or active pharmaceutical ingredients necessary to manufacture sufficient quantities of our product candidates may have a material adverse effect on our business.

Our third-party manufacturers are subject to inspection and approval by regulatory authorities before we can commence the manufacture and sale of any of our product candidates, and thereafter subject to ongoing inspection from time to time. Third-party manufacturers may not be able to comply with current good manufacturing practices ("cGMP") regulations or similar regulatory requirements outside of the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. If any of our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement or be unable to reach agreement with an alternative manufacturer.

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

We currently rely, and may in the future rely, on single-source suppliers for certain materials and components used in the manufacturing of our product candidates.

We currently rely, and may in the future rely, on single-source suppliers for certain materials and components used in the manufacturing of our product candidates. There are, for certain of these materials and components, few, if any, alternative sources of supply and there is limited need for multiple suppliers at this stage of our business. We cannot ensure that these suppliers will remain in business, have sufficient capacity or supply to meet our needs, be able to supply materials to us at costs that are acceptable to us, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to work with us. Our use of single-source suppliers of certain materials and components exposes it to several risks, including disruptions in supply, price increases or late deliveries. Our suppliers may be unable or unwilling to meet our future demands for our clinical trials. Establishing additional or replacement suppliers for these materials and components could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from these single-source suppliers could lead to supply delays or interruptions which would materially adversely affect our business, financial condition and results of operations.

We may enter into collaborations with third parties for the research, development and commercialization of certain of our product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates and our business could be adversely affected.

We may enter into third-party collaborators for the research, development and commercialization of certain of our product candidates. Our likely collaborators include large and mid-size pharmaceutical companies and biotechnology companies. Any such arrangements with third parties will likely limit our control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates we may seek to develop with them. 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. We cannot predict the success of any collaboration that we enter into.

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

- collaborators 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 or business combination, that divert resources or create competing priorities;
- collaborators may not pursue development and commercialization of any product candidates that achieve marketing approval or may elect not to continue or renew commercialization 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 or business combination, that may 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;
- we may not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product candidates on a discretionary basis;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates and products if the collaborators believe that the 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 product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- a collaborator may seek to renegotiate or terminate their relationship with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve marketing approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over intellectual property or proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations 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 be time-consuming and expensive;
- we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control;
- collaborators may not properly obtain, maintain, enforce, defend or protect our intellectual property or proprietary rights or may use our proprietary information in such a way as to potentially lead to disputes or legal proceedings that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property or proprietary rights of third parties, which may expose us to litigation and potential liability;

- collaborations may be terminated, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If a present or future collaborator of ours was to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

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, or do not receive it in the timeframe in which we expect to receive it, the 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, marketing approval and commercialization described herein also apply to the activities of our collaborators.

We may in the future decide to collaborate with biopharmaceutical companies for the development and potential commercialization of any product candidates we may develop. These relationships, or those like them, may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. In addition, we could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex. Our ability to reach a definitive collaboration agreement will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of several factors. If we license rights to any product candidates we or our collaborators may develop, we may not be able to realize the benefit of such transactions if it is unable to successfully integrate them with our existing operations and company culture.

We may seek to establish additional collaborations. If we are not able to establish or maintain additional collaborations, on commercially reasonable terms, we may have to alter our development and commercialization plans and our business could be adversely affected.

We plan to selectively pursue collaborations with leading biopharmaceutical companies with particular experience, including development and commercial expertise and capabilities. We face significant competition in attracting appropriate collaborators, and a number of more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or other regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, the terms of any existing collaboration agreements, and industry and market conditions generally. 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, document and execute. In addition, there have been a significant number of recent business combinations among large biopharmaceutical companies that have resulted in a reduced number of potential future collaborators. Any collaboration we may enter into may limit our ability to enter into future agreements on particular terms or covering similar target indications with other potential 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 a product candidate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we expect 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 and generate revenue from product sales, which could have an adverse effect on our business, prospects, financial condition and results of operations.

Any acquisitions or in-license transactions that we complete could disrupt our business, cause dilution to our stockholders or reduce our financial resources.

We may enter into transactions to in-license or acquire other businesses, intellectual property, technologies, product candidates or products. If we determine to pursue a particular transaction, we may not be able to complete the transaction on favorable terms, or at all. Any in-licenses or acquisitions we complete may not strengthen our competitive position, and these transactions may be viewed negatively by investors. We may decide to incur debt in connection with an in-license or acquisition or issue our common stock or other equity securities to the stockholders of the target company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities that are not covered by the indemnification it may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and nondisruptive manner. In-license and acquisition transactions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of additional future in-licenses or acquisitions or the effect that any such transactions might have on our operating results.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our technology, our product candidates, and product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and, if approved, commercialize our product candidates may be adversely affected.

We rely upon a combination of patents, trademarks, trade secret protection, and confidentiality agreements to protect the intellectual property related to our development programs and product candidates. Our success depends in part on our ability to obtain and maintain patent protection in the United States and other countries with respect to TH103 or our other current or future product candidates. If we are unable to obtain or maintain patent protection with respect to TH103 or our other current or future product candidates, and their uses, our business, financial condition, resultant operations and prospects could be materially harmed.

We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our development programs, product candidates and novel discoveries that are important to our business, as appropriate. Our pending and future patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties, including generics. The patent prosecution process is expensive and time-consuming, and we may not be able to file, prosecute, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner.

Our patents and patent applications may fail to result in issued patents with claims that adequately protect TH103 and our other current or future product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application, or be used to invalidate a patent. Even if patents do successfully issue and even if such patents cover TH103 or our other current or future product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, the scope and coverage of such patents may be so narrow that a third party could successfully design around our patents without materially impacting the therapeutic effectiveness of the resulting drug product. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the U.S. Patent and Trademark Office (“USPTO”) and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- the USPTO requires us to disclose all material references to the Patent Examiner during prosecution of our patent applications at the USPTO, and failure to do so could result in a third party successfully challenging our ability to enforce a patent against an infringer;

- patent applications may not result in any patents being issued;
- granted patents may not have a claim scope that covers TH103 or our other current or future product candidates;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or block our ability to make, use and sell our product candidates;
- there may be significant pressure on the United States government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for treatments of diseases or conditions that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop and market competing products.

The patent prosecution process is also expensive and time-consuming, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. Additionally, recent reforms and changes at government agencies of the United States and those of non-U.S. jurisdictions could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications, and the maintenance, enforcement, or defense of our issued patents. For example, the ability of the USPTO and other applicable patent authorities to properly administer their functions is highly dependent on the levels of funding available to the agency and their ability to retain key personnel and fill key leadership appointments, among various factors. Termination of employees or delays in replacing or hiring for key positions could significantly impact the ability of the USPTO and other applicable patent authorities to fulfill their functions and could greatly impact our ability to timely and adequately prosecute or maintain our patent applications, and our ability to timely and adequately maintain, enforce, or defend our issued patents. We may not be able to obtain or maintain patent applications and patents due to the subject matter claimed in such patent applications and patents being in disclosures in the public domain. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, for patent rights that we have or will in license from third parties, we may not have the right to control the preparation, filing, and prosecution of such patent applications, or to maintain the patents, directed to technology that we license from those third parties. We may also require the cooperation of our licensor(s) in order to enforce the licensed patent rights, and such cooperation may not be provided. Therefore, any licensed patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by any of our current or future licensors have been or will be conducted in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If they fail to do so, this could cause us to lose rights in any applicable intellectual property that we in-license, and as a result, our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

If the patent applications we hold or in-license (or will hold or in-license) with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for TH103 or our other current or future product candidates, it could dissuade other companies from collaborating with us to develop product candidates, and threaten our ability to commercialize TH103 and our other current or future product candidates. Any such outcome could have a materially adverse effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been and will continue to be the subject of litigation and new legislation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, many countries restrict the patentability of methods of treatment of the human body. Publications in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our own patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result of these and other factors, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products.

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. For example, the Leahy-Smith America Invents Act created new administrative post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings that allow third parties to challenge the validity of issued patents. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the United States Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of defending patents or enforcing proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. 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 products 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.

The issuance of a patent is not conclusive as to inventorship, scope, validity, or enforceability, and our owned and licensed patents and patent applications may be challenged in the courts or patent offices in the United States and abroad. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. An adverse decision in any 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 and products, or limit the duration of the patent protection of our technology and products. Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, patent term can be adjusted to recapture a portion of delay incurred by the USPTO in examining the patent application (patent term adjustment). The scope of patent protection may also be limited.

If we are unable to secure adequate patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. 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.

We cannot be certain that the claims in patents or our pending patent applications directed to TH103 and our other current or future product candidates will be considered patentable by the USPTO, by patent offices in foreign countries, by the courts, or by other relevant authority. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim relevant to our business. There is no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. Even if the patents do issue based on the patent applications we solely own, co-own, or exclusively license, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

We rely on patent, trademark, trade secret and other intellectual property protection in the development, manufacturing and sale of TH103 and our other current and any future product candidates. In particular, patent protection is important in the development and eventual commercialization of TH103 and our other current or any future product candidates. Patents covering TH103 and our other current or any future product candidates normally provide market exclusivity, which is important in order for TH103 and our other current or any future product candidates to become profitable.

Patent rights are of limited duration. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years after the filing date of the first non-provisional patent application in the patent family. Various extensions may be available, but the life of a patent, and the protection it affords is limited. 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 product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. Upon issuance in the United States, the term of a patent can be increased by patent term adjustment, which is based on certain delays caused by the USPTO, but this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. The term of a U.S. patent may also be shortened if the patent is terminally disclaimed over an earlier-filed patent.

Depending upon the timing, duration and specifics of FDA marketing approval of TH103 and our other current and future product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during drug development and the FDA regulatory review process, which is limited to the approved indication (or any additional indications approved during the period of extension). This extension is based on the first approved use of a product and is limited to only one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. Such patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time-period or the scope of patent protection afforded could be less than we project or request. If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following our patent expiration and launch their product earlier than might otherwise be the case.

Laws governing analogous patent term extension ("PTE") in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain PTE or restoration, or the term of any such extension is less than we project or request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially.

Obtaining and maintaining our 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 noncompliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or patent applications will be due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of our patents and patent applications. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. 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. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit

formal documents. We employ reputable law firms and other professionals to help us comply with these provisions. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business. If we or any of our licensors fail to maintain the patents and patent applications covering TH103 and our other current or any future product candidates, our competitors may be able to enter the market, which would have an adverse effect on our business, financial conditions, results of operations and growth prospects. We do not have granted patents in certain markets and cannot guarantee that we will obtain patent coverage in such markets that cover TH103 and our other current or any future product candidates.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.

TH103 and our other current or any future product candidates may be subject to claims of infringement of the patent rights of third parties. There can be no assurance that our operations do not, or will not in the future, infringe, misappropriate or otherwise violate existing or future third-party patents or other intellectual property rights. Identification of third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot provide any assurances that third-party patents do not exist which might be enforced against our existing products or current technology, including our research programs, TH103 and our other current or future product candidates, their respective methods of use, and manufacture thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our current and future product candidates in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. We do not always conduct independent reviews of pending patent applications and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the United States can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that may be infringed by the manufacture, use or sale of our product candidates or will prevent, limit or otherwise interfere with our ability to make, use or sell our product candidates.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. For example, we may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

We may become involved in third-party claims of intellectual property infringement, which may delay or prevent the development and commercialization of our current and any future product candidates.

Our commercial success depends in part on our ability to develop, manufacture, market and sell TH103 and our other current and any future product candidates, while avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation, and administrative law proceedings, inter partes review, and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights who allege that our product candidates, uses and/or other proprietary technologies infringe their intellectual

property rights. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization.

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Also, there may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our current and future product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our current or future product candidates may infringe.

In addition, third parties may obtain patent rights in the future and claim that use of our technologies infringes upon their rights. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any products formed during the manufacturing process, methods of treating certain diseases or conditions that we are pursuing with our product candidates, our formulations including combination therapies, or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that it is infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our current and future product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property rights, or the patents or other intellectual property rights of any licensors, which could be expensive, time consuming, and unsuccessful, and could result in a court or administrative body finding our patents to be invalid or unenforceable.

Competitors may challenge, infringe, or otherwise violate our patents, the patents of our licensors, or our other intellectual property rights. To counter challenges, infringement, or unauthorized use or misappropriations, we or any licensors may be required to file or defend legal claims, which can be expensive and time-consuming. In addition, in such a proceeding, a court may decide that one or more patents of ours or any of our current or future licensors is not valid or is unenforceable, or may 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 or defense proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness (inventive step), non-enablement, insufficient written description, or failure to claim patent-eligible subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Additionally, we may be subject to claims of patent infringement during those proceedings, and delays caused by the federal agencies may increase the time period that we are subject to such claims. For example, administrative changes, including reduced staff and budgets experienced by the Patent and Trial Appeal Board, could further delay our ability to timely challenge any such patents. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours (or of our licensor(s)) is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our (or any licensors') patent claims do not cover the invention, or decide that the other party's use of ours (or any licensors') patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). An adverse outcome in a litigation or proceeding involving our or any licensors' patents could limit our ability to assert our own or any licensors' patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive position, and our business, financial condition, results of operations, and prospects. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For any patents and patent applications that we may license from third parties in the future, we may have limited or no right to participate in the defense of such licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock. Moreover, we cannot assure you that it will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our patents, any patents that may be issued as a result of our future patent applications, or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

Changes in United States patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents relating to TH103 and our other current and any future product candidates. Obtaining, defending, maintaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents. The United States has enacted and implemented wide-ranging patent reform legislation. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect June 1, 2023, which significantly impacts European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent subject to the jurisdiction of the Unitary Patent Court ("UPC"). As the UPC is a relatively new court system, there is limited precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC over the first seven years of the court's existence and remaining as national patents in the UPC countries. 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. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC provides our competitors with a new forum to centrally revoke our European patents and allow for the possibility of a competitor to obtain a pan-European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates due to increased competition and, resultantly, on our business, financial condition, prospects and results of operations.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Patents are of national or regional effect, and filing, prosecuting, and defending patents covering TH103 and our other current and any future product candidates throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we do pursue patent protection, 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 may have or obtain patent protection, but where patent enforcement is not as strong as that in the United States. These competitors' products may compete with our products in such jurisdictions and take away our market share where we do not have any issued or licensed patents, and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so 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. In addition, certain jurisdictions do not protect to the same extent (or at all) inventions that constitute new methods of treatment. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, 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 and 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 rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market its product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize TH103 and our other current or future product candidates in all of our expected significant foreign markets.

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. As a result, the patent owner may have limited remedies in certain circumstances, which could materially diminish the value of such patent. If we or any of our licensor(s) are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. Accordingly, our efforts to protect or enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market its product candidates.

Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize TH103 and our other current or future product candidates in all of our expected significant foreign markets.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our technologies, products and product candidates. While we will endeavor to try to protect our technologies, products and product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time-consuming, expensive and unpredictable.

Further, geo-political actions in the United States and in foreign countries (such as the Russia and Ukraine conflict) could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of its issued patents or those of any current or future licensors. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws within the United States. We may need to share our trade secrets and proprietary know-how with current or future partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. In addition, some courts inside and outside the United States are sometimes less willing or unwilling to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. Even if we are successful, these types of lawsuits may consume our time and other resources. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

In addition to the protection afforded by patents, we may seek to rely on trade secret protection to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product development processes that involve proprietary know-how, information, or technology that is not covered by our patents. We may not be able to meaningfully protect our trade secrets. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access our its proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will

not be disclosed to our competitors or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws within the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, and financial condition.

Because we expect to rely on third parties to manufacture TH103 and our other current and any future product candidates, and we expect to collaborate with third parties on the continuing development of TH103 and our other current and any future product candidates, we must, at times, share trade secrets with them. We also expect to conduct research and development programs that may require us to share trade secrets under the terms of our partnerships or agreements with CROs. We seek to protect our proprietary technology in part by entering into agreements containing confidentiality and use restrictions and obligations, including material transfer agreements, consulting agreements, manufacturing and supply agreements, confidentiality agreements or other similar agreements with our advisors, employees, contractors, CDMOs, CROs, other service providers and consultants prior to disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets.

Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by its competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements.

Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors CDMOs, CROs, other service providers and consultants to publish data potentially relating to our trade secrets, although such agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover such trade secrets, either through breach of our agreements with third parties, independent development, or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Monitoring unauthorized disclosure and detection of unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time-consuming, and the outcome would be unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third party from using any of its trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. For example, significant elements of our products, including confidential aspects of sample preparation, methods of manufacturing, and related processes and software, are based on unpatented trade secrets. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties or claims asserting ownership of what we regard as our own intellectual property.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies, or at research institutions, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals have or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Further, although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators, and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of its employees' former employers or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. An inability to incorporate such technologies or features would harm our business and may prevent us from successfully commercializing our technologies or product candidates. In addition, we may lose personnel as a result of such claims and any such litigation, or the threat thereof, may adversely affect our

ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our technologies or product candidates, which could adversely affect our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, we may also be subject to claims that former employers, consultants or other third parties have an ownership interest in our patents or patent applications as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such challenges may also result in our inability to develop, manufacture, or commercialize our technologies and product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future technologies and product candidates. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Any of the foregoing could adversely affect our business, financial condition, results of operations, and prospects.

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

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings.

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in its markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

In addition, any proprietary name we propose to use with our current or future product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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

- others may be able to make formulations, compositions, or products that are the same as or similar to our current and future product candidates, but that are not covered by the pending patent applications or patents that we own or any pending patent applications or patents that we in-license;
- others may be able to make product that is similar to our current and future product candidates that we intend to commercialize and that is not covered by the patents that we own or have exclusively licensed and have the right to enforce;
- we, our licensors, or collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or in-license;
- we or our licensor(s) might not have been the first to file patent applications covering certain of our or those licensors' inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing or otherwise violating our owned intellectual property rights or any patent applications that we have licensed;
- it is possible that our pending patent applications, whether owned or in-licensed, will not lead to issued patents;
- issued patents that we either own or have licensed may be revoked, modified or held valid or unenforceable, as a result of legal challenges by our competitors;
- issued patents that we either own or have licensed may not provide us with any competitive advantages;
- others may have access to the same intellectual property rights licensed to us in the future on a non-exclusive basis;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our or our licensor(s) patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims directed to our product candidates or uses thereof in the United States or in other foreign countries;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents are valid, enforceable or infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patent applications.

If we fail to comply with our obligations under any license, collaboration or other agreements, such agreements may be terminated, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates.

We license rights to current and future product candidates or data from third parties, and may enter into additional licensing agreements in the future. For example, we are party to a purchase and research use agreement relating to the license of a cell line for use in the production of TH103, and we are party to a license agreement pursuant to which we have licensed the intellectual property rights to develop and commercialize TH103. If any licensors fail to prosecute, maintain, enforce, and defend such patents, or lose

rights to those patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize future product candidates that may be subject of such licensed rights could be adversely affected. In spite of our efforts, any licensors might conclude that we are in material breach of obligations under our license agreements. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture, and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. If such in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, our competitors will have the freedom to seek regulatory approval of, and to market, products identical to our product candidates and the licensors to such in-licenses could prevent us from developing or commercializing product candidates that rely upon the patents or other intellectual property rights which were the subject matter of such terminated agreements. Any of these events could adversely affect our business, financial condition, results of operations, and prospects.

Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- either party's financial or other obligations under the license agreement;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights under our collaborative development relationships to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by any of our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we license prevent or impair our ability to maintain its licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected product candidates, which would have a material adverse effect on our business.

In addition, certain of our current or future agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities.

Further, we or our licensor(s) may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects of form in the preparation or filing of its patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, ownership, claim scope, or requests for patent term adjustments. If such defects are identified in a granted patent, we may reissue the granted patent, which would require us to relinquish the patent, and subject the patent to subsequent reissue patent examination. During reissue examination, there is no guarantee that a similar scope of claim would again be granted or that any claim would be granted at all. In addition, if defects in ownership or assignment of rights are identified, there is no guarantee that we would be able to perfect such ownership or assignment of rights. If our licensor(s) are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on its business.

In addition, even where we have the right to control patent prosecution of patents and patent applications under a license from third parties, we may still be adversely affected or prejudiced by actions or inactions of our predecessors or licensors and their counsel that took place prior to us assuming control over patent prosecution.

Our acquired technologies and current or future licensed technology may be subject to retained rights. Our predecessors or licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our predecessors or future licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

If we are limited in our ability to utilize acquired technologies or current or future licensed technologies, or if we lose our rights to critical acquired or in-licensed technology, we may be unable to successfully develop, out-license, market and sell our products, which could prevent or delay new product introductions. Our business strategy depends on the successful development of acquired technologies, and current or future licensed technology, into commercial products. Therefore, any limitations on our ability to utilize these technologies may impair our ability to develop, out-license or market and sell our product candidate.

We may not be able to license or acquire new or necessary intellectual property rights or technology from third parties.

Because our development programs may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. Further, other parties, including our competitors, may have patents and have filed (or will file) patent applications potentially relevant to its business. In order to avoid infringing these patents, we may find it necessary or prudent to obtain licenses to such patents from such parties. The licensing or acquisition of intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on its investment or at all. No assurance can be given that we will be successful in licensing any additional rights or technologies from third parties. Our inability to license the rights and technologies that we have identified, or that we may in the future identify, could have a material adverse impact on our ability to complete the development of our product candidates or to develop additional product candidates. Even if we were able to obtain a license, it could be non-exclusive, thereby giving its competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Failure to obtain any necessary rights or licenses may detrimentally affect our planned development of our current or future product candidates could be impacted and costs could increase, extending timelines associated with the development of such other product candidates if we fail to acquire necessary rights or licenses. We may even have to abandon the development of the relevant program or product candidate. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our existing or future product candidates. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and product candidates in the future. In that event, we may be required to expend significant time and resources to redesign our product candidates, or the methods for manufacturing them, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current manufacturing methods, product candidates, or future methods or product candidates resulting in either an injunction prohibiting their manufacture or future sales, or, with respect to their future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Risks Related to Regulatory and Legal Compliance Matters

Even if we complete the necessary preclinical studies and clinical trials for our product candidates, the regulatory approval process is expensive, time-consuming and uncertain and we may not receive approvals for the commercialization of some or all of our product candidates in a timely manner, or at all.

Our long-term success and ability to sustain and grow revenue depends on our ability to continue to successfully develop our product candidates and obtain regulatory approval to market our products both in and outside of the United States. In order to market and sell our products in the European Union and many other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The FDA and comparable foreign regulatory authorities, whose laws and regulations may differ from country to country, impose substantial requirements on the development of product candidates to become eligible for marketing approval, have substantial discretion in the process, and may refuse to accept any application or may decide that the data are insufficient for approval and require additional preclinical studies, clinical trials or other studies and testing. The time required to obtain approval outside of the United States may differ substantially from that required to obtain FDA approval. For

example, in many countries outside of the United States, it is required that the product also be approved for reimbursement before the product can be sold in that country. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside of 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.

The process of obtaining marketing approvals, both in the United States and abroad, is lengthy, expensive and uncertain. It 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. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information, including manufacturing information, to regulatory authorities for each indication to establish the product candidate's safety and efficacy.

In addition, changes in or the enactment of additional statutes, promulgation of regulations or issuance of guidance during preclinical or clinical development, or comparable changes in the regulatory review process for each submitted product application, may cause delays in the approval or rejection of an application. For example, in December 2022, with the passage of the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), Congress required sponsors to develop and submit a developmentally appropriate practice ("DAP") for each Phase 3 clinical trial or any other "pivotal study" of a 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 DAPs. Unlike most guidance documents issued by the FDA, the DAP guidance when finalized will have the force of law because FDORA specifically dictates that the form and manner for submission of DAPs are specified in FDA guidance.

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 (the "APA"). The court ordered the restoration of many of these webpages. In late July 2025, the FDA restored the draft DAP guidance to its website with a statement that "information on this page may be modified and/or removed in the future subject to the terms of the court's order and implemented consistent with applicable law." 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.

Further, on January 31, 2022, the new Clinical Trials Regulation (EU) No 536/2014 became applicable in the European Union and replaced the prior Clinical Trials Directive 2001/20/EC. The new regulation aims at simplifying and streamlining the authorization, conduct and transparency of clinical trials in the European Union. Under the new coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial to be conducted in more than one European Union Member State will only be required to submit a single application for approval. The submission will be made through the Clinical Trials Information System, a new clinical trials portal overseen by the EMA, and available to clinical trial sponsors, competent authorities of the European Union Member States and the public. We have not previously secured authorization to conduct clinical studies in the European Union pursuant to this new regulation and, accordingly, there is a risk that we may be delayed in commencing such studies.

Moreover, principal investigators for our future 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 FDA or other regulatory authorities may determine that (1) our product candidates are not safe and effective, are only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude us obtaining marketing approval or prevent or limit commercial use; (2) the dose used in a clinical trial has not been optimized and require us to conduct additional dose optimization studies; or (3) the comparator arm in a trial is no longer the appropriate comparator due to the evolution of the competitive landscape or subsequent data of the comparator product, even if the FDA or other regulatory authority had previously approved the trial design, and we may be required to amend the trial or we may not receive approval of the indication.

Under the Pediatric Research Equity Act, a Biologics License Application ("BLA") or supplement to a BLA for certain biological products must contain data to assess the safety and effectiveness 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 and effective, 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 or effectiveness data needs 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 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 United States 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 United States 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 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 the Centers for Medicare & Medicaid Services ("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.

Finally, our ability to develop and market new products may be impacted if litigation challenging the FDA's approval of mifepristone continues. In April 2023, the U.S. District Court for the Northern District of Texas invalidated the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and whose distribution is governed by various measures adopted under a Risk Evaluation and Mitigation Strategy ("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, which the FDA authorized in 2016 and 2021, were arbitrary and capricious. In June 2024, the Supreme Court reversed that decision after unanimously finding that the plaintiffs (anti-abortion doctors and organizations) 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 district court in Texas challenging the FDA's actions. On January 16, 2025, the District Court agreed to allow these states to file an amended complaint and continue to pursue this challenge. Thereafter, on September 30, 2025, the District Court declined to dismiss the case and, instead, transferred it to the federal district court in the Eastern District of Missouri. Depending on the outcome of this litigation, our ability to develop new drug product candidates and to maintain approval of existing drug products could be delayed, undermined or subject to protracted litigation.

The approval of our product candidates for commercial sale could also be delayed, limited or denied or we may be required to conduct additional studies for a number of reasons, including, but not limited to, the following:

- regulatory authorities may determine that our product candidates do not demonstrate safety and effectiveness in accordance with regulatory agency standards based on a number of considerations, including adverse events that are reported during clinical trials;
- regulatory authorities could analyze and/or interpret data from clinical trials and preclinical testing in different ways than we interpret them and determine that our data is insufficient for approval;
- regulatory authorities may require more information, including additional preclinical or clinical data or the conduct of new trials, to support approval;
- regulatory authorities could determine that our manufacturing processes are not properly designed, are not conducted in accordance with federal or other laws or otherwise not properly managed, and we may be unable to obtain regulatory approval for a commercially viable manufacturing process for our product candidates in a timely manner, or at all;

- the supply or quality of our product candidates for our clinical trials may be insufficient, inadequate or delayed;
- the size of the patient population required to establish the efficacy of our product candidates to the satisfaction of regulatory agencies may be larger than we anticipated;
- our failure or the failure of clinical sites, and the records kept at the respective locations, including records containing clinical trial data, to be in compliance with the FDA's GCP, requirements or comparable regulations outside of the United States;
- regulatory authorities may change their approval policies or adopt new regulations;
- regulatory authorities may not be able to undertake reviews of our marketing applications, conduct applicable inspections or proceed through their approval processes in a timely manner;
- the results of our earlier clinical trials may not be representative of our future, larger trials;
- regulatory authorities may not agree with our regulatory approval strategies or components of our regulatory filings, such as the design or implementation of the relevant clinical trials; or
- a product may not be approved for the indications that we request or may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Accordingly, we may not be able to submit applications for marketing approvals/authorizations and may not receive necessary approvals to commercialize our products in any market. Any failure, delay or setback in obtaining regulatory approval for our product candidates could materially adversely affect our ability to generate revenue from a particular product candidate, which could result in significant harm to our financial position.

Failure to obtain marketing approval in foreign jurisdictions would prevent our medicines from being marketed in such jurisdictions and any of its medicines that are approved for marketing in such jurisdiction will be subject to risk associated with foreign operations.

In order to market and sell our medicines in the European Union and many other foreign jurisdictions, we or our 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. The time required to obtain approval 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, a product must be approved for reimbursement before the product can be approved for sale in that country. We or our collaborators may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Moreover, 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.

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 United Kingdom 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 (the "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). In anticipation of these new requirements, on October 1, 2025, the MHRA updated its guidance for clinical trials to address, among other things, research transparency requirements for clinical trials, the approvals process, the Research Ethics Committee review of clinical trials, simplified arrangements for consent in clinical trials and pharmacovigilance. 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 ("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 ("RRs"). The RRs notably include EMA and regulators in the EU/European Economic Area ("EEA") member states for approvals in the European Union 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 UK 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 (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. On December 11, 2025, the European Parliament and European Council reached a provisional political agreement on the legislation which is expected to be adopted by mid-2026. Key changes include updating regulatory exclusivity to a new system with eight years of data exclusivity and a reduced market exclusivity period to one year, which can be extended if specific conditions are fulfilled up to a maximum of 11 years. This measure, and others, are expected to be adopted by mid-2026 and, following a transition period of 24 months, will likely take effect in mid-2028.

We expect that we will be subject to additional risks in commercializing any of our product candidates that receive marketing approval outside the United States, including tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; and workforce uncertainty in countries where labor unrest is more common than in the United States. In addition, we do not have experience commercializing products outside of the United States and such efforts may depend on our ability to find a suitable collaborator.

Any of our product candidates for which we obtain marketing approval in the future may be subject to post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products following approval.

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. Any of our product candidates for which we obtain marketing clearance or approval in the future, as well as the manufacturing processes, post-approval studies and measures, labeling, advertising and promotional activities for such products, among other things, will be subject to continual requirements of and review by the FDA and other United States and foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and related compliance requirements such as price reporting, transparency reporting and requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing authorization is granted, it may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including in the case of biological products, the requirement to implement a REMS, which could include requirements for a restricted distribution system.

The FDA and comparable foreign regulatory authorities may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a biological product. There are similar potential requirements for medical devices. In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive requirements by the FDA and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our contract manufacturers could be subject to periodic unannounced inspections by the FDA or foreign regulatory authorities to monitor and ensure compliance with cGMPs (and similar foreign requirements) or other regulations.

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

- refuse to approve pending applications or supplements to approved applications;
- require us to change the way a product is distributed, conduct additional clinical trials, change the labeling of a product or require us to conduct additional post-marketing studies or surveillance;
- restrict our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- require additional warnings on the product label, such as a "black box" warning or a contraindication;
- impose restrictions on the products, manufacturers or manufacturing process;
- require warning or untitled letters;

- seek injunctions or civil or criminal penalties;
- suspend or withdraw regulatory approvals;
- seize or detain products or implement import bans;
- impose voluntary or mandatory product recalls and publicity requirements;
- totally or partially suspend production; and
- impose restrictions on operations, including costly new manufacturing requirements.

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

Assuming we receive marketing approval for one or more of our product candidates, we and our contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we are not able to comply with post-approval regulatory requirements, our ability to market any future products could be limited, which could adversely affect our ability to sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found or alleged to have improperly promoted off-label uses, it may become subject to significant liability.

The FDA and other United States or foreign agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of biological products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use, and if we communicate about any of our product candidates for which we receive marketing approval in a way that regulators assert goes beyond their approved indications, we may be subject to warnings or enforcement action for off-label marketing. Alleged violations of the Federal Food, Drug and Cosmetic Act or other statutes, including the False Claims Act (the "FCA"), relating to the promotion and advertising of prescription products may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws.

For example, on September 9, 2025, President Trump issued a Memorandum directing the United States Department of Health and Human Services ("HHS") to "ensure transparency and accuracy in direct-to-consumer prescription drug advertising, including by increasing the amount of information regarding any risks associated with the use of any such prescription drug required to be provided in prescription drug advertisements." The same day, the FDA declared that it will no longer tolerate what it characterized as "deceptive practices" in prescription drug advertising and that the FDA would "aggressively deploy" its available enforcement tools, with "heightened scrutiny" of fair balance and disclosures in social media promotions. The FDA issued a generic "notice letter" to a substantial number of companies directing such companies to "remove any noncompliant advertising and bring all promotional communications into compliance." When and if our product candidates are approved, we will need to maintain a robust compliance program and processes designed to ensure that all such advertising activities are performed in a legal and compliant manner and anticipate rule changes at the FDA and possibly other agencies.

In September 2021, the FDA published final regulations which describe the types of evidence that the agency will consider in determining the intended use of a biologic. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our products and any product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific communications concerning their products in certain circumstances. For example, 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.

In addition, under some relatively recent guidance from the FDA and the Pre-Approval Information Exchange Act ("PIE Act"), signed into law as part of the Consolidated Appropriations Act of 2023, companies may also promote information that is consistent with the prescribing information and proactively speak to formulary committee members of payors regarding data for an unapproved drug or unapproved uses of an approved drug. We may engage in these discussions and communicate with healthcare providers, payors and other constituencies in compliance with all applicable laws, regulatory guidance and industry best practices. 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 approved, our product candidates that are licensed and regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Biologics Price Competition and Innovation Act of 2009 (the "BPCIA") was enacted as part of the Patient Protection and the Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act Health Information Technology for Economic and Clinical Health Act (the "ACA"), to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic.

Under the BPCIA, a reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In addition, the licensure of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still develop and receive licensure of a competing biologic, so long as its BLA does not rely on the reference product, sponsor's data or submit the application as a biosimilar application.

We believe that any of the product candidates it develops as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Further, the FDA may revise the standards governing approval of biosimilars so as to bring such products to the market more quickly. For example, in October 2025, the FDA issued draft guidance which proposes to eliminate the need for sponsors of biosimilar products to conduct comparative human clinical efficacy studies, allowing them to rely instead on analytical testing to demonstrate product differences from a reference product.

Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing. Nonetheless, the approval of a biosimilar to our product candidates would have a material adverse impact on our business due to increased competition and pricing pressure.

Our relationships with healthcare providers, physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare professionals, including but not limited to physicians, nurses, medical directors, hospitals, pharmacies, pharmacy benefit managers, group purchasing organizations, wholesalers, insurers, and all individuals employed by such entities, which we refer to collectively as HCPs, may influence the recommendation and prescription of our approved products. Our arrangements with HCPs and others who have the ability to improperly influence the recommendation and prescription of its products 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 our approved products. Restrictions under applicable federal, state and foreign healthcare laws and regulations include the following:

- the federal healthcare Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, arranging for or recommendation of, any good or service, for which payment may be made under federal healthcare programs 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;

- the FCA imposes 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, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties. 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 FCA;
- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or service. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal transparency requirements under the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies to report to HHS information related to payments and other transfers of value to physicians (as defined by statute), other healthcare providers and teaching hospitals and ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations; 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, and certain state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring product manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of its operations, any of which could adversely affect our business, financial condition, results of operations and prospects.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will 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, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Liabilities they incur pursuant to these laws could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Disruptions at the FDA and other government agencies from funding cuts, personnel losses, regulatory reform, government shutdowns and other developments could hinder our ability to obtain guidance from the FDA regarding our clinical development program and develop and secure approval of our product candidates in a timely manner, which would negatively impact our business.

The FDA and comparable regulatory agencies in foreign jurisdictions, such as the EMA and the Committee for Medicinal Products for Human Use ("CHMP"), play a vital role in the development of our product candidates by providing guidance on our clinical development programs and reviewing and approving our regulatory submissions, including INDs, requests for special designations and marketing applications. If these oversight and review activities are disrupted or delayed, then correspondingly our ability to develop and secure timely approval of our product candidates could be impacted in a negative manner.

For example, the loss and retirement of FDA leadership and personnel could lead to disruptions and delays in FDA guidance, review and approval of our product candidate. Pursuant to President Trump's E.O. 14210, "Implementing the President's 'Department of Government Efficiency' Workforce Optimization Initiative," the Secretary of HHS announced on March 27, 2025, a reorganization and reduction in force across the Department of approximately 20,000 employees (82,000 to 62,000), with FDA's workforce of approximately 20,000 to decrease by 3,500 full-time employees. Subsequently, the FDA indicated that roughly a quarter of those employees who received RIF notices had been reinstated. On July 14, 2025, following litigation reaching the U.S. Supreme Court, the

administration began to carry out these layoffs across HHS, including the FDA. In November 2025, a Congressional Continuing Resolution ended the government shutdown, providing full-year funding of the FDA through the 2026 federal fiscal year at approximately $7 billion with a slight increase in user fees for drug and device companies.

While the FDA's review of marketing applications and other activities for new drugs and biologics is largely funded through the user fee program established under the Prescription Drug User Fee Act ("PDUFA"), it remains unclear how the administration's FDA reduction in force and budget cuts will impact this program and the ability of the FDA to provide guidance and review our product candidate in a timely manner. For example, while the FDA reduction in force did not reportedly specifically target FDA reviewers, many operations, administrative and policy staff that help support such reviews were affected and those losses could lead to delays in PDUFA reviews and related activities. There have been several reports in which the FDA failed to meet a PDUFA goal date for approval of an NDA or BLA due to heavy workload and limited resources. In addition, while currently unclear, there is a risk that the FDA reduction in force and budget cutbacks could threaten the integrity of the PDUFA program itself. That is because, for the FDA to obligate user fees collected under PDUFA in the first place, a certain amount of non-user fee appropriations must be spent on the process for the review of applications plus certain other costs during the same fiscal year.

There is also substantial uncertainty as to how regulatory reform measures being implemented by the Trump Administration across the government will impact the FDA and other federal agencies with jurisdiction over our activities. For example, since taking office, the President has issued a number of executive orders that could have a significant impact on the manner in which the FDA conducts its operations and engages in regulatory and oversight activities. These include E.O. 14192, "Unleashing Prosperity Through Deregulation," January 31, 2025; E.O. 14212, "Establishing the President's Make America Healthy Again Commission," February 13, 2025; and E.O. 14219, Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency" Deregulatory Initiative," February 21, 2025. If these or other orders or executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Similarly, actions by the U.S. government have significantly disrupted the operations of U.S. government agencies such as the National Institutes of Health, National Science Foundation, Centers for Disease Control and Prevention, and FDA, which have traditionally provided funding for basic research, research and development, and clinical testing. These U.S. government actions have included, among other things, suspending, terminating and withholding of disbursements of funds owed under ongoing contracts, grants, and other financial assistance agreements; declining to continue multi-year research projects for additional annual budget periods; canceling or delaying solicitations for new contract, grant and other financial assistance awards; canceling or delaying proposal evaluation processes and issuance of such new awards; substantially reducing federal agency staff responsible for managing contract and financial assistance programs; eliminating agency information and resources for facilitating research activity; delaying or terminating federal agency procedures for authorizing international transactions; initiating aggressive enforcement actions that may disrupt the operations of major research universities that are significant contributors to life sciences research in the U.S., and threatening access to federal agency contracts and other funding awards based on companies' otherwise lawful corporate policies and choice of counsel. These U.S. government actions could, directly or indirectly, significantly disrupt, delay, prevent, or increase the costs of our research and product commercialization programs, including our ability to develop new product candidates, conduct clinical trials, implement research collaborations with other companies or institutions, and obtain approvals to market and sell new products.

In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. During the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions and could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

For example, the federal government shut down on October 1, 2025, and reopened on November 13, 2025. At the outset of that shutdown, the FDA issued a public notice stating that FDA operations would continue to the extent permitted by law, such as activities necessary to address imminent threats to the safety of human life and activities funded by carryover user fee funds. The FDA declared that, during the shutdown period, it does not have legal authority to accept user fees assessed for fiscal year 2026 until a fiscal year 2026 appropriation or Continuing Resolution for the FDA is enacted. As a result, during the government shutdown, the FDA did not accept any regulatory submissions for fiscal year 2026 that require a fee payment. In addition, the FDA indicated that some of its regulatory science research, crucial for advancing product innovation, safety, and quality, would be curtailed during the lapse period.

At the same time, disruptions at the FDA and other government agencies may result from public health events similar to the COVID-19 pandemic. For example, during the 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.

Accordingly, if any of the foregoing developments and others impact the ability of the FDA to provide us with guidance regarding our clinical development programs or delay the agency's review and processing of our regulatory submissions, including INDs, New Drug Applications and BLAs, our business would be negatively impacted. Further, any future government shutdown could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Recently enacted and future legislation may increase the difficulty and cost for us to commercialize our product candidates, if approved, and affect the prices we may obtain.

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, among other things, restrict or regulate post-approval activities and affect our ability to profitably sell or commercialize any product candidate for which we obtain marketing approval. We expect that 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, or any collaborators, may receive for any approved products. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed.

In March 2010, the ACA was enacted. The ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expanded eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the 340B pricing program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Rebate Program; established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare & Medicaid Innovation at the CMS, an agency within HHS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been executive, judicial, and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the United States Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. During the first Trump Administration, the Congress and administration sought to overturn the ACA and related measures. Shortly after taking office in January 2025, President Trump revoked numerous executive orders issued by President Biden, including at least two executive orders (e.g., EO 14009, Strengthening Medicaid and the Affordable Care Act, and EO 14070, Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage) where were designed to further implement the ACA. We anticipate similar efforts to undermine the ACA, and the accompanying uncertainty, for the foreseeable future.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least US$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers, which went into effect in April 2013 and will remain in effect through 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. Further, with the passage of the Inflation Reduction Act (the "IRA") in August 2022, Congress extended the expansion of ACA premium tax credits through 2025.

These and other laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our products or product candidates for which we may obtain regulatory approval or the frequency with which any such product is prescribed or used. For example, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory cap on the Medicaid drug rebate, beginning January 1, 2024. The rebate was previously capped at 100% of a product's average manufacturer price.

In the European Union, on December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment ("HTA"), amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. The Regulation intends to boost cooperation among European Union Member States in assessing health technologies, including new medicinal products as well as certain high-risk medical devices, and provide the basis for cooperation at the European Union level for joint clinical assessments in these areas. It will permit European Union member states to use common HTA tools, methodologies, and procedures across the European Union, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual European Union Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria and new payment methodologies that govern any approved product 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. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates.

The insurance coverage and reimbursement status of newly approved products is uncertain. Product candidates, if approved, may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices, or healthcare reform initiatives, which would harm our business. Failure to obtain or maintain coverage and adequate reimbursement for any product candidates for which we obtain approval could limit our ability to market those products and decrease our ability to generate revenue.

The regulations that govern marketing approvals, pricing, coverage, and reimbursement for new drugs and other medical products vary widely from country to country. In the United States, healthcare reform legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more products or product candidates, even if any product candidates we may develop obtain marketing approval.

Our ability to successfully commercialize our products and product candidates also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments such as gene therapy products. Sales of these or other product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our products and product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our products or product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. A primary trend in the United States healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products and product candidates. Accordingly, in markets outside the United States, the reimbursement for products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payer to payer. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products.

Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer products have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates, and our overall financial condition.

Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from third-party payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Increasingly, third-party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product or product candidate for which we obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard-of-care products, including lower-priced generic versions of standard-of-care products. We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription products and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

The prices of prescription pharmaceuticals in the United States and foreign jurisdictions are subject to considerable legislative and executive actions and could impact the prices we obtain for our products, if and when approved.

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been 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 addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program ("SIP") to import certain prescription products from Canada into the United States. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America ("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 number of states have submitted SIP proposals to the FDA with the goal of obtaining authority to import drugs from Canada, subject to conditions. On January 5, 2024, the FDA approved Florida's plan for Canadian importation. That state now has authority to import certain products 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 product selected for importation, which must be approved by the FDA. The state will also need to relabel the products 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 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 final rule would also eliminate the current safe harbor for Medicare rebates and create new safe harbors for beneficiary point-of-sale discounts and pharmacy benefit manager service fees. It was originally set to go into effect on January 1, 2022, but with passage of the IRA, has been delayed by Congress to January 1, 2032.

On August 16, 2022, the IRA was enacted. The new legislation 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 product 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 products to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap and it replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). In addition, 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 issuance of its 2025 Physician Fee Schedule final regulation, CMS finalized its rules governing the IRA inflation rebate programs. The IRA permits the Secretary of 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 products 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 nine years and biologics that have been licensed for 13 years. With passage of the One Big Beautiful Bill Act ("OBBBA") in July 2025, Congress expanded the exemption from this provision to drugs and biologics with multiple orphan drug designations. Since CMS may establish a maximum price for these products in price negotiations, we would be fully 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 drug 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.

The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023 with the negotiated prices for ten selected drug products becoming effective on January 1, 2026. The second cycle of negotiations with participating drug companies occurred during 2025, and the negotiated prices for this second set of 15 drugs will be effective on January 1, 2027. On January 27, 2026, CMS published the list of 15 drugs selected for the third cycle of negotiations. These negotiated prices will become effective on January 1, 2028.

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 legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out-of-pocket drug costs at an estimated US$4,000 a year in 2024 and, thereafter beginning in 2025, at US$2,000 a year.

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, a number of other parties also filed lawsuits in various courts with similar constitutional claims. HHS has generally won the substantive disputes in these cases or succeeded in getting claims dismissed for lack of standing or on the merits. For example, on May 8, 2025, the U.S. Court of Appeals for the Third Circuit rejected AstraZeneca L.P.'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.

Since adoption of the IRA, the Trump Administration has taken a number of actions to reduce the costs of pharmaceutical products. On April 15, 2025, President Trump issued an Executive Order which directs HHS to take steps to reduce the prices of pharmaceutical products. Further, on May 12, 2025, President Trump issued an additional Executive Order calling on pharmaceutical manufacturers to voluntarily reduce the prices of medicines in the United States. The Executive Order directs the Secretary of HHS to communicate MFN price targets to pharmaceutical manufacturers to bring prices in line with comparably developed nations. The Executive Order further provides that if such actions do not lower the costs of pharmaceuticals, the Secretary of HHS would pursue other actions, including proposing a rulemaking that imposes MFN pricing in the United States.

Thereafter, on July 31, 2025, President Trump issued letters to 17 pharmaceutical companies reiterating the requirements of the May 12, 2025, Executive Order and demanding that such companies extend MFN pricing to Medicaid patients. Virtually all of these pharmaceutical companies entered into agreements with the Trump Administration to provide for lower prices on certain pharmaceuticals. On February 5, 2026, President Trump launched TrumpRx.gov, a website that directs individuals to pharmaceutical manufacturer websites that are offering price discounts based on the administration's pricing agreements with pharmaceutical manufacturers.

Separately, on December 23, 2025, CMS, through its Center for Medicare and Medicaid Innovation, proposed two five-year pilot programs to implement a "reference pricing" regime for drugs paid for under Medicare for 25% of covered beneficiaries. The programs are referred to as the Global Benchmark for Efficient Drug Pricing (GLOBE) Model for Medicare Part B drugs, and the Guarding U.S. Medicare Against Rising Drug Costs for Medicare Part D drugs. Under the proposed pilot programs, a manufacturer would owe rebates to Medicare if prices for their drugs exceeded the prices paid by other economically comparable reference countries, defined in the proposed regulations as OECD countries with a GDP of $400 billion and a per capita GDP that is at least 60% of the U.S. per capita GDP (an initial list of 19 reference countries is included in the proposed rule). These pilot programs are proposed to go into effect beginning October 1, 2026.

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. 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. In addition, regional healthcare organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription product and other healthcare 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 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.

Finally, outside of the United States, in some countries, including those of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, official list price country pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies.

These measures, as well as others adopted in the future, may result in additional downward pressure on the price that we receive for any approved product it or its collaborators might bring to market. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates.

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 United States, European Union, United

Kingdom and other countries in which we may conduct business. 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 its 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 United States federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to the Health Insurance Portability and Accountability Act ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act 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.

If we are unable to properly protect the privacy and security of protected health information, we could be found to have breached its 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 its operations in the future. 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 2018, California passed into law the California Consumer Privacy Act ("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 2016/679 ("EU GDPR") (regarding individuals in the EEA) and, the UK General Data Protection Regulation ("UK GDPR") (regarding individuals in the United Kingdom ("UK")), as well as applicable data protection laws in effect in the Member States of the EEA and in the UK (including the UK Data Protection Act 2018), 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 EU and UK data protection regimes are independent of each other but remain largely aligned. In this Current Report on Form 8-K, "GDPR" refers to both the EU GDPR and the UK GDPR, unless specified otherwise, and applies to any company established in the EEA/UK and to companies established outside the EEA/UK that process personal data in connection with the offering of goods or services to data subjects in the EEA/UK or the monitoring of the behavior of data subjects in the EEA/UK. The CCPA also affords California residents the right to opt-out of the "sale" of their personal information. The CCPA contains significant penalties for companies that violate its requirements. In November 2020, California voters passed a ballot initiative for the California Privacy Rights Act (the "CPRA"), which 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 before the end of 2026. 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 that will go into effect in 2025 and beyond. Congress has also been debating passing a federal privacy law. 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.

Similar to the laws in the United States, there are significant privacy and data security laws that apply in Europe 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 ("EEA"), and the processing of personal data that takes place in the EEA, is regulated by the GDPR, which went into effect in May 2018 and 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 we or our partners' or 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 it 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 by the European Commission 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 (the "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 also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the United States. This CJEU decision may lead to increased scrutiny on data transfers from the EEA to the United States generally and increase our costs of compliance with data privacy legislation as well as its costs of negotiating appropriate privacy and security agreements with its vendors and business partners.

Following the July 2020 Court of Justice of the European Union judgement invalidating the so-called EU-U.S. Privacy Shield, the European Commission adopted an adequacy decision for the EU-U.S. Data Privacy Framework in July 2023. This adequacy decision permits U.S. companies who self-certify under 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, and there is currently one pending litigation against the EU-U.S. Data Privacy Framework before the Court of Justice of the European Union (CJEU), C-703/25 P – *Latombe v Commission*. 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 so-called standard contractual clauses and other data transfer mechanisms.

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 Union initiated the process to adopt an adequacy decision for the EU-U.S. Data Privacy Framework in December 2022, and the European Commission adopted the adequacy decision on July 10, 2023. The adequacy decision permits United States 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. Following the withdrawal of the United Kingdom from the European Union, the United Kingdom Data Protection Act 2018 applies to the processing of personal data that takes place in the United Kingdom and includes parallel obligations to those set forth by GDPR. In relation to data transfers, both the United Kingdom and the European Union have determined, through separate "adequacy" decisions, that data transfers between the two jurisdictions are in compliance with the U.K. Data Protection Act and the GDPR, respectively. The United Kingdom and the United States have also agreed to a U.S.-U.K. "Data Bridge," which functions similarly to the EU-U.S. Data Privacy Framework and provides an additional legal mechanism for companies to transfer data from the United Kingdom to the United States. In addition to the United Kingdom, Switzerland is also in the process of approving an adequacy decision in relation to the Swiss-U.S. Data Privacy Framework (which would function similarly to the EU-U.S. Data Privacy Framework and the U.S.-U.K. Data Bridge in relation to data transfers from Switzerland to the United States). Any changes or updates to these developments have the potential to impact our business.

Beyond GDPR, there are privacy and data security laws in a growing number of countries around the world. While many loosely follow GDPR as a model, other laws contain different or conflicting provisions. These laws will impact our ability to conduct its business activities, including both our clinical trials and the sale and distribution of commercial products, through increased compliance costs, costs associated with contracting and potential enforcement actions.

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.

Changes in and uncertainty surrounding U.S. and internal trade policy could have a material adverse impact on our business, financial condition and results of operations.

In the spring of 2025, the Trump Administration initiated a series of tariff-related actions against U.S. trading partners. On April 2, 2025, President Trump issued an Executive Order announcing a "baseline" reciprocal tariff of 10% on all U.S. trading partners effective April 5, 2025, and higher individualized reciprocal tariffs on 57 countries (with certain product exemptions for pharmaceutical-related products, among others). Previously, the administration had imposed a 25% tariff on Canada and Mexico for goods not covered by the United States-Mexico-Canada Agreement ("USMCA"), and tariffs equaling 20% on imports from China. In response, several countries threatened retaliatory measures, including Canada and China, which then imposed retaliatory tariffs. Prior to when the country-specific reciprocal tariffs were scheduled to take effect, the administration delayed the effective date of such tariffs for all countries except China to August 1, 2025. Later, the United States and China reached a framework agreement that ultimately resulted in the suspension of the higher reciprocal tariffs on China until November 10, 2025. Shortly before that expiration date, the United States and China reached a one-year agreement with an expiration of November 10, 2026, that includes the continued suspension of the heightened reciprocal tariffs on China and delayed enforcement of new U.S. export rules targeting affiliates of blacklisted firms.

Since the April 2025 reciprocal tariffs announcement, several countries have reached framework agreements to reduce tariff rates and other measures with the United States, including the United Kingdom, Vietnam and Indonesia, Japan, the Philippines, the EU, South Korea, Thailand, Malaysia, Cambodia, China, El Salvador, Argentina, Ecuador, Guatemala, Switzerland and Liechtenstein, and Taiwan. On July 31, 2025, the United States administration issued an executive order detailing new reciprocal tariff rates for individual countries that took effect on August 7, 2025. The deals with the European Union, Japan, South Korea, Switzerland (and Liechtenstein), the United Kingdom and others cap pharmaceutical tariffs at 15%. In addition, an agreement with Malaysia provides a zero percent tariff exemption for pharmaceutical products that are not patented in the U.S. and are used in pharmaceutical applications and an agreement with Switzerland and Lichenstein caps tariffs on pharmaceuticals imported from those two countries at 15%. Finally, an agreement with Taiwan concluded on January 15, 2026 eliminates tariffs on generic pharmaceuticals and their active ingredients imported from Taiwan.

The reciprocal tariffs were imposed pursuant to the International Emergency Economic Powers Act (the "IEEPA"). These tariffs were found to be unconstitutional by multiple federal courts in the spring and summer of 2025. On February 20, 2026, the U.S. Supreme Court held that IEEPA does not authorize the President to impose tariffs, invalidating the reciprocal tariffs. Shortly thereafter, President Trump issued a new Executive Order revoking the IEEPA tariffs and Customs and Border Protection ceased collecting the tariffs as of 12:01 am on February 24, 2026. At the same time, however, the Trump Administration imposed a new 10% global tariff under Section 122 of the Trade Act of 1974, or the Trade Act, effective February 24, 2026. Pursuant to the statute, absent an extension by Congress, these tariffs will expire in 150 days on July 24, 2026. For those countries that have concluded trade deals with the United States, the tariff rates agreed to, including with regard to pharmaceuticals and pharmaceutical ingredients, have now reverted to 10% until July 24, 2026.

Like the IEEPA tariffs, pharmaceuticals and pharmaceutical ingredients are exempt from the tariffs under Section 122 of the Trade Act along with a list of other products. The Trump Administration has announced that it also plans to initiate new investigations on "most major trading partners" under Section 301 of the Trade Act, which will likely lead to additional tariffs. Neither the U.S. Supreme Court's decision nor the Executive Order revoking the IEEPA tariffs addressed refunds, leaving the issue to renewed proceedings before the U.S. Court of International Trade, where importers may need to pursue administrative remedies and/or litigation amid continued uncertainty.

Sustained uncertainty about, or the further escalation of, trade and political tensions between the United States and China could result in a disadvantageous research and manufacturing environment in China, particularly for U.S. based companies, including retaliatory restrictions that hinder or potentially inhibit our ability to rely on CDMOs and other service providers that operate in China..

Separately, in April 2025, the Department of Commerce initiated an investigation under Section 232 of the Trade Expansion Act of 1962 into the impact on U.S. national security of the imports of pharmaceuticals and pharmaceutical ingredients, including finished drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients, and key starting materials, and derivative products of those items. On September 25, 2025, via a post on Truth Social, President Trump announced that, beginning October 1, 2025, all branded or patented drugs imported in the United States would face a 100% tariff. At the same time, President

Trump indicated that these tariffs could be avoided by building pharmaceutical manufacturing facilities in the United States. Thereafter, President Trump delayed the October 1, 2025 effective date of the tariffs on branded or patented pharmaceutical products announcing that the Trump Administration had now "begun preparing" tariffs on manufacturers that do not build in the United States or enter into a most-favored-nation drug pricing agreement with the Trump Administration.

As a result of changes in tariffs that have been announced and/or implemented, and the underlying uncertainty currently surrounding international trade, we could experience a negative impact to our costs of materials and production processes, and supply chain disruptions and delays as a result of any new tariff policies or trade restrictions. If we are unable to obtain necessary raw materials or product components in sufficient quantity and in a timely manner due to disruptions in the global supply chain caused by macroeconomic events and conditions, the development, testing and clinical trials of our product candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. We cannot yet predict the effect of the recently imposed U.S. tariffs on imports, or the extent to which other countries will impose quotas, duties, tariffs, taxes or other similar restrictions upon imports or exports in the future, nor can we predict future trade policy or the terms of any renegotiated trade agreements and their impact on our business.

Risks Related to Employee Matters and Managing Growth

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

We are highly dependent on the research and development, clinical, financial, operational and other business expertise of our executive officers, as well as the other principal members of our management, scientific and clinical teams. Although we entered into employment agreements with certain of our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of its executives or other employees. Recruiting and retaining qualified scientific, clinical, manufacturing, accounting, legal and sales and marketing personnel is also critical to our success.

In addition, the loss of the services of our executive officers or other key employees, including temporary loss due to illness, could impede the achievement of our 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 marketing 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 biopharmaceutical companies for similar personnel.

We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Failure to succeed in clinical trials may make it even more challenging to recruit and retain qualified scientific personnel. Our success as a public company also depends on implementing and maintaining internal controls and the accuracy and timeliness of its financial reporting. If we are unable to continue to attract and retain high quality personnel, our ability to pursue its growth strategy will be limited.

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly as we function as a public company and in the areas of product development, clinical, regulatory affairs, manufacturing and quality control and, if any of our product candidates receives marketing approval, sales, marketing, and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Future growth will impose significant added responsibilities on members of our management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and regulatory review process for TH103 and other product candidates we may develop, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to advance development of and, if approved, commercialize TH103 and any other product candidate we are developing or may develop in the future will depend, in part, on our ability to effectively manage any future growth. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. If we do not effectively manage the expansion of our operations, we could experience weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The expansion of our operations could also lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Many of the biopharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can develop product candidates and operate our business will be limited.

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

Our internal computer systems and those of any of our collaborators, vendors, suppliers, contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such systems are also vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third-party vendors and/or business partners, or from cyber-attacks by malicious third parties. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-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-attacks also could include phishing attempts or email fraud to cause payments or information to be transmitted to an unintended recipient.

If we experience any material system failure, accident, cyber-attack or security that causes 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 its trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our marketing 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 or proprietary information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be delayed.

Our employees, independent contractors, including principal investigators, consultants and vendors and any third parties we may engage in connection with research, development, regulatory, manufacturing, quality assurance and other pharmaceutical functions and commercialization may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, including principal investigators, consultants and vendors and any other third parties we engage. Misconduct by these parties could include intentional, reckless or negligent conduct or unauthorized activities that include failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide complete and accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards, comply with federal and state data privacy, security, fraud and other healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report complete financial information or data accurately or disclose unauthorized activities to us. Misconduct by employees and other third parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. This could include violations of HIPAA, other United States federal and state law, and requirements of non-United States jurisdictions, including the European Union Data Protection Directive. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards, regulations, guidance or codes of conduct. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other United States federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

Risks Related to the Ownership of Our Common Stock

The market price of our common stock has been and is expected to continue to be volatile.

The trading price of our common stock has been and is expected to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "*Risk Factors*" section, these factors include:

- results of clinical trials and preclinical studies of our product candidate, or those of our competitors or our existing or future collaborators;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- actions taken by regulatory agencies with respect to our product candidate, clinical studies, manufacturing process or sales and marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of qualified scientific and management personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions or market conditions in the biopharmaceutical sector;
- sales of securities by us or our stockholders in the future;
- if we fail to raise an adequate amount of capital to fund our operations and continued development of our product candidate;
- trading volume of our common stock;
- announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to product candidates, including with respect to other products in such markets;
- the introduction of technological innovations or new therapies that compete with the products and services of ours;
- period-to-period fluctuations in our financial results; and
- general economic, industry and market conditions, such as those caused by the ongoing conflict between Russia and Ukraine, conflicts in the Middle East, inflation, fluctuations in interest rates and tariffs and other trade restrictions.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In addition, a recession, depression or other sustained adverse market event could materially and adversely affect our business and the value of our common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies. Furthermore, market volatility may lead to increased shareholder activism if we experience a market valuation that activists believe is not reflective of its intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition.

We incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies.

As a public company, we incur significant legal, accounting and other expenses as a public company that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which requires, among other things, that we file with the SEC annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, the Dodd-Frank Act, the listing requirements of The Nasdaq Global Market and other applicable securities rules and regulations impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

Our executive officers and other personnel need to devote substantial time to gaining expertise related to public company reporting requirements and compliance with applicable laws and regulations to ensure that we comply with all of these requirements. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on the board of directors or on board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

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 to and intend to rely on exemptions from disclosure requirements that are applicable to other public companies that are not smaller reporting companies, including:

- reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002;
- 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 if we rely 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.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of us or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;

- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we will be governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These antitakeover provisions and other provisions in our restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer, or proxy contest involving us. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors of their choosing or cause us to take other corporate actions they desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our amended and restated bylaws designates certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claim for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our restated certificate of incorporation or our amended and restated bylaws or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein (the "Delaware Forum Provision"). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the United States District Court for the District of Massachusetts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (the "Federal Forum Provision"). In addition, our amended and restated bylaws will provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision that are in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a forum that they 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 even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court and other state courts have upheld the validity of forum selection provisions purporting to require claims under the Securities Act be brought in federal court, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the United States District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us and our stockholders.

We do not anticipate paying any cash dividends in the foreseeable future.

We currently anticipate that we will retain our future earnings, if any, to fund the growth of our business as opposed to paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain, if any, for the foreseeable future.

We do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and, as a result, it may be difficult for our stockholders to sell shares of our common stock.

AlloVir's IPO closed on August 3, 2020. Prior to AlloVir's IPO, there was no public market for shares of its common stock. Prior to the Merger, there had been no public market for shares of Legacy Kalaris capital stock. Although AlloVir completed its IPO and the Merger has closed, and shares of our common stock are listed and trading on The Nasdaq Global Market, an active trading market for our shares may never develop or be sustained. Our stockholders may not be able to sell shares quickly or at the market price if trading in shares of our common stock is not active. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

Transfers of our securities utilizing Rule 144 of the Securities Act may be limited.

A significant portion of our securities are restricted from immediate resale. Holders should be aware that transfers of our securities pursuant to Rule 144 may be limited as Rule 144 is not available, subject to certain exceptions, for the resale of securities initially issued by shell companies (other than business combination related shell companies) or issuers that have been at any time previously a shell company. Our possible disposal of certain of AlloVir's historical assets and operations in connection with the Merger made AlloVir subject to the SEC requirements applicable to reporting shell company business combinations. Following the consummation of the Merger, we are no longer a shell company. As a result, we anticipate that holders will not be able to sell their restricted securities of ours pursuant to Rule 144 without registration until one year after March 18, 2025, the date that we filed the Current Report on Form 8-K following the closing of the Merger that includes the required Form 10 information which reflects that we are no longer a shell company.

Our possible disposal of certain of AlloVir's historical assets and operations, the discontinuation of AlloVir's product development programs and the Merger made AlloVir subject to the SEC requirements applicable to reporting shell company business combinations. As a result, we are subject to more stringent reporting requirements, offering limitations and resale restrictions.

According to SEC guidance, the requirements applicable to reporting shell company business combinations apply to any company that sells or otherwise disposes of its historical assets or operations in connection with or as part of a plan to combine with a non-shell private company in order to convert the private company into a public one. AlloVir discontinued the development of its product candidates and we may seek to dispose of certain of AlloVir's historical assets and operations. As such, the Merger was subject to the SEC requirements applicable to reporting shell company business combinations, which are as follows:

- we were required to file a Current Report on Form 8-K following the closing of the Merger to report the Form 10 type information with the SEC reflecting our status as an entity that is not a shell company;
- we are not eligible to use a Form S-3 until 12 full calendar months after the date of the Current Report on Form 8-K following the closing of the Merger;
- we were required to wait at least 60 calendar days after the date of the Current Report on Form 8-K following the closing of the Merger to file a Form S-8 for any equity plans or awards such as the 2020 Stock Option and Grant Plan, as amended (the "2020 Plan") and the 2019 Equity Incentive Plan, as amended (the "2019 plan");
- we are an "ineligible issuer" for three years following the closing the Merger, which will prevent us from (i) incorporating by reference in our Form S-1 filings, (ii) use a free writing prospectus, or (iii) take advantage of the well-known seasoned issuer (WKSI) status despite our public float;
- investors who (i) were affiliates of Legacy Kalaris at the time the Merger was submitted for the vote or consent of Legacy Kalaris' stockholders, (ii) received securities of us in the Merger (i.e., Rule 145(c) securities) and (iii) publicly offer or sell such securities will be deemed to be engaged in a distribution of such securities, and therefore to be underwriters with respect to resales of those securities; and
- Rule 144(i)(2) will limit the ability to publicly resell Rule 145(c) securities per Rule 145(d), as well as any other "restricted" or "control" securities of ours per Rule 144 (e.g., holders of restricted securities and any affiliates of the public company are also affected) until one year after the date that we filed the Current Report on Form 8-K following the closing of the Merger that includes the required Form 10 information with the SEC.

The foregoing SEC requirements will increase our time and cost of raising capital, offering stock under equity plans, and compliance with securities laws. Further, such requirements will add burdensome restrictions on the resale of our shares by affiliates of Legacy Kalaris and any holders of "restricted" or "control" securities.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to the 2020 Plan or the 2019 Plan, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, expanded research and development activities, and costs associated with operating as a public company. To raise capital, we may sell common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities, or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences, and privileges senior to the holders of our common stock.

Pursuant to the 2020 Plan and the 2019 Plan, our management is authorized to grant stock options to our employees, directors, and consultants.

The number of shares of common stock reserved for issuance under the 2020 Plan increased on January 1, 2026 and shall be cumulatively increased each January 1 thereafter by 5% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

Additionally, at a special meeting of our stockholders held on March 12, 2025, our stockholders approved an amendment to the 2020 Plan which increased the number of shares of our common stock reserved and available for future issuance under the 2020 Plan by a number of shares of common stock equal to five percent of the total number of shares of common stock that were issued and outstanding immediately following the closing of the Merger.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

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.

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, 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.

Moreover, in December 2025, we sold to certain institutional investors shares of our common stock and pre-funded warrants in our 2025 Private Placement. We have entered into a registration rights agreement with the investors in the 2025 Private Placement entitling them to certain resale registration rights with respect to the shares of common stock issued in the 2025 Private Placement and the shares of common stock issuable upon the exercise of the pre-funded warrants issued in the 2025 Private Placement, and we have agreed to keep each such registration statements 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. 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 will 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.

Our executive officers, directors and principal stockholder, Samsara LP, have the ability to control or significantly influence all matters submitted to our stockholders for approval.

Our executive officers, directors and principal stockholder, Samsara LP, in the aggregate, beneficially owned approximately 68.0% of our outstanding shares of common stock as of December 31, 2025. As a result, if these stockholders were to choose to act together (or, in the case of Samsara LP, alone), they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together (or, in the case of Samsara LP, alone), they would be able to control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of us on terms that other stockholders may desire. In addition, as a result of this concentration of ownership, there may be a limited number of shares of our common stock that are not held by officers, directors and the principal stockholder, thereby adversely impacting the liquidity of our common stock and potentially depressing the price at which stockholders may be able to sell shares of common stock.

Samsara LP, our principal stockholder, beneficially owns greater than 50% of our outstanding shares of capital stock, which has caused us to be deemed a "controlled company" under the rules of Nasdaq.

Samsara LP controlled approximately 56.5% of the voting power of our capital stock as of December 31, 2025. As a result, Samsara LP owns more than 50% of our outstanding capital stock, and as such, we are a "controlled company" under the rules of Nasdaq. Under these rules, a company of which more than 50% of the voting power is held by an individual, a group or another company is a "controlled company" and, as such, can elect to be exempt from certain corporate governance requirements, including requirements that:

- a majority of the board of directors consist of independent directors;
- director nominations be made, or recommended to the full board of directors, by independent directors or by a nominating committee that is composed entirely of independent directors that has adopted a written charter addressing the nominations process; and
- the compensation committee be composed entirely of independent directors with a written charter addressing the committee's purpose and responsibility.

We rely on certain of these exemptions. As a result, our stockholders will not have the same protections afforded to stockholders of companies that are subject to all of the Nasdaq corporate governance requirements.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

We have broad discretion in the use of our cash and cash equivalents and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

We have broad discretion over the use of our cash and cash equivalents. You may not agree with our decisions, and our use of our cash and cash equivalents may not yield any return on your investment. Our failure to apply these resources effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of our cash and cash equivalents. You will not have the opportunity to influence our decisions on how to use our cash resources.

General Risk Factors

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

Income, sales, use or other tax laws, statutes, rules, or regulations could be enacted or amended at any time, which could affect our business or financial condition, including causing potentially adverse impacts to our effective tax rate, tax liabilities, and cash tax obligations. For example, the IRA was signed into law in August 2022, and the OBBBA was signed into law in July 2025. 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. The OBBBA contains numerous tax provisions that we are currently in the process of evaluating, and which may significantly affect our business or financial condition. The recent changes under the OBBBA include tax rate extensions and changes to the business interest deduction limitation, the expensing of domestic research and development expenditures (in contrast to the continued capitalization and amortization of foreign research and development expenditures), the bonus depreciation deduction rules, and the international tax framework. Regulatory guidance under the IRA, the OBBBA, and other tax-related legislation is and continues to be forthcoming, and such guidance could ultimately increase or lessen the impact of these laws on our business and financial condition. In addition, it is uncertain if and to what extent various states will conform to changes to federal tax legislation.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cyber Risk Management and Strategy

We rely on information technology systems and cloud-based services to support our business operations, including collaboration, communication, and the storage and processing of information. These systems include platforms and services that are operated by us and by third-party providers.

We have developed and implemented a cybersecurity program with certain processes for assessing, identifying and managing cybersecurity risk, which are intended to manage risk and protect the confidentiality, integrity, and availability of our critical systems and information. We design and assess our cybersecurity program with reference to the National Institute of Standards and Technology Cybersecurity Framework ("NIST CSF").

Our cybersecurity risk management activities and processes are supported principally by internal personnel and third-party service providers, including an outside information technology management/cybersecurity consultant, which provide information technology support, cybersecurity operations, and infrastructure and security engineering services, including procedural and technical safeguards, response plans, incident simulations and routine review of our policies and procedures to identify risks and refine our practices.

Key elements of our cybersecurity program include, but are not limited to, the following:

- identity and access management controls, including multi-factor authentication using Microsoft Entra ID;
- email security controls designed to help detect and prevent phishing and other email-based threats;
- endpoint management and security controls, including device management and patching using Microsoft Intune;
- network security controls, including perimeter firewalls and outbound web filtering at our office location;
- periodic security awareness training for employees; and
- phishing simulation campaigns conducted periodically to reinforce employee awareness and support identification of potential social engineering risks.

We also take a risk-based approach to evaluating third-party vendors and service providers based on their access to our systems and information and their criticality to our operations. 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.

We have not identified any cybersecurity incidents that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition. Like other companies, we face risks from cybersecurity threats that could result in unauthorized access to systems or information, service disruptions, or other impacts.

Governance Related to Cybersecurity Risks

Our Chief Accounting Officer and management are responsible for the day-to-day oversight of cybersecurity risk management, including coordinating with our managed service provider to support cybersecurity operations and infrastructure and security engineering efforts. Management periodically reviews cybersecurity risks and the steps taken to monitor and manage such risks. Our Chief Accounting Officer has many years of experience overseeing company-wide information technology risks, and is supported by our outside information technology management/cybersecurity consultant.

Our audit committee oversees risks from cybersecurity threats as part of its broader risk oversight responsibilities. The audit committee receives periodic updates from our Chief Accounting Officer and management regarding cybersecurity matters, including material risks and, if applicable, significant cybersecurity incidents.

Item 2. Properties.

We lease office space in Berkeley Heights, New Jersey under a lease agreement that is expected to terminate in December 2031, which serves as our corporate headquarters. We have the option to extend the lease term twice, each for an additional three years. We believe these facilities will be adequate for the foreseeable future and that suitable additional or substitute space will be available as and when needed.

Item 3. Legal Proceedings.

From time to time, we may become subject to arbitration, litigation or claims arising in the ordinary course of business.

Litigation Related to the Merger

Two complaints have been filed by purported AlloVir stockholders as individual actions against AlloVir and the members of its board of directors in the Supreme Court of the State of New York, New York County, captioned Keller v. AlloVir, Inc. et al., No. 650989/2025 (N.Y. Sup. Ct. Feb. 20, 2025), and Morgan v. AlloVir, Inc. et al., No. 650965/2025 (N.Y. Sup. Ct. Feb. 19, 2025) (the "Complaints"). The Complaints allege that the proxy statement/prospectus describing the transaction between Legacy Kalaris and AlloVir misrepresented and/or omitted certain purportedly material information, and assert claims for negligent misrepresentation and concealment and negligence under New York common law. The Complaints seek various remedies including, among other things, an order enjoining the consummation of the merger, requiring the defendants to file an amended proxy statement/prospectus, rescinding the merger or granting rescissory damages, and awarding costs, including plaintiff's attorneys' fees and experts' fees, and other relief the court may deem just and proper. AlloVir and Legacy Kalaris deny the allegations in the Complaints and deny that any further disclosure beyond that already contained in the proxy statement/prospectus was required under applicable law.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock has been publicly traded on The Nasdaq Global Market under the symbol "KLRS" since the closing of the Merger on March 18, 2025. Prior to the consummation of the Merger, our common stock had been listed on The Nasdaq Capital Market under the symbol "ALVR" since July 30, 2020.

Holders of Record

As of March 10, 2026, we had approximately 72 holders of record of our common stock. Certain shares are held in "street" name and accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our common stock or any other securities. We anticipate that we will retain all available funds and any future earnings, if any, for use in the operation of our business and do not anticipate paying cash dividends in the foreseeable future. In addition, future debt instruments may materially restrict our ability to pay dividends on our common stock. Payment of future cash dividends, if any, will be at the discretion of the board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, the requirements of then-existing debt instruments and other factors the board of directors deems relevant.

Information About our Equity Compensation Plans

The information required by this item will be set forth in our Proxy Statement for the 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Recent Sales of Unregistered Securities

We did not sell any shares of our common stock, shares of preferred stock or warrants to purchase shares of our stock, or grant any stock options, restricted stock units or restricted stock awards, during the year ended December 31, 2025 that were not registered under the Securities Act, and that have not otherwise been disclosed in a Current Report on Form 8-K or Quarterly Report on Form 10-Q.

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

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 consolidated financial statements and related notes thereto appearing elsewhere in this Annual Report. This Annual Report contains forward-looking statements that involve risks and uncertainties, such as our plans, objectives, expectations, intentions, and beliefs. There are a number of important risks and uncertainties that could cause our actual results to differ materially from those discussed in these forward-looking statements. 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. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section titled "Risk Factors" under Part I, Item 1A of this Annual Report and those discussed in our other disclosures and filings. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make. All historical common share data and per-share amounts prior to the Merger (as defined below) have been retrospectively adjusted to reflect the exchange ratio of 0.2016 per one share, which was determined in accordance with the Merger Agreement (as defined below).

Overview

We are a clinical stage biopharmaceutical company dedicated to the development and commercialization of treatments for prevalent retinal diseases with major unmet medical needs.

We are developing TH103, a novel, clinical stage anti-vascular endothelial growth factor ("VEGF") drug, specifically engineered to achieve extended intraocular retention with enhanced VEGF inhibition in patients with exudative and/or neovascular retinal diseases. TH103 is a fully humanized recombinant fusion protein, functioning as a "decoy receptor" (a VEGF trap), leveraging salient molecular properties of the human body's native, highest affinity VEGF receptor 1. In head-to-head preclinical studies, TH103 showed more anti-VEGF activity and longer duration of activity compared to aflibercept, the current global market-leading anti-VEGF agent, which also functions as a decoy receptor VEGF trap but differs from TH103 in key molecular elements. Initial data from our Phase 1a single ascending dose ("SAD") trial of TH103 in treatment-naïve neovascular Age-related Macular Degeneration ("nAMD") patients showed that TH103 was generally well tolerated and exhibited improvements on functional and anatomical outcomes at 1-month post-dosing. Preliminary single dose pharmacokinetic data and retreatment results provide evidence that TH103 may offer extended treatment durability after a standard four-dose loading regimen.

We are investigating TH103 as a treatment for patients with nAMD, a leading cause of blindness in the United States and Europe that affect an estimated 1.6 million adults in the United States. We are currently conducting a Phase 1b/2 multiple ascending dose clinical trial of TH103 in patients with nAMD, which is intended to build upon our ongoing Phase 1a single ascending dose clinical trial. The Phase 1b/2 dose-finding trial is designed to evaluate multiple dose levels of TH103 in approximately 60 to 80 nAMD patients. In the trial, patients are expected to receive four initial monthly intravitreal injections of TH103 and assessments are expected to include safety and preliminary efficacy with a primary time point for analysis at one month following the last injection. Patients will then be followed in an extension phase of the study. We expect to report preliminary data from the Phase 1b/2 clinical trial in the first half of 2027. Assuming successful completion of the ongoing Phase 1b/2 clinical trial of TH103, and subject to the favorable results from such trial and discussions with regulators, we intend to initiate Phase 3 clinical trials of TH103 for nAMD by year-end 2027. We also plan to expand the development of TH103 beyond nAMD into other prevalent VEGF-mediated retinal diseases, such as Diabetic Macular Edema ("DME"), diabetic retinopathy ("DR"), and Retinal Vein Occlusion ("RVO").

Since our inception in September 2019, we have devoted substantially all of our resources to organizing and staffing, business planning, raising capital, acquiring technology, establishing our intellectual property portfolio and performing research and development of our product candidate. We do not have any products approved for sale and have not generated any revenue from product sales or otherwise. We have incurred significant losses and negative cash flows from operations since our inception. Our net losses were $43.4 million and $69.2 million for the years ended December 31, 2025 and 2024, respectively. Our negative cash flows from operations were $38.4 million and $20.7 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $160.0 million. To date, we have funded our operations primarily from sales of our redeemable convertible preferred stock, issuances of convertible promissory notes and a simple agreement for future equity ("SAFE"), from cash and cash equivalents of AlloVir, Inc. ("AlloVir") received in the Merger (as defined below), and from proceeds from the 2025 Private Placement (as defined below).

From inception through December 31, 2025, we have received gross proceeds of $67.5 million from sales of redeemable convertible preferred stock, issuances of convertible promissory notes and a SAFE, we received cash and cash equivalents of AlloVir of approximately $102.1 million in the Merger, and we received aggregate gross proceeds of $50.0 million from the 2025 Private Placement.

As of December 31, 2025, we had $118.0 million in cash, cash equivalents and short-term marketable securities. Based on our current operating plans, our management expects that our cash, cash equivalents and short-term marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2027. However, management has based these estimates on assumptions that may prove to be wrong, and our operating plans may change as a result of many factors currently unknown to us. In addition, changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. As a result, we could deplete our capital resources sooner than we currently expect.

We expect to continue to incur substantial losses for the foreseeable future, including costs associated with operating as a public company. We do not expect to generate any revenue from commercial product sales unless and until we successfully complete development and obtain regulatory approval for our product candidate. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of our product candidate, which may never occur. We may never achieve or maintain profitability. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations.

We anticipate that our expenses will increase substantially if and as we:

- conduct our ongoing Phase 1a and Phase 1b/2 clinical trials of TH103 in patients with nAMD;
- continue to progress the development of TH103 in future preclinical studies and clinical trials;
- advance any future product candidate that we may develop into preclinical and clinical development;
- maintain, expand, enforce and protect our intellectual property portfolio;
- seek regulatory and marketing approvals for TH103 and any other product candidate that successfully completes clinical trials;
- seek to identify and maintain additional collaborations and license agreements, and the success of those collaborations and license agreements;
- make any payments under our existing or future strategic collaboration agreements, licensing agreements or sponsored research agreements, including with the University of California, San Diego (“UCSD”);
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval;
- generate revenue from commercial sales of product candidates that may receive marketing approval;
- hire additional clinical, regulatory, manufacturing, quality control, development and scientific personnel;
- in-license or acquire additional technologies or product candidates;
- establish a commercial manufacturing source and secure supply chain capacity sufficient to provide commercial quantities of any product candidates we may develop for which we obtain regulatory approval; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts and our operations as a public company.

We do not currently own or operate any drug development or manufacturing facilities. We rely on Contract Development and Manufacturing Organizations (“CDMOs”) to help develop and produce TH103 in accordance with the U.S. Food and Drug Administration’s (“FDA”) current Good Manufacturing Practices regulations for use in our clinical trials. We use external contract research organizations (“CROs”) to conduct our preclinical studies and clinical trials.

Given our stage of development, we do not yet have a marketing or sales organization or commercial infrastructure. Accordingly, if we obtain regulatory approval for our product candidate, we also expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution.

Because of the numerous risks and uncertainties associated with product development, our management is unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability, if at all. Even if we are able to generate revenue from the sale of our product candidate, we may not achieve or maintain profitability. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

Macroeconomic Trends

The disruption and volatility in the global and domestic capital markets resulting from heightened inflation, current and potential tariffs and other trade restrictions, interest rate and currency rate fluctuations, disruptions at government agencies under the U.S. administration (such as workforce reductions or funding cuts), any potential economic slowdown or recession, including trade wars or civil or political unrest (such as the ongoing war between Ukraine and Russia, conflicts in the Middle East, and tension between China and Taiwan) may increase the cost of capital and limit our ability to access capital. These and similar adverse market conditions may negatively impact our business, financial position and results of operations.

Additionally, in April 2025, the U.S. administration initiated a series of tariff-related actions against U.S. trading partners. Although several countries have threatened or imposed retaliatory measures in response, the U.S. has reached agreements with a number of trading partners, and negotiations with others remain ongoing. Tariff-related actions are likely to remain a prominent part of U.S. economic policy for the foreseeable future, which may introduce uncertainty in international trade, including impacts to the costs of materials and production processes, supply chain stability, and other factors. While we have not experienced, and do not currently expect to experience, any direct impact from these tariffs and retaliatory measures, the full extent of the future impact of these and other threatened measures remains uncertain. We continue to monitor these tariffs and retaliatory measures and their possible effects on our business.

Legacy Kalaris Financing

In October 2024, Kalaris Tx, Inc. (formerly, Kalaris Therapeutics, Inc.), a Delaware corporation ("Legacy Kalaris") entered into a convertible note purchase agreement with Samsara BioCapital L.P. ("Samsara") to issue to Samsara and other investors who subsequently joined the agreement up to $25.0 million of convertible promissory notes with a maturity date of May 31, 2025 (the "Convertible Note Financing"). In October and November 2024, Legacy Kalaris received $10.0 million from the initial closings of the Convertible Note Financing. Under the Merger Agreement (as defined below), Legacy Kalaris was permitted to issue additional convertible promissory notes pursuant to the Convertible Note Financing or otherwise to fund its operations prior to the closing of the Merger (as defined below) in an amount not to exceed $15.0 million in the aggregate on a to be converted post-money basis, with up to $7.5 million to be provided by AlloVir and up to $7.5 million to be provided by existing Legacy Kalaris stockholders (the "Additional Permitted Bridge Financing"). In January 2025, as part of the first tranche of the Additional Permitted Bridge Financing, Legacy Kalaris issued a convertible promissory note in an aggregate principal amount of up to $7.5 million to AlloVir (the "AlloVir Note") under which AlloVir funded a principal amount of $3.75 million, and Legacy Kalaris issued convertible promissory notes in an aggregate principal amount of $3.75 million to existing Legacy Kalaris stockholders. No additional tranches of the convertible notes financing closed prior to the closing of the Merger. Immediately prior to the closing of the Merger, Legacy Kalaris' outstanding convertible promissory notes held by its existing stockholders were converted into shares of Legacy Kalaris' common stock or shares of Legacy Kalaris' Series B-2 redeemable convertible preferred stock ("Series B-2 Preferred Stock") that were then converted into shares of Legacy Kalaris' common stock, which, at the effective time of the Merger, were converted into the right to receive shares of AlloVir's common stock calculated in accordance with the Exchange Ratio (as defined below). Immediately prior to the closing of the Merger, Legacy Kalaris' outstanding convertible promissory note issued to AlloVir was cancelled.

Merger with AlloVir

On March 18, 2025 (the "Closing Date"), AlloVir consummated the previously announced merger (the "Merger") pursuant to the terms of the Agreement and Plan of Merger, dated as of November 7, 2024 (the "Merger Agreement"), by and among AlloVir, Aurora Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of AlloVir ("Merger Sub") and Legacy Kalaris.

In connection with the Merger, at the effective time of the Merger (the "Effective Time"), Merger Sub merged with and into Legacy Kalaris, with Legacy Kalaris continuing as a wholly-owned subsidiary of AlloVir and the surviving corporation of the Merger and, after giving effect to the Merger, Legacy Kalaris became a wholly-owned subsidiary of AlloVir, and immediately following the Effective Time, AlloVir changed its name to "Kalaris Therapeutics, Inc." At the Effective Time, our business became primarily the business conducted by Legacy Kalaris.

Subject to the terms and conditions of the Merger Agreement, at the Effective Time, all issued and outstanding shares of Legacy Kalaris' common stock (including common stock issued upon conversion of Legacy Kalaris' preferred stock and outstanding convertible promissory notes) converted into the right to receive 0.2016 shares of AlloVir's common stock calculated in accordance with an exchange ratio equal to 1:0.2016 (the "Exchange Ratio"). Each award of restricted shares of Legacy Kalaris' common stock that was unvested and outstanding was converted into and exchanged for the right to receive a number of restricted shares of AlloVir common stock based on the Exchange Ratio. Each outstanding option to purchase shares of Legacy Kalaris' common stock under Legacy Kalaris' 2019 Equity Incentive Plan, whether or not vested, was converted into an option to acquire a number of shares of AlloVir's common stock based on the Exchange Ratio. Exercise prices of assumed options were determined as the product of the exercise price immediately prior to the Effective Time multiplied by the reciprocal of the Exchange Ratio, and rounding up to the nearest whole cent. There were no changes to any other terms of such options or restricted share awards. Immediately following the

Merger, stockholders of Legacy Kalaris owned approximately 74.47% of the outstanding common stock of the combined company on a fully diluted basis. The Merger was accounted for as a reverse recapitalization in accordance with accounting principles generally accepted in the United States ("GAAP"). Under this method of accounting, Legacy Kalaris was deemed to be the accounting acquirer for financial reporting purposes. Accordingly, for accounting purposes, the Merger was treated as the equivalent of Legacy Kalaris issuing stock to acquire the net assets of AlloVir. As a result of the Merger, the net assets of AlloVir were recorded at their carrying value and our financial statements are consolidated after the Effective Time.

2025 Private Placement

On December 17, 2025, we entered into a securities purchase agreement (the "2025 Securities Purchase Agreement") with certain institutional investors named therein, pursuant to which, we issued and sold in a private placement (the "2025 Private Placement"), an aggregate of (i) 4,200,000 shares of our common stock at a purchase price of $10.00 per share, and (ii) pre-funded warrants ("Pre-Funded Warrants") to purchase up to an aggregate of 800,000 shares of our common stock at a purchase price of $9.9999 per Pre-Funded Warrant, which represents the per share purchase price of our common stock less the $0.0001 per share exercise price for each Pre-Funded Warrant. The Pre-Funded Warrants are exercisable at any time after the date of issuance and will be exercisable until the Pre-Funded Warrant is exercised in full. In connection with the closing of the 2025 Private Placement, we received aggregate gross proceeds from the 2025 Private Placement of $50.0 million, before deducting placement agent fees and offering expenses.

License Agreement with the University of California, San Diego

In April 2021, we entered into a license agreement with UCSD (as amended, the "UCSD Agreement") pursuant to which we obtained (i) an exclusive license under the patent rights to make, use, sell, offer for sale, and import licensed products and (ii) a non-exclusive license to use the technology with a right to sublicense, each (i) and (ii) related to new anti-VEGF agents and novel long-acting VEGF inhibitors for intraocular neovascularization for the treatment of patients with retinal pathologies. As partial consideration for the license, we agreed to pay UCSD $0.2 million and were obligated to issue shares of our common stock to UCSD equal to 5% of our fully diluted issued and outstanding securities until such time as an aggregate of $5.0 million in gross proceeds from the sale of equity securities had been raised by us. In June 2022, after the closing of the Series A financing, we issued 137,234 shares of our common stock to UCSD. We were also obligated to pay $0.1 million of patent costs incurred prior to the effective date and are required to reimburse future patent expenses incurred by UCSD during the term of the UCSD Agreement. Under the UCSD Agreement, we are required to make annual license maintenance payments of $10,000 during the first four anniversaries and $15,000 on the fifth and every subsequent anniversary of the effective date. We are obligated to pay an aggregate of up to $4.6 million upon the achievement of various development and regulatory milestones and low single-digit royalties on net sales of licensed products. The royalty is payable, on a licensed product-by-licensed product and country-by country basis, until expiration of the last-to-expire issued patent of the applicable licensed product in the country of sale or the manufacture. If we enter into a sublicensing agreement, we are required to pay UCSD a sublicense fee as a percentage of the fair market value of any sublicense fee received that is not earned royalties for each sublicense granted. The sublicense fee percentage ranges from 50% if the applicable sublicense agreement is entered into within one year from the UCSD Agreement effective date and decreases to 10% if the applicable sublicense agreement is entered into after the first dosing of a patient for a phase 2 clinical trial.

In case of a closing of a merger, or sale of at least 50% of our voting stock or the sale by us of all or substantially all of our assets (collectively referred to as "Liquidity Event"), we are obligated to make a one-time cash milestone payment to UCSD ranging from $0.1 million to $1.0 million based on the valuation of our outstanding shares at the Liquidity Event closing date. The Merger did not meet the definition of the Liquidity Event.

The UCSD Agreement is effective until the expiration date of the longest-lived patent rights or last to be abandoned patent or future patent of the licensed products, whichever is later. We can terminate the agreement upon 60 days written notice. UCSD can terminate the agreement in the event of an uncured material breach, such as a failure to make payments due, or to perform or a violation of any other material term of the UCSD Agreement, is not cured by us within 60 days after a breach written notice provided by UCSD.

The acquisition of the license under the UCSD Agreement, including patent rights and know-how, was accounted for as an asset acquisition. As the acquired technology did not have an alternative future use, we recognized the $0.2 million initial cash consideration, $0.1 million patent reimbursement costs incurred prior to the effective date and $0.2 million related to the obligation to issue shares of our common stock as research and development expenses. The obligation to issue shares of common stock included two components, the initial shares obligation and the additional shares obligation. The fair value of the initial shares obligation was estimated as $0.1 million based on the fair value of 55,440 shares of common stock, which represented 5% of the outstanding fully diluted equity at the effective date. As the initial share obligation was indexed to our own stock, it was recorded as additional paid-in capital. The additional shares obligation was accounted for when the next round of financing closed in March 2022. We estimated the fair value of an additional 81,794 shares of common stock as $0.2 million and recognized it as research and development expenses and additional paid-in capital in March 2022.

We recognized $0.2 million and $0.1 million in patent reimbursement costs for the years ended December 31, 2025 and 2024, respectively. We made a payment of $0.1 million in connection with our achievement of the first development milestone related to the dosing of the first patient in our Phase 1a clinical trial in August 2024, which was recorded as research and development expense in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2024. No other milestones were achieved or probable through December 31, 2025. No milestone expense was recorded for the year ended December 31, 2025.

Royalty Agreement with Samsara – Related Party

In July 2024, we entered into a royalty agreement (the "Royalty Agreement") with Samsara. Under the Royalty Agreement, we redeemed 10,080 shares of our common stock issued to Samsara under a founder's restricted stock purchase agreement in exchange for our agreement to pay Samsara a low single digit percentage tiered royalty on net sales, if any, of our products developed using the technology licensed under the UCSD Agreement. Such royalties are payable on a product-by-product and country-by-country basis until the later of (i) ten years after the first commercial sale of such product in such country and (ii) the expiration of the last-to-expire issued claim of our patents for such product in such country.

We identified two elements in the Royalty Agreement: repurchased shares, and future royalty payments to Samsara. The repurchase of shares was accounted at an estimated fair value of $32,000 as a reduction of common stock and additional paid-in-capital in the consolidated balance sheet and the consolidated statement of redeemable convertible preferred stock and shareholders' deficit. We recorded $32.1 million as a long-term liability related to the obligation to make royalty payments to Samsara. The fair value of the royalty obligation was estimated using a risk-adjusted net present value model, based on the contractual royalty rates applied to the future net sales forecast, adjusted by the probability of success of product development and discounted to the effective date of the Royalty Agreement. The excess of the royalty liability over the fair value of the redeemed shares of $32.0 million was recorded as a research and development expense.

Once royalty payments to Samsara are deemed probable and estimable, and if such amounts exceed the initially recorded royalty obligation balance, we will impute interest to accrete the liability on a prospective basis based on such estimates. If and when we make royalty payments under the Royalty Agreement, the royalty obligation balance will be reduced. As of December 31, 2025, royalty payments were not probable and estimable and, therefore, for the year ended December 31, 2025, no interest expense was recognized for the royalty liability.

Financial Operations Overview

Operating Expenses

Our operating expenses consist of research and development expenses and general and administrative expenses.

Research and Development Expenses

The largest component of our total operating expenses since inception has been research and development activities, including preclinical development of our product candidate. Research and development costs are expensed as incurred.

External research and development costs include:

- costs associated with acquiring technology and intellectual property licenses that have no alternative future uses, milestone payments and annual license maintenance fees under its licensing agreements;
- costs incurred under agreements with third-party CDMOs, CROs and other third parties that conduct preclinical and clinical activities on our behalf and manufacture our product candidate;
- consulting fees associated with our research and development activities;
- costs related to compliance with regulatory requirements; and
- other costs associated with our research and development programs.

Internal research and development costs include:

- employee-related costs, including salaries, benefits, travel and meals expenses, and stock-based compensation expense for our research and development personnel; and
- allocated overhead costs, including software and other miscellaneous expenses incurred in connection with our research and development programs.

Costs for certain development activities are recognized based on our management's evaluation of the progress to completion of specific tasks using information and data provided by our vendors and third-party service providers. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense when the goods have been delivered or the services have been performed, or when it is no longer expected that the goods will be delivered or the services rendered. Upfront payments under license agreements are expensed upon receipt of the license, and annual maintenance fees under license agreements are expensed in the period in which they are incurred. Milestone payments under license agreements are accrued, with a corresponding expense being recognized, in the period in which the milestone is determined to be probable of achievement and the related amount is reasonably estimable. Research and development expenses incurred from inception relate to the development of our lead product candidate, TH103.

We expect our research and development expenses to increase substantially for the foreseeable future as we advance our product candidate through clinical trials, pursue regulatory approval of our product candidate and expand the indications for our product candidate. The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidate may be affected by a variety of factors, including the timing and progress of clinical development activities, our ability to successfully complete clinical trials with safety, potency and purity profiles that are satisfactory to the FDA or any comparable foreign regulatory authority, our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize, our product candidate; our ability to establish and maintain agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidate is approved; the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder; our ability to obtain and maintain patent, trade secret and other intellectual property protection and our ability to commercialize products, if and when approved, whether alone or in collaboration with others. We may never receive regulatory approval for our product candidate. As a result of the uncertainties discussed above, our management is unable to determine the duration and completion costs of our research and development activities or if, when and to what extent we will generate revenue from the commercialization and sale of our product candidate, if approved.

General and Administrative Expenses

General and administrative expenses consist of payroll and personnel-related expenses, including salaries, bonuses, employee benefit costs and stock-based compensation expense. General and administrative expenses also include rent expense, insurance, professional fees for legal, consulting, accounting and tax services, as well as allocated overheads, including information technology costs, and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses will increase as a result of increased personnel costs, including salaries, benefits and stock-based compensation expense. We also expect to continue to incur significant expenses associated with being a public company, including personnel costs, expanded infrastructure and higher consulting, legal and accounting services, investor relations costs and director and officer insurance premiums.

Change in fair value of tranche liability

Change in fair value of tranche liability represents gains or losses from the remeasurement of tranche liability related to the investors' rights to receive additional convertible promissory notes in subsequent tranches of the Convertible Note Financing with a predetermined conversion price. The tranche liability was remeasured at fair value at the end of each reporting period until the tranche liability was cancelled in March 2025.

Change in fair value of derivative liabilities

Change in fair value of derivative liabilities represents gains or losses from the remeasurement of the derivative liabilities embedded in the convertible promissory notes issued to Samsara and other investors at the end of each reporting period until settlement or extinguishment. The derivative liabilities expired in connection with the closing of the Merger on the Closing Date.

Interest expense

Interest expense represents non-cash interest expense accrued on issued and previously outstanding convertible promissory notes and amortization of a debt discount on the advances under the convertible promissory note issued to Samsara in March 2024.

Loss on extinguishment and on issuance of convertible promissory notes

Loss on issuance of convertible promissory notes represents the excess fair value of the convertible promissory over the cash proceeds received on the date of issuance. Loss on extinguishment of convertible promissory notes represents the excess fair value of redeemable convertible preferred stock issued over the net carrying value of the convertible promissory notes at the extinguishment date. All outstanding convertible promissory notes, other than the AlloVir Note, were converted into shares of redeemable convertible preferred stock or common stock of Legacy Kalaris immediately prior to the closing of the Merger on March 18, 2025.

Other income, net

Other income, net includes interest income received from money market marketable securities, U.S. government treasury securities, and bank deposits, the amortization of premiums and accretion of discounts on U.S. government treasury securities, and realized and unrealized foreign currency gains (losses).

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

The following table summarizes our results of operations (in thousands):

	Year Ended December 31,		
	2025	2024	Change
Operating expenses:			
Research and development	$ 30,753	$ 45,042	$ (14,289)
General and administrative	15,399	6,690	8,709
Total operating expenses	46,152	51,732	(5,580)
Loss from operations	(46,152)	(51,732)	5,580
Other income (expense), net:			
Change in fair value of tranche liability	365	21,012	(20,647)
Change in fair value of derivative liabilities	1,229	2,084	(855)
Interest expense	(1,443)	(2,701)	1,258
Loss on extinguishment and on issuance of convertible promissory notes	(186)	(38,018)	37,832
Other income, net	2,749	188	2,561
Total other income (expense), net	2,714	(17,435)	20,149
Net loss	$ (43,438)	$ (69,167)	$ 25,729

Research and Development Expenses

The following table summarizes our research and development expenses (in thousands):

	Year Ended December 31,		
	2025	2024	Change
CDMO, CRO and other third-party preclinical studies, clinical trials and consulting costs	$ 25,108	$ 10,324	$ 14,784
License fees, milestone payments and annual maintenance fees related to acquired technologies	10	32,099	(32,089)
Personnel related costs (including stock-based compensation)	5,244	2,490	2,754
Other expense	391	129	262
Total research and development expenses	$ 30,753	$ 45,042	$ (14,289)

Research and development expenses decreased by $14.2 million, from $45.0 million for the year ended December 31, 2024, to $30.8 million for the year ended December 31, 2025.

License fees, milestone payments and annual maintenance fees related to acquired technologies decreased by $32.1 million due to royalty obligation expense incurred in connection with the Royalty Agreement entered into with Samsara that was recorded as research and development expense during the year ended December 31, 2024.

CDMO, CRO and other third-party preclinical studies, clinical trials and consulting costs increased by $14.8 million as we initiated our Phase 1a clinical trial in TH103 in June 2024 and our Phase 1b/2 clinical trial in the third quarter of 2025. CRO and other clinical expenses increased by $3.1 million as we opened additional investigational sites and enrolled patients in our clinical program. CDMO and other third-party preclinical studies and consulting costs increased by $11.7 million due to the additional manufacturing process development activities and manufacturing of our clinical supplies to support our clinical trials.

Personnel related costs (including stock-based compensation) increased by $2.8 million due to hiring in our research and development organization.

General and Administrative Expenses

General and administrative expenses increased by $8.7 million, from $6.7 million for the year ended December 31, 2024 to $15.4 million for the year ended December 31, 2025. The increase in general and administrative expenses was primarily attributable to an increase of $3.9 million in legal, accounting and other professional and outside services, an increase of $2.1 million related to directors' and officers' insurance recognized following the closing of the Merger, and an increase of $2.5 million in personnel related costs (including stock-based compensation). General and administrative expenses increased as we invested in our corporate infrastructure and in connection with the closing of the Merger.

Change in fair value of tranche liability

We recognized a $0.4 million gain for the year ended December 31, 2025, related to the changes in the fair value of tranche liability. We recognized a $21.0 million gain for the year ended December 31, 2024 related to the changes in fair value of the tranche liability. The convertible promissory notes issued in the Convertible Note Financing in October and November 2024 and amended in November 2024 included three subsequent tranches for the issuance of convertible promissory notes at the predetermined conversion price that were concluded to be liabilities and are accounted for at fair value until the tranches' expiration or settlement. The fair value of the tranche liability is estimated using a probability weighted scenario analysis discounted to the current period. Refer to Note 5, *Fair Value Measurements*, in our consolidated financial statements included elsewhere in this Annual Report for additional details. In January 2025, as part of the first tranche of the Additional Permitted Bridge Financing, we issued additional convertible promissory notes for $3.75 million and one of three tranches was settled. In March 2025, we and other noteholders entered into an acknowledgment of conversion and termination agreement to cancel all unfunded tranches and the tranche liability expired unexercised.

Change in fair value of derivative liabilities

We recognized $1.2 million and $2.1 million gain for the years ended December 31, 2025 and 2024, respectively, related to the changes in the fair value of derivative liabilities embedded into convertible promissory notes issued to Samsara and other investors. We estimated the fair value of the derivative liabilities embedded in the convertible promissory notes using a with-and-without scenario analysis. Refer to Note 5, *Fair Value Measurements*, in our consolidated financial statements included elsewhere in this Annual Report for additional details. All outstanding convertible promissory notes, other than the AlloVir Note, were converted into either shares of redeemable convertible preferred stock or common stock and the derivative liability expired in connection with the closing of the Merger on March 18, 2025.

Interest expense

We recognized $1.4 million and $2.7 million for the years ended December 31, 2025 and 2024, respectively, of interest expense, which included the accrued interest and amortization of debt discount related to issued and outstanding convertible promissory notes issued to Samsara and other investors. Refer to Note 8, *Convertible Promissory Notes*, in our consolidated financial statements included elsewhere in this Annual Report for additional details.

Loss on extinguishment and on issuance of convertible promissory notes

We recognized $0.2 million and $38.0 million of loss on extinguishment and on issuance of convertible promissory notes to Samsara and other investors for the years ended December 31, 2025 and 2024, respectively. The decrease of $37.8 million in loss on extinguishment and on issuance of convertible promissory notes was related to the lower amount of premium recognized at the issuance of the notes in January 2025 compared to the premium on the notes issued in March 2024 and May 2024. Refer to Note 8, *Convertible Promissory Notes*, in our consolidated financial statements included elsewhere in this Annual Report, for additional details.

Other income, net

Other income, net increased by $2.6 million from $0.2 million for the year ended December 31, 2024 to $2.7 million for the year ended December 31, 2025. This increase was primarily attributable to interest income received from money market marketable securities and U.S. government treasury securities as a result of our increased cash position following the Merger.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. From inception, we have primarily funded our operations from sales of redeemable convertible preferred stock, issuances of convertible promissory notes and a SAFE, from cash and cash equivalents of AlloVir received in the Merger, and from proceeds from the 2025 Private Placement.

From inception through December 31, 2025, we have received gross proceeds of $67.5 million from sales of redeemable convertible preferred stock, issuances of convertible promissory notes and a SAFE, we received cash and cash equivalents of AlloVir of approximately $102.1 million in the Merger, and we received aggregate gross proceeds of $50.0 million from the 2025 Private Placement. As of December 31, 2025, we had $118.0 million in cash, cash equivalents and short-term marketable securities.

Funding Requirements

Our primary uses of cash are to fund our operations, which consist primarily of research and development expenditures related to the development of our lead product candidate, TH103, and, to a lesser extent, general and administrative expenditures. We expect to continue to incur significant and increasing expenses for the foreseeable future as we continue to advance TH103, expand our corporate infrastructure, further our research and development initiatives and incur costs associated with the potential commercialization activities. Conducting preclinical testing and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, TH103, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of a product that we do not expect to be commercially available for several years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

We have incurred significant losses and negative cash flows from operations since our inception. As of December 31, 2025, we had an accumulated deficit of $160.0 million. Based on our current operating plans, we believe that our existing cash, cash equivalents and short-term marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2027. However, we have based these estimates on assumptions that may prove to be wrong, and our operating plans may change as a result of many factors currently unknown to us. In addition, changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more than currently expected because of circumstances beyond our control. As a result, we could deplete our capital resources sooner than we currently expect.

This forecast of cash resources and planned operations involves risks and uncertainties, and the actual amount of expenses could vary materially as a result of a number of factors. Because of the numerous risks and uncertainties associated with product development, and because the extent to which we may enter into collaborations with third parties for the development of TH103 is unknown, we may incorrectly estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of TH103. Our future funding requirements will depend on many factors, including, but not limited to, the following:

- the timing, scope, progress and results of our preclinical studies and clinical trials for our current and future product candidates;
- the number, scope and duration of clinical trials required for regulatory approval of our current and future product candidates;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities for our product candidates, including any requirement to conduct more studies or generate additional data;
- the cost of manufacturing clinical and commercial supplies, as well as scale-up of our current and future product candidates;
- the potential increase in the number of our employees and the acquisition and expansion of physical facilities to support growth initiatives;

- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the cost of filing and prosecuting our patent applications, and maintaining and enforcing our patents and other intellectual property rights;
- the extent to which we acquire or in-license other product candidates and technologies;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against our product candidates;
- the effect of competing technological and market developments;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our ' product candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of TH103 or any future product candidates, should any product candidates receive marketing approval;
- our implementation of various computerized informational systems and efforts to enhance operational systems;
- the costs associated with being a public company; and
- the impact of inflation, tariffs and other trade restrictions, as well as other factors, including economic uncertainty and geopolitical tensions, which may exacerbate the magnitude of the factors discussed above.

Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings or debt financings, or potentially other capital sources, such as collaboration or licensing arrangements with third parties or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing to support our business plans when needed on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration or licensing arrangements with third parties or other strategic transactions, we may have to relinquish rights to our intellectual property, future revenue streams, research programs, or product candidates, or we may have to grant licenses on terms that may not be favorable to us. If we are unable to raise capital as and when needed or on attractive terms, or at all, we may have to significantly delay, reduce or discontinue the development or future commercialization of TH103 or any future product candidate.

Cash Flows

The following table summarizes primary sources and uses of cash for the periods presented (in thousands):

	Year Ended December 31,	
	2025	2024
Net cash used in operating activities	$ (38,370)	$ (20,670)
Net cash used in investing activities	(19,723)	—
Net cash provided by financing activities	155,007	19,140
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 96,914	$ (1,530)

Operating Activities

Net cash used in operating activities was $38.4 million and $20.7 million for the years ended December 31, 2025 and 2024, respectively.

Cash used in operating activities for the year ended December 31, 2025, was primarily due to a net loss of $43.4 million, offset by non-cash charges of $1.6 million and further offset by net changes of $3.4 million in net operating assets and liabilities. Non-cash charges primarily consist of $1.9 million in stock-based compensation expense and 1.4 million in non-cash interest expense, offset by

a gain of $1.2 million related to the change in fair value of derivative liabilities and a gain of $0.4 million related to the change in fair value of tranche liability. The favorable net change in net operating assets and liabilities was primarily due to a decrease in prepaid expenses and other current assets of $1.8 million, of which $1.7 million relates to the Merger, and an increase in accrued expenses and other current liabilities of $2.1 million, net of $2.6 million relating to the Merger and $1.7 million relating to unpaid issuance costs for the 2025 Private Placement.

Cash used in operating activities for the year ended December 31, 2024, was primarily due to a net loss of $69.2 million, offset by non-cash charges of $50.6 million and increased by net changes of $2.1 million in the net operating assets and liabilities. Non-cash changes primarily consist of a $32.0 million royalty obligation expense incurred in connection with the Royalty Agreement, a loss on issuance of convertible promissory notes of $38.0 million, a $21.0 million change in fair value of the tranche liability, a non-cash interest expense of $2.7 million, stock-based compensation expense of $0.9 million, and offset by $2.1 million gain related to the change in fair value of derivative liabilities. The change in net operating assets and liabilities was primarily due to a decrease in accounts payable of $1.0 million, an increase in prepaid expenses and other current assets of $0.8 million, an increase in other non-current assets of $0.4 million, and an increase in accrued expenses and other current liabilities of $0.1 million.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2025 was $19.7 million, which primarily consisted of $34.5 million in purchases of short-term marketable securities offset by $15.0 million in proceeds from maturities of marketable securities. There was no cash used in investing activities for the year ended December 31, 2024.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2025 was $155.0 million, which consisted of $102.1 million of cash and cash equivalents of AlloVir received in connection with the Merger, proceeds from the issuance of a convertible promissory note of $7.5 million, and aggregate gross proceeds from the 2025 Private Placement of $50.0 million, partially offset by payments of deferred transaction costs related to the Merger of $2.9 million and payments of issuance costs related to the 2025 Private Placement of $1.7 million.

Net cash provided by financing activities for the year ended December 31, 2024 was $19.1 million, which consisted of $20.0 million net cash proceeds from the issuance of convertible promissory notes and $1.6 million from the issuance of redeemable convertible preferred stock to existing and new investors, offset by payment of deferred transaction costs of $2.4 million in connection with the Merger.

Contractual and Other Obligations

We enter into contracts in the normal course of business with CDMOs for clinical supply manufacturing, with CROs for clinical trials and with other vendors for preclinical studies, supplies and other products and services for operating purposes. These agreements generally provide for termination at the request of either party generally with less than one-year notice and, therefore, our management believes that non-cancellable obligations under these agreements are not material. We do not currently expect any of these agreements to be terminated and did not have any non-cancellable obligations under these agreements as of December 31, 2025 and 2024.

We are required to pay certain milestone payments contingent upon the achievement of specific development and regulatory events in accordance with the UCSD Agreement. Refer to Note 7, *Significant Agreements,* in our consolidated financial statements included elsewhere in this Annual Report for additional details. As of December 31, 2025 and 2024, we recognized $0.03 million and $0.2 million related to the UCSD Agreement in accrued expenses and other current liabilities in the consolidated balance sheets, respectively. Over the life of the agreement through December 31, 2025, development milestones totaling $0.1 million have been achieved and incurred as research and development expenses. We did not achieve any development milestones and did not incur any related milestone expense during the year ended December 31, 2025. We are required to pay royalties on sales of products developed under the UCSD Agreement. Our product candidate was in development as of December 31, 2025 and 2024, and no such royalties were due.

We are obligated to pay royalties to Samsara under the Royalty Agreement. Refer to Note 7, *Significant Agreements,* in our consolidated financial statements included elsewhere in this Annual Report for additional details. We recognized an initial royalty liability in the amount of $32.1 million, which was based on its estimated fair value at the effective date of the Royalty Agreement. Once royalty payments to Samsara are deemed probable and estimable, and if such amounts exceed the royalty liability balance, we will impute interest to accrete the royalty liability on a prospective basis based on such estimates. As of December 31, 2025 these royalties were not probable and estimable.

In February 2025, we entered into an operating lease agreement for office space in Berkeley Heights, New Jersey. The lease commenced in September 2025 and is expected to terminate in December 2031. We can extend the lease term twice for an additional three years and can terminate the lease after four years and four months after the lease commencement date with a termination penalty of $0.3 million. Total remaining undiscounted payments under this lease are approximately $2.1 million. In addition to the base rent, we will pay our share of operating expenses and taxes. The lessor provided a tenant improvement allowance of up to $0.4 million, which we fully utilized during the year ended December 31, 2025.

Recently Issued Accounting Pronouncements

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

Critical Accounting Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. On an ongoing basis, management evaluates these estimates and judgments, including, but not limited to, those related to the accrual of research and development expenses, the fair value of royalty obligation, the fair value of convertible promissory notes, the fair value of tranche liability, the fair value of derivative liabilities, the fair value of common stock and preferred stock, and stock-based compensation. These estimates and assumptions are monitored and analyzed by management for changes in facts and circumstances, and material changes in these estimates and assumptions could occur in the future. Our management's estimates are based on our historical experience and on various other factors that management believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ from these estimates under different assumptions or conditions.

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

Research and Development Expenses

Research and development expenses are charged to expense as incurred. Research and development expenses include certain payroll and personnel expenses, license fees, laboratory supplies, consulting costs, external contract research and development expenses and allocated overhead costs, including software and other miscellaneous expenses incurred in connection with its research and development programs.

We estimate manufacturing and product development costs, preclinical study and clinical trial and other research and development expenses based on the services performed. We have entered into various agreements with outsourced vendors, contract development and manufacturing organizations and clinical research organizations. The financial terms of these contracts are subject to negotiation, which vary by contract and may result in payments that do not match the periods over which materials or services are provided. Generally, these agreements set forth the scope of work to be performed at a fixed fee, unit price or on a time and materials basis. We record the estimated costs of research and development activities based on the level of services performed, the progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development services provided, but not yet invoiced, are included in accrued expenses on the balance sheets. Advance payments for goods or services for future research and development activities are deferred as prepaid expenses and are expensed as the goods are delivered or the related services are performed. We make these estimates based on facts and circumstances known at that time. If the actual timing of the performance of services or the level of effort varies from the original estimates, we will adjust the accrual accordingly. Amounts ultimately incurred in relation to amounts accrued for these services at a reporting date may be substantially higher or lower than our estimates. To date, there have been no material differences between estimates of such expenses and the amounts actually incurred.

Convertible Promissory Notes

Tranche Liability

Under the Convertible Note Financing's amended note purchase agreement, Legacy Kalaris was eligible to receive additional proceeds in the Convertible Note Financing to fund Legacy Kalaris's operations prior to the closing of the Merger at three subsequent closings upon Legacy Kalaris's written notice to investors and subject to Samsara's consent. The investors' right to receive additional

convertible promissory notes in subsequent tranches of the Convertible Note Financing with a predetermined conversion price was concluded to be a freestanding financial instrument that is required to be accounted for separately as a liability at fair value. We estimated the fair value of the tranche liability at inception and remeasures it at the end of each reporting period until the tranche liability expires or is settled. The changes in the fair value are recorded as a change in fair value of tranche liability in the statements of operations and comprehensive loss. We estimate the fair value of the tranche liability using a probability weighted model, which considers as inputs the timing of issuing convertible notes and notes conversion, probabilities of conversion scenarios, the estimated fair value of our shares into which the note is convertible and a discount rate. A significant change in probabilities of conversion scenarios and changes in the estimated conversion price will significantly change the estimated fair value of the tranche liability. We recognized $21.3 million as a tranche liability at the issuance dates in October and November 2024 and recognized a gain of $21.0 million as the change in fair value of the tranche liability for the year ended December 31, 2024. The decrease in fair value was a result of the modification of the subsequent tranche amounts in January 2025 and the parties agreeing to convert tranches at a price per share equal to the Company Value Per Share, as defined in the Merger Agreement. At the closing of the Merger, in March 2025, all subsequent tranches of the Convertible Notes Financing that were not funded prior to the closing were cancelled.

Derivative Liabilities

The convertible promissory notes contained embedded features that provided the noteholder with multiple settlement alternatives. Certain of these settlement features provided the noteholder the right to receive cash or a variable number of shares upon a change in control or the completion of a capital raising transaction by us (the “redemption features”).

The redemption features of the convertible promissory notes met the requirements for separate accounting and were accounted for as compound derivative instruments recorded as a liability at fair value at inception and were subject to remeasurement to fair value at each balance sheet date, with any changes in fair value recorded as a change in fair value of derivative liabilities in the consolidated statements of operations and other comprehensive loss. Derivative liabilities were classified in the consolidated balance sheets as current or non-current consistent with the classification of the respective convertible promissory notes they were related to. We estimate the fair value of the derivative liabilities embedded in the convertible promissory notes using a with-and-without scenario analysis, which involves valuing the whole instrument on an as-is basis and then valuing the instrument without the embedded derivative. The difference between the entire instrument with the embedded derivatives compared to the instrument without the embedded derivatives is the fair value of the derivative liabilities. A significant increase in probabilities of a qualified financing or redemption scenario, a change of control scenario and a decrease in a discount rate would significantly increase the estimated fair value of derivative liabilities.

Royalty Obligation - Related Party

In July 2024, we entered into the Royalty Agreement with Samsara. Under the Royalty Agreement, we redeemed 10,080 shares of our common stock with a fair value of $32,000 issued to Samsara. In return, we are obligated to pay Samsara royalties on a product-by-product and country-by-country basis at low single-digit royalty rates on future net product sales. At the effective date of the Royalty Agreement, we recognized our obligation to make future royalty payments to Samsara at estimated fair value as a liability on the consolidated balance sheets and as a research and development expense in the consolidated statements of operations and comprehensive loss. Once royalty payments to Samsara are deemed probable and estimable, and if such amounts exceed the royalty liability balance recognized at the effective date of the agreement, we will impute interest to accrete the royalty liability on a prospective basis based on such estimates. The fair value of the royalty obligation at the effective date of the Royalty Agreement was estimated using a risk-adjusted net present value model, based on the contractual royalty rates applied to the future net sales forecast, adjusted by the probability of success of product development and discounted to the effective date of the Royalty Agreement. Significant changes to any of the following assumptions would significantly impact the estimated liability amount: future timing and amounts of net product revenues, estimated probabilities of success based on a stage of product development and the discount rate.

Stock-Based Compensation Expense

We measure stock-based awards made to employees and non-employees based on the estimated fair value of the awards as of the grant date using the Black-Scholes option-pricing model. The model requires management to make a number of assumptions including common stock fair value, expected volatility, expected term, risk-free interest rate and expected dividend yield.

Fair Value of Common Stock - Prior to the Merger, the fair market value of our common stock was determined by the board of directors with assistance from management and external valuation experts. The approach to estimating the fair market value of common stock is consistent with the methods outlined in the American Institute of Certified Public Accountants’ Accounting and Valuation Guide, *Valuation of Privately- Held-Company Equity Securities Issued as Compensation* (the “Practice Aid”). After the closing of the Merger, the fair value of common stock is our closing price per share on The Nasdaq Global Market on the grant date.

Expected Volatility - Expected volatility is estimated by studying the volatility of the prices of shares of common stock of comparable public companies for similar terms. We will continue to apply this process until enough historical information regarding the volatility of our stock price becomes available.

Expected Term - Expected term represents the period that our stock-based awards are expected to be outstanding and is determined by calculating the midpoint of the contractual term of the options and the weighted-average vesting period.

Risk-Free Interest Rate - The risk-free interest rate is based on the U.S. Treasury zero-coupon bonds issued in effect at the time of grant for periods corresponding with the expected term of the option.

Expected Dividend - The Black-Scholes valuation model calls for a single expected dividend yield as an input. To date, we have not declared or paid any dividends and we do not expect to declare or pay any dividends in the future.

Significant changes in estimated fair value of common stock, expected volatility and expected term would significantly impact recognized stock-based compensation expense amounts.

Smaller Reporting Company Status

We are a “smaller reporting company” because the market value of our common stock held by non-affiliates was less than $700.0 million and our annual revenue was less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of its stock held by non-affiliates is less than $250.0 million or (ii) its annual revenue was less than $100.0 million during the most recently completed fiscal year and the market value of its stock held by non-affiliates is less than $700.0 million.

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. Specifically, as a smaller reporting company we have chosen to present only the two most recent fiscal years of audited financial statements in this Annual Report on Form 10-K and we have reduced disclosure obligations regarding executive compensation.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company, we are not required to provide the information required by this item.

Item 8. Financial Statements and Supplementary Data.

Our consolidated financial statements, together with the independent registered public accounting firm report thereon, are presented beginning on page F-1 of this Annual Report.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer (“CEO”), and Chief Financial Officer (“CFO”) (our principal executive officer and principal financial officer, respectively), 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 an issuer that are designed to ensure that information required to be disclosed by an issuer 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 SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Based on their evaluation, the CEO and the CFO have concluded that our disclosure controls and procedures were not effective as of December 31, 2025, because of the material weaknesses in our internal control over financial reporting described below.

We have identified material weaknesses in our internal control over financial reporting as of December 31, 2024. These material weaknesses have not been fully remediated as of December 31, 2025. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements would not be prevented or detected on a timely basis.

We did not fully maintain components of the Committee of Sponsoring Organizations of the Treadway Commission framework, including elements of the control environment, risk assessment, monitoring activities, information and communication, and control activities components, relating to: (i) our commitment to attract, develop, and retain competent individuals; (ii) identifying, assessing, and communicating appropriate internal control objectives, (iii) identifying and analyzing risks to achieve these objectives; (iv) selecting, developing, and performing ongoing evaluations to ascertain whether the components of internal controls are present and functioning; (v) communicating accurate information internally and externally, including providing information pursuant to objectives, responsibilities, and functions of internal control; (vi) selecting and developing control activities that contribute to the mitigation of risks and support achievement of objectives and (vii) deploying control activities through policies that establish what is expected and procedures that put policies into action.

These material weaknesses could result in a misstatement of substantially all of our accounts or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected.

Remediation Efforts and Plans

Management has taken actions to remediate the deficiencies in our internal controls over financial reporting, including implementing additional processes and controls designed to address the underlying causes of the above-mentioned material weaknesses.

Management's internal control remediation efforts include the following:

- We completed the implementation of multiple financial systems, including a new company-wide enterprise resource planning (ERP) system, which provides additional systematic controls and segregation of duties for our business processes.

- We recruited additional accounting personnel with appropriate experience, certification, education and training. For example, following the closing of the Merger, AlloVir's Chief Accounting Officer serves as our Chief Accounting Officer, and AlloVir's Controller serves as our Controller. In addition, in April 2025, we appointed a new member to our board of directors, who was also appointed as chair of the audit committee of the board of directors and was deemed to be an audit committee financial expert by our board of directors. Additionally, in August 2025, we hired a Director of Accounting and, in November 2025, we hired a Chief Financial Officer.

- We engaged a third-party to assist us with the implementation of internal controls over financial reporting. Specifically, with their assistance, we have begun to design and implement policies, procedures and controls around key business reporting processes and general information technology controls.

- We have identified, assessed, and communicated appropriate internal control objectives to key stakeholders across the organization and implemented a risk assessment over financial reporting which is updated and reassessed on a periodic basis.

- We have begun to perform manual procedures to validate the completeness and accuracy of certain reports generated from various financial systems that are relevant to the preparation of the financial statements.

- We regularly report on the progress of our material weaknesses remediation efforts to key stakeholders across our organization, including our Audit Committee.

To the extent that we are not able to retain key individuals or are unable to successfully design and implement required controls, the material weaknesses identified may not be remediated and we may be required to record additional adjustments to our financial statements in the future or otherwise not be able to produce timely or accurate financial statements. The material weaknesses will not be considered remediated until management completes the design and implementation of the measures described above, the controls

operate for a sufficient period of time, and management has concluded, through testing, that these controls are effective. These remediation measures will be time-consuming and require financial and operational resources. Our failure to implement and maintain effective internal control over financial reporting could result in errors in our financial statements that may lead to a restatement of our financial statements or cause us to fail to meet our reporting obligations.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed by, or under the supervision of, our principal executive officer and principal financial officer and effected by our 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. Under the supervision of our management, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2025 based on the criteria set forth in the Committee of Sponsoring Organizations of the Treadway Commission framework. Our management identified control deficiencies, as previously disclosed, that, individually or in the aggregate, constitute a material weakness in our internal control over financial reporting. While our management, with the oversight of the audit committee of our board of directors, has made progress toward remediating the material weakness, our management has determined that the material weakness has not yet been fully remediated. Consequently, our management has concluded our internal control over financial reporting was not effective as of December 31, 2025.

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

Except as discussed above under "Remediation Efforts and Plans", there were no changes in our internal control over financial reporting during the quarter ended December 31, 2025, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving the desired control objectives. Our management recognizes that any control system, no matter how well designed and operated, is based upon certain judgments and assumptions and cannot provide absolute assurance that its objectives will be met. Similarly, an evaluation of controls cannot provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected.

Item 9B. Other Information.

(b) Director and Officer 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 quarter 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.

The information required by this Item 10 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item 11 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(1) Consolidated Financial Statements

The following documents are included this Annual Report:

Report of Independent Registered Public Accounting Firm
Consolidated Balance Sheets
Consolidated Statements of Operations and Comprehensive Loss
Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
Consolidated Statements of Cash Flows
Notes to the Consolidated Financial Statements

(2) Financial Statement Schedules

All financial statement schedules have been omitted because they are not applicable, not required, or the information required is shown in the consolidated financial statements or the notes thereto.

(3) Exhibits

The exhibits required by Item 601 of Regulation S-K and Item 15(b) of this Annual Report are listed in the Exhibit Index below. The exhibits listed in the Exhibit Index are incorporated by reference herein.

Exhibit Index

Exhibit Number	Description
2.1+	Agreement and Plan of Merger, dated as of November 7, 2024, by and among the Registrant, Aurora Merger Sub, Inc. and Kalaris Tx, Inc. (formerly, Kalaris Therapeutics, Inc.) (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K (File No. 001-39409) filed on November 8, 2024).
3.1	Restated Certificate of Incorporation of the Registrant, dated March 18, 2025 (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-39409) filed on March 18, 2025).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.3 to the Registrant's Current Report on Form 8-K (File No. 001-39409) filed on March 18, 2025).
4.1*	Description of the Registrant's Securities Registered under Section 12 of the Exchange Act
4.2	Registration Rights Agreement (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-39409) filed on December 18, 2025).
4.3	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-39409) filed on December 18, 2025).
10.1#	Employment Agreement, dated April 10, 2025, by and between Andrew Oxtoby and the Registrant (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-39409) filed on April 16, 2025).
10.2#	Employment Agreement, dated May 12, 2025, by and between Matthew Feinsod and the Registrant (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39409) filed on May 14, 2025).
10.3#	Employment Agreement, dated November 1, 2025, by and between Matthew Gall and the Registrant (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-39409) filed on November 3, 2025).
10.4#	Offer Letter, dated December 17, 2024, by and between Brett Hagen and the Registrant, as amended by that certain Offer Letter Amendment, dated April 15, 2025 (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39409) filed on May 14, 2025).
10.5#	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39409) filed on May 14, 2025)
10.6#	Kalaris Therapeutics, Inc. 2019 Equity Incentive Plan, as amended, and form of award agreements thereunder (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K (File No. 001-39409) filed on March 18, 2025).

10.7#	Kalaris Therapeutics, Inc. 2020 Stock Option and Grant Plan, as amended, and form of award agreements thereunder (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K (File No. 001-39409) filed on March 18, 2025).
10.8#	Kalaris Therapeutics, Inc. 2020 Employee Stock Purchase Plan (incorporated by reference to Exhibit 99.3 to the Registrant's Registration Statement on Form S-8 (File No. 333-287772) filed on June 4, 2025).
10.9#	Form of Indemnification Agreement for Directors of Kalaris Therapeutics, Inc. (incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K (File No. 001-39409) filed on March 18, 2025).
10.10#	Form of Indemnification Agreement for Directors of Kalaris Therapeutics, Inc. (incorporated by reference to Exhibit 10.7 to the Registrant's Current Report on Form 8-K (File No. 001-39409) filed on March 18, 2025).
10.11	Agreement of Lease, dated as of February 4, 2025, between The Connell Company and Kalaris Therapeutics, Inc. (incorporated by reference to Exhibit 10.8 to the Registrant's Current Report on Form 8-K (File No. 001-39409) filed on March 18, 2025).
10.12	License Agreement, dated as of April 8, 2021, by and between Kalaris Therapeutics, Inc. (formerly Theia Therapeutics, Inc.) and the Regents of the University of California, as amended by Amendment #1 to the License Agreement (incorporated by reference to Exhibit 10.2 to AlloVir, Inc.'s Registration Statement on Form S-4 (File No. 333-283678) originally filed with the Securities and Exchange Commission on December 9, 2024).
10.13	Royalty Agreement, dated as of July 18, 2024, by and between Kalaris Therapeutics, Inc. and Samsara BioCapital L.P. (incorporated by reference to Exhibit 10.3 to AlloVir, Inc.'s Registration Statement on Form S-4 (File No. 333-283678) originally filed with the Securities and Exchange Commission on December 9, 2024).
10.14	Business Services Agreement, dated as of July 1, 2023, by and between Kalaris Therapeutics, Inc. (formerly Theia Therapeutics, Inc.) and Samsara BioCapital, LLC (incorporated by reference to Exhibit 10.4 to AlloVir, Inc.'s Registration Statement on Form S-4 (File No. 333-283678) originally filed with the Securities and Exchange Commission on December 9, 2024).
10.15	Consulting Agreement, dated as of July 1, 2021, by and between Kalaris Therapeutics, Inc. and Napoleone Ferrara (incorporated by reference to Exhibit 10.6 to AlloVir, Inc.'s Registration Statement on Form S-4 (File No. 333-283678) originally filed with the Securities and Exchange Commission on December 9, 2024).
19.1*	Insider Trading Policy
21.1*	Subsidiaries of the Registrant
23.1*	Consent of Deloitte & Touche, LLP, independent registered public accounting firm of Kalaris Therapeutics, Inc.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1*#	Dodd-Frank Compensation Recovery Policy
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.
# Indicates management contract or compensatory plan.

+ The annexes, schedules, and certain exhibits to the merger agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Registrant hereby agrees to furnish supplementally a copy of any omitted annex, schedule or exhibit to the SEC upon request.

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, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Kalaris Therapeutics, Inc.

Date: March 17, 2026

By: /s/ Andrew Oxtoby
Andrew Oxtoby
President and Chief Executive Officer
(Principal Executive Officer)

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/ Andrew Oxtoby **Andrew Oxtoby**	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 17, 2026
/s/ Matthew Gall **Matthew Gall**	Chief Financial Officer *(Principal Financial Officer)*	March 17, 2026
/s/ Brett Hagen **Brett Hagen**	Chief Accounting Officer *(Principal Accounting Officer)*	March 17, 2026
/s/ David Hallal **David Hallal**	Chairman	March 17, 2026
/s/ Anthony Adamis **Anthony Adamis, M.D**	Director	March 17, 2026
/s/ Srinivas Akkaraju **Srinivas Akkaraju, M.D., Ph.D.**	Director	March 17, 2026
/s/ Michael Dybbs **Michael Dybbs, Ph.D.**	Director	March 17, 2026
/s/ Napoleone Ferrara **Napoleone Ferrara, M.D.**	Director	March 17, 2026
/s/ Morana Jovan-Embiricos **Morana Jovan-Embiricos, Ph.D.**	Director	March 17, 2026
/s/ Leone Patterson **Leone Patterson**	Director	March 17, 2026

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Consolidated Financial Statements for the Years Ended December 31, 2025 and 2024:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Kalaris Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Kalaris Therapeutics, Inc. and subsidiaries (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' equity, and cash flows, for each of the two years in the period 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 2024, and the results of its operations and its cash flows for each of the two years in the period 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 matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates 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 matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrued research and development expenses and research and development expenses — Refer to Notes 2 and 6 to the financial statements

Critical Audit Matter Description

The Company estimates manufacturing and product development costs, clinical trial and other research and development expenses based on the services performed. The Company has entered into various agreements with outsourced vendors, contract development and manufacturing organizations and clinical research organizations. The Company records the estimated costs of research and development activities based on the level of services performed, the progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development services provided, but not yet invoiced, are included in accrued expenses on the consolidated balance sheets.

We identified the recording of certain third-party research and development costs as a critical audit matter because of the judgments necessary for management to estimate the cost of services provided but not yet invoiced, the significant volume of transactions and the varied nature of audit evidence obtained from vendor to vendor. This required extensive audit effort due to the volume and variability in the arrangements and available information from the vendors and required a high degree of auditor judgment when performing audit procedures to audit management's estimates of total expenses, accrued research and development expense and evaluating the results of those procedures.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the estimate of research and development expenses and the accrued research and development expense balances included the following, among others:

- We met with the Company's research and development personnel and inspected Board of Directors materials to understand the status of clinical trial activities. We compared this information to the inputs in management's estimate of the recorded expenses and accrued research and development expenses.

- For a sample of contracts, we evaluated the third-party research and development expenses and the accrued research and development expense balances by:

    - Sending written confirmations directly to contract research organizations or contract development and manufacturing organizations to confirm completeness of agreements and the total budgeted amount and percentage of completion for services provided as of year-end.

    - Inspecting the development and manufacturing services agreement and related amendments, change orders, statements of work, and agreeing key provisions of the agreements including timeline, budget, and relevant rates, to the Company's analysis of estimated expenses incurred to date.

    - Performing substantive testing over the operating expense arising from contract research organizations or contract development and manufacturing organizations activity during the year by obtaining invoices, contracts and other underlying support and comparing to information recorded within the Company's general ledger to test the occurrence, accuracy, completeness and cutoff of such operating expense.

    - Testing cash disbursements after period end to test the completeness of the accrual.

/s/ Deloitte & Touche LLP

San Francisco, California
March 17, 2026

We have served as the Company's auditor since 2024.

Kalaris Therapeutics, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share data)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 98,054	$ 1,639
Short-term marketable securities	19,928	—
Prepaid expenses and other current assets	827	967
Total current assets	118,809	2,606
Deferred transaction costs	—	3,146
Operating lease right-of-use assets	1,475	—
Restricted cash	499	—
Other non-current assets	953	410
Total assets	$ 121,736	$ 6,162
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,281	$ 1,560
Accrued expenses and other current liabilities (including $67 and $85 due to a related party)	8,117	2,195
Convertible promissory notes, net of discount of $1,298 (including $0 and $18,670 due to a related party)	—	19,541
Derivative liabilities (including $0 and $995 due to a related party)	—	1,042
Tranche liability (including $0 and $331 due to a related party)	—	365
Operating lease liabilities, current	316	—
Total current liabilities	9,714	24,703
Royalty obligation – related party	32,076	32,076
Operating lease liabilities, long-term	1,132	—
Total liabilities	42,922	56,779
Commitments and contingencies (Note 10)		
Redeemable convertible preferred stock, $0.00001 par value, no shares authorized, issued and outstanding as of December 31, 2025; 75,151,340 shares authorized as of December 31, 2024; 43,151,340 shares issued and outstanding as of December 31, 2024; liquidation preference of $0 as of December 31, 2025	—	45,999
Stockholders' equity (deficit):		
Common stock, $0.0001 and $0.00001 par value as of December 31, 2025 and 2024, respectively; 300,000,000 and 86,000,000 shares authorized as of December 31, 2025 and 2024, respectively; 22,902,418 and 1,356,431 shares issued and outstanding as of December 31, 2025 and 2024, respectively	2	—
Additional paid-in capital	238,805	19,945
Accumulated other comprehensive income	6	—
Accumulated deficit	(159,999)	(116,561)
Total stockholders' equity (deficit)	78,814	(96,616)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 121,736	$ 6,162

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

Kalaris Therapeutics, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)

	Year Ended December 31,	
	2025	2024
Operating expenses:		
Research and development (including $27 and $32,128 for a related party)	30,753	$ 45,042
General and administrative (including $322 and $230 for a related party)	15,399	6,690
Total operating expenses	46,152	51,732
Loss from operations	(46,152)	(51,732)
Other income (expense), net:		
Change in fair value of tranche liability (including $331 and $19,064 for a related party)	365	21,012
Change in fair value of derivative liabilities (including $1,165 and $2,039 for a related party)	1,229	2,084
Interest expense (including $1,384 and $2,656 for a related party)	(1,443)	(2,701)
Loss on extinguishment and on issuance of convertible promissory notes (including $169 and $34,692 for a related party)	(186)	(38,018)
Other income, net	2,749	188
Total other income (expense), net	2,714	(17,435)
Net loss	$ (43,438)	$ (69,167)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.85)	$ (51.77)
Weighted-average shares outstanding, basic and diluted	15,267,817	1,335,925
Comprehensive loss:		
Net loss	$ (43,438)	$ (69,167)
Other comprehensive income:		
Unrealized gain on marketable securities, net of tax	6	—
Total other comprehensive income	6	—
Comprehensive loss	$ (43,432)	$ (69,167)

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

Kalaris Therapeutics, Inc.
Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares (1)	Amount				
Balance at December 31, 2023	41,871,340	$ 44,408	1,362,481	$ —	$ 2,377	$ —	$ (47,394)	$ (45,017)
Issuance of Series B-2 redeemable convertible preferred stock, net of issuance costs of $9	1,280,000	1,591	—	—	—	—	—	—
Capital contributions – in-kind services – related party	—	—	—	—	60	—	—	60
Premium on issuance of convertible promissory notes	—	—	—	—	16,641	—	—	16,641
Issuance of common stock upon stock option exercises	—	—	4,030	—	3	—	—	3
Repurchase of common stock in connection with the royalty agreement	—	—	(10,080)	—	(32)	—	—	(32)
Stock-based compensation expense	—	—	—	—	895	—	—	895
Vesting of restricted stock awards	—	—	—	—	1	—	—	1
Net loss	—	—	—	—	—	—	(69,167)	(69,167)
Balance at December 31, 2024	43,151,340	$ 45,999	1,356,431	$ —	$ 19,945	$ —	$ (116,561)	$ (96,616)
Premium on issuance of convertible promissory notes	—	—	—	—	186	—	—	186
Issuance of Series B-2 redeemable convertible preferred stock upon conversion of convertible promissory notes in connection with the Merger	794,499	3,695	—	—	—	—	—	—
Conversion of convertible promissory notes into common stock in connection with the Merger	—	—	3,418,839	—	20,799	—	—	20,799
Conversion of redeemable convertible preferred stock into common stock in connection with the Merger	(43,945,839)	(49,694)	8,859,474	1	49,693	—	—	49,694
Recognition of AlloVir common stock outstanding at the closing of the Merger	—	—	5,067,674	1	104,989	—	—	104,990
Transaction costs related to the Merger	—	—	—	—	(5,357)	—	—	(5,357)
Issuance of common stock in private placement, net of issuance costs of $2,844	—	—	4,200,000	—	39,156	—	—	39,156
Issuance of pre-funded warrants in private placement, net of issuance costs of $542	—	—	—	—	7,458	—	—	7,458
Stock-based compensation expense	—	—	—	—	1,936	—	—	1,936
Unrealized gain on available-for-sale securities, net of tax	—	—	—	—	—	6	—	6
Net loss	—	—	—	—	—	—	(43,438)	(43,438)
Balance at December 31, 2025	—	$ —	22,902,418	$ 2	$ 238,805	$ 6	$ (159,999)	$ 78,814

1) The shares of common stock have been retroactively recast in connection with the Merger to reflect the exchange ratio of 0.2016 (Note 3).

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

Kalaris Therapeutics, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2025	2024
Cash flows from operating activities:		
Net loss	(43,438)	$ (69,167)
Adjustments to reconcile net loss to net cash used in operations:		
Royalty obligation expense – related party	—	32,044
Depreciation expense	13	—
Stock-based compensation expense	1,936	895
Capital contributions – in-kind services – related party	—	60
Change in fair value of derivative liabilities (including $1,165 and $2,039 for a related party)	(1,229)	(2,084)
Change in fair value of tranche liability (including $331 and $19,064 for a related party)	(365)	(21,012)
Non-cash interest expense (including $1,384 and $2,656 for a related party)	1,443	2,701
Non-cash operating lease expense	53	—
Net amortization of premiums and accretion of discounts on marketable securities	(399)	—
Loss on extinguishment and on issuance of convertible promissory notes (including $169 and $34,692 for a related party)	186	38,018
Changes in assets and liabilities:		
Prepaid expense and other current assets	1,810	(803)
Other non-current assets	(355)	(410)
Accounts payable	(88)	(1,027)
Accrued expenses and other current liabilities (including $16 and $0 for a related party)	2,144	115
Operating lease liabilities	(81)	—
Net cash used in operating activities	(38,370)	(20,670)
Cash flows from investing activities:		
Purchases of short-term marketable securities	(34,523)	—
Maturities of short-term marketable securities	15,000	
Purchase of property and equipment	(200)	—
Net cash used in investing activities	(19,723)	—
Cash flows from financing activities:		
Proceeds from issuance of common stock in private placement	42,000	—
Proceeds from issuance of pre-funded warrants in private placement	8,000	—
Payment of issuance costs	(1,669)	
Proceeds from the issuance of redeemable convertible preferred stock, net of issuance costs	—	1,591
Proceeds from the issuance of convertible promissory notes (including $3,402 and $19,041 from a related party), net of issuance costs	7,500	19,966
Cash acquired in connection with the Merger	102,113	—
Payment of deferred transaction costs and issuance costs	(2,937)	(2,420)
Proceeds from the exercise of stock options	—	3
Net cash provided by financing activities	155,007	19,140
Net increase (decrease) in cash and cash equivalents and restricted cash	96,914	(1,530)
Cash and cash equivalents and restricted cash, at beginning of the period	1,639	3,169
Cash and cash equivalents and restricted cash, at end of the period	98,553	$ 1,639
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	98,054	1,639
Restricted cash	499	—
Total cash, cash equivalents and restricted cash, at end of the period	98,553	$ 1,639

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

Kalaris Therapeutics, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2025	2024
Supplemental disclosure of cash flow information:		
Right-of-use assets obtained in exchange for operating lease liability	$ 1,528	$ —
Merger transaction costs recognized in additional paid-in capital	$ 5,357	$ —
Recognition of AlloVir common stock outstanding at the closing of the Merger	$ 104,990	$ —
Issuance of redeemable convertible preferred stock upon conversion of convertible promissory notes	$ 3,695	$ —
Conversion of redeemable convertible preferred stock into common stock in connection with the Merger	$ 49,694	$ —
Conversion of convertible promissory notes and accrued interest in connection with the Merger	$ 20,799	$ —
Deferred transaction and financing issuance costs included in accounts payable and accrued expenses and other current liabilities	$ 1,717	$ 748
Unrealized gain on available-for-sale securities	$ 6	$ —
Capital contributions – in-kind services – related party	$ —	$ 60
Premium on issuance of convertible promissory notes (including $169 and $15,296 for a related party)	$ 186	$ 16,641
Repurchase of common stock shares for royalty obligation	$ —	$ 32
Vesting of restricted stock awards	$ —	$ 1

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

1. Nature of the Business

Description of the Business

Kalaris Therapeutics, Inc. ("Kalaris" or "the Company") is a clinical stage biopharmaceutical company dedicated to the development and commercialization of treatments for prevalent retinal diseases with major unmet medical needs. The Company is developing TH103, a novel, clinical stage anti-vascular endothelial growth factor ("VEGF") drug, specifically engineered to achieve extended intraocular retention with enhanced VEGF inhibition in patients with exudative and/or neovascular retinal diseases.

On March 18, 2025 (the "Closing Date"), AlloVir, Inc., a Delaware corporation ("AlloVir"), consummated the previously announced merger (the "Merger") pursuant to the terms of the Agreement and Plan of Merger, dated as of November 7, 2024 (the "Merger Agreement"), by and among AlloVir, Aurora Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of AlloVir ("Merger Sub") and Kalaris Tx, Inc. (formerly Kalaris Therapeutics, Inc.), a Delaware corporation ("Legacy Kalaris"). At the effective time of the Merger (the "Effective Time"), Merger Sub merged with and into Legacy Kalaris, with Legacy Kalaris continuing as a wholly-owned subsidiary of AlloVir and the surviving corporation of the Merger and, after giving effect to the Merger, Legacy Kalaris became a wholly-owned subsidiary of AlloVir. Immediately following the Effective Time, AlloVir changed its name to "Kalaris Therapeutics, Inc." At the Effective Time, the Company's business became primarily the business conducted by Legacy Kalaris. The Company's common stock, which was previously listed on The Nasdaq Capital Market and traded under the ticker symbol "ALVR" through the close of business on the Closing Date, commenced trading on The Nasdaq Global Market under the ticker symbol "KLRS" on March 19, 2025. Refer to Note 3, "*Merger with AlloVir*", for further details of the Merger.

Samsara BioCapital L.P. and its affiliates (collectively, "Samsara"), the Company's majority stockholder and a related party, have provided Legacy Kalaris with significant equity and debt financing since its inception, and management and operational support services to the Company. Refer to Note 16 for further details of the related party transactions with Samsara.

Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception. During the years ended December 31, 2025 and 2024, the Company incurred net losses of $43.4 million and $69.2 million, respectively. During the years ended December 31, 2025 and 2024, the Company had negative cash flows from operations of $38.4 million and $20.7 million, respectively. As of December 31, 2025 and December 31, 2024, the Company had an accumulated deficit of $160.0 million and $116.6 million, respectively. The Company expects to continue to incur substantial losses for the foreseeable future, and its ability to achieve and sustain profitability will depend on the successful development, approval, and commercialization of product candidates and on the achievement of sufficient revenues to support the Company's operations.

Since its inception, the Company has funded its operations primarily with proceeds from sales of its redeemable convertible preferred stock, issuances of convertible promissory notes and a simple agreement for future equity ("SAFE"), from cash and cash equivalents of AlloVir received in the Merger, and with proceeds from the 2025 Private Placement (as defined below). Refer to Note 12 for further details of the 2025 Private Placement.

As of December 31, 2025, the Company had cash, cash equivalents and short-term marketable securities of $118.0 million. The Company expects that the existing cash, cash equivalents and short-term marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months from the issuance date of these consolidated financial statements.

The Company will need to raise additional financing to continue its product's development for the foreseeable future until it becomes profitable. The Company plans to monitor expenses and raise additional capital through a combination of equity and debt financings, strategic alliances, and licensing arrangements. The Company's ability to access capital when needed is not assured and, if capital is not available to the Company when, and in the amounts needed, the Company may be required to significantly curtail, delay or discontinue one or more of its research or development programs or the commercialization of any product candidate, or be unable to expand its operations or otherwise capitalize on the Company's business opportunities, as desired, which could materially harm the Company's business, financial condition and results of operations.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") and pursuant to the rules and regulations of the Securities and Exchanges Commission ("SEC") regarding financial reporting. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB"). AlloVir and its subsidiaries' operating results are included in the Company's consolidated financial statements from the Closing Date of the Merger. All other accompanying financial data as of and for the year ended December 31, 2024, include only the accounts and disclosures of Legacy Kalaris. All intercompany transactions and balances have been eliminated upon consolidation.

All historical common share data and per-share amounts prior to the Merger were retrospectively recast to reflect the effect of the exchange ratio of 0.2016 per one share, which was determined in accordance with the Merger Agreement. The number of authorized shares and par value per share were not recast. The conversion ratios for each series of redeemable convertible preferred stock, which were converted into shares of common stock in connection with the closing of the Merger, were proportionally recast.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. The Company bases its estimates on historical experience and on various other assumptions believed to be reasonable. Actual results could differ from those estimates and such differences could be material to the financial position and results of operations. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, the accrual of research and development expenses, the fair value of convertible promissory notes, the fair value of derivative liabilities, the fair value of tranche liability, the fair value of Legacy Kalaris' common stock and Legacy Kalaris' redeemable convertible preferred stock, stock-based compensation expense, and valuation of deferred tax assets.

Concentrations of Credit Risk and Other Risks and Uncertainties

Cash balances are held at financial institutions and account balances may exceed federally insured limits. The Company also had marketable securities in money market funds, which can be subject to certain credit risks. The Company mitigates the risks by investing in high-grade instruments, limiting its exposure to any one issuer and monitoring the ongoing creditworthiness of the financial institutions and issuers. To date, the Company has not experienced any losses on its cash and cash equivalents balances and periodically evaluates the creditworthiness of its financial institutions.

The Company is subject to risks common to companies in the development stage, including, but not limited to, development and regulatory approval of product candidates, development of markets and distribution channels, dependence on key personnel, and the ability to obtain additional capital as needed to fund its product plans and business operations. To achieve profitable operations, the Company must successfully develop and obtain requisite regulatory approvals for, manufacture, and market its product candidate. There can be no assurance that such product candidate can be developed and approved or manufactured at an acceptable cost and with appropriate performance characteristics, or that such product will be successfully marketed. These factors could have a material adverse effect on the Company's future financial results.

The product candidate being developed by the Company requires approval from the U.S. Food and Drug Administration or other international regulatory agencies prior to commercial sales. There can be no assurance that the Company's product candidate will receive the necessary regulatory approvals. If the Company is unable to complete clinical development, obtain regulatory approval for or commercialize its product candidate, or experiences significant delays in doing so, its business will be materially harmed.

Cash and Cash Equivalents

Cash and cash equivalents include cash in readily available checking accounts and money market funds. The Company considers all highly liquid marketable securities purchased with an original maturity of three months or less as of the purchase date to be cash equivalents. Cash and cash equivalents are recorded at cost, which approximates fair value.

Restricted Cash

Cash accounts with any type of restriction are classified as restricted cash. The Company has restricted cash deposits with a bank, which serve as collateral for a letter of credit issued to the landlord of the Company's leased facility for a security deposit. The Company classified this amount as restricted cash in the accompanying consolidated balance sheets.

Fair Value Measurement

ASC Topic 820, *Fair Value Measurement* ("ASC 820"), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. ASC 820 identifies fair value as the price that would be received to sell an asset or paid to transfer a liability, in an orderly transaction between market participants at the measurement date.

The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements, as follows:

Level 1 - Quoted prices in active markets for identical assets or liabilities.

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

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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

The majority of our financial assets have been classified as Level 1. Our financial assets (which typically include cash equivalents and marketable equity securities) have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third-party pricing services or option pricing valuation models. The pricing services utilize industry standard valuation models, including both income and market-based approaches and observable market inputs to determine value. These observation market inputs included reportable tables, benchmark yields, broker quotes, bids, offers, current spot rates and other industry and economic events.

Segment Information

Operating segments are defined as components of an enterprise for which separate and discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company operates and manages its business as one reportable and operating segment, which is the business of developing retinal therapies. The chief executive officer, who is the chief operating decision maker (the "CODM"), reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance.

Acquisitions

The Company evaluates acquisitions of assets and other similar transactions to assess whether the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen test is met, the transaction is accounted for as an asset acquisition. If the screen test is not met, further determination is required as to whether the Company has acquired inputs and processes that have the ability to create outputs which would meet the definition of a business. Significant judgment is required in the application of the screen test to determine whether an acquisition is a business combination or an acquisition of assets.

The Company measures and recognizes asset acquisitions that are not deemed to be business combinations based on the cost to acquire the assets, which includes transaction costs. Goodwill is not recognized in an asset acquisition. In an asset acquisition, the cost allocated to the acquired in-process research and development assets with no alternative future use is charged to research and development expense at the acquisition date.

Deferred Transaction Costs

Deferred transaction costs capitalized were $3.1 million as of December 31, 2024. There were no deferred transaction costs capitalized as of December 31, 2025. Deferred transaction costs relate to legal, consulting, and accounting fees incurred in connection with the Merger. The Company capitalizes certain legal, consulting, and accounting fees that are directly associated with in-process equity financings as deferred transaction costs in the consolidated balance sheets until such financings are consummated. After consummation of an equity financing or upon the consummation of the Merger, these costs are recorded as a reduction of the proceeds from the offering in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. Should the Company choose to not initiate such financing, the deferred transaction costs would be immediately expensed as operating expenses in the consolidated statements of operations and comprehensive loss. All deferred transaction costs were recognized to additional paid-in capital upon the consummation of the Merger.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty of the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses in the statements of operations and comprehensive loss.

Tranche Liability

Under the convertible note financing's amended note purchase agreement, Legacy Kalaris was eligible to receive additional proceeds in the Convertible Note Financing prior to the closing to the Merger to fund Legacy Kalaris's operations prior to the closing of the Merger at three subsequent closings upon Legacy Kalaris's written notice to investors and subject to Samsara's consent. The investors' right to receive additional convertible promissory notes in subsequent tranches of this convertible note financing with a predetermined conversion price was concluded to be a freestanding financial instrument that was required to be accounted for separately as a liability at fair value. The Company estimated fair value of the tranche liability at inception and remeasured it at the end of each reporting period until the tranche liability expired or was settled. The changes in the fair value were recorded as a change in fair value of tranche liability in the statements of operations and comprehensive loss. In connection with the closing of the Merger, the outstanding convertible promissory notes issued by the Company in October and November 2024 converted into shares of common stock and the tranche liability expired.

Convertible Promissory Notes Derivative Liabilities

The convertible promissory notes contained embedded features that provided the noteholder with multiple settlement alternatives. Certain of these settlement features provided the noteholder the right to receive cash or a variable number of shares upon a change in control or the completion of a capital raising transaction by the Company (the "redemption features"). The redemption features of the convertible promissory notes met the requirements for separate accounting and were accounted for as compound derivative instruments recorded as a liability at fair value at inception and were subject to remeasurement to fair value at each reporting period when outstanding, with any changes in fair value recorded as a change in fair value of derivative liabilities in the statements of operations and other comprehensive loss (Note 4). Derivative liabilities were classified in the balance sheets as current consistent with the classification of the respective convertible promissory notes they were related to. The Company estimated the fair value of the derivative liabilities embedded in the convertible promissory notes using a with-and-without scenario analysis, which involved valuing the whole instrument on an as-is basis and then valuing the instrument without the embedded derivative. The difference between the entire instrument with the embedded derivatives compared to the instrument without the embedded derivatives was the fair value of the derivative liabilities. A significant increase in probabilities of qualified financing or redemption scenario, a change of control scenario and a decrease in a discount rate would significantly increase the estimated fair value of derivative liabilities. In connection with the closing of the Merger, all outstanding convertible promissory notes, other than the AlloVir Note (as defined below), converted into shares of either redeemable convertible preferred stock or common stock in accordance with the terms of the agreements and the derivatives expired.

Royalty Obligation – Related Party

In July 2024, the Company entered into a royalty agreement with Samsara (Note 6). In exchange for the shares of common stock the Company redeemed from Samsara, the Company is obligated to pay royalties on a product-by-product and country-by-country basis at low single-digit royalty rates on future net product sales. Given the significant related party relationships with Samsara, the Company concluded that the royalty agreement is a funded research and development agreement under ASC 730-20, *Research and Development Arrangements*. The Company recognized the royalty obligation at its estimated fair value at the effective date of the agreement. Once royalty payments are deemed probable and estimable, and if such amounts exceed the royalty obligation balance, the Company will impute interest to accrete the royalty obligation on a prospective basis based on such estimates. If and when the Company makes royalty payments under the royalty agreement, the royalty obligation balance will be reduced.

Redeemable Convertible Preferred Stock

The Company recorded redeemable convertible preferred stock at fair value on the date of issuance, net of issuance costs. The redeemable convertible preferred stock was recorded separately from stockholders' equity (deficit) because the shares contained deemed liquidation features that were not solely within the Company's control. The holders of the preferred stock controlled a majority of the votes of the board of directors of the Company. Accordingly, the preferred stock was classified as temporary equity in the Company's consolidated balance sheets. The Company did not adjust the carrying values of the redeemable convertible preferred stock to the liquidation preferences of such stock because it was uncertain whether or when a deemed liquidation event would occur that would obligate the Company to pay the liquidation preferences to holders of redeemable convertible preferred stock. Subsequent adjustments to the carrying values to the liquidation preferences would be made only when it became probable that such a deemed liquidation event would occur. In connection with the closing of the Merger, all outstanding shares of redeemable convertible preferred stock were converted into shares of common stock.

Research and Development Expenses

Research and development expenses are charged to expenses as incurred. Research and development expenses include payroll and personnel related expenses, license fees, laboratory supplies, consulting costs, external contract research and development expenses and allocated overhead costs, including software and other miscellaneous expenses incurred in connection with its research and development programs.

The Company estimates manufacturing and product development costs, clinical trial and other research and development expenses based on the services performed. The Company has entered into various agreements with outsourced vendors, contract development and manufacturing organizations and clinical research organizations. The financial terms of these contracts are subject to negotiation, which vary by contract and may result in payments that do not match the periods over which materials or services are provided. Generally, these agreements set forth the scope of work to be performed at a fixed fee, unit price or on a time and materials basis. The Company records the estimated costs of research and development activities based on the level of services performed, the progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development services provided, but not yet invoiced, are included in accrued expenses on the consolidated balance sheets. Advance payments for goods or services for future research and development activities are deferred as prepaid expenses and are expensed as the goods are delivered or the related services are performed. The Company makes these estimates based on facts and circumstances known at that time. If the actual timing of the performance of services or the level of effort varies from the original estimates, the Company will adjust the accrual accordingly. Amounts ultimately incurred in relation to amounts accrued for these services at a reporting date may be substantially higher or lower than the Company's estimates. To date, there have been no material differences between estimates of such expenses and the amounts actually incurred.

Stock-Based Compensation Expense

The Company provides stock-based awards in the form of stock options and restricted stock awards to its employees, directors and consultants. The Company accounts for stock-based compensation expense by measuring and recognizing compensation expense for all stock-based awards based on estimated grant-date fair values. For awards with service-based vesting conditions, the Company recognizes stock-based compensation expense on a straight-line basis over the requisite service or vesting period. The vesting period generally approximates the expected service period of the awards. The Company accounts for forfeitures as they occur.

The Company estimates the fair value of stock options using the Black-Scholes option valuation model. The Black-Scholes model requires the input of subjective assumptions, including expected volatility, expected dividend yield, expected term, risk-free rate of return and the estimated fair value of the underlying common stock on the date of grant. Prior to the Merger, the fair value of the Company's common stock on the date of grant was determined by the Board, taking into consideration its most recently available third-party valuations of common stock as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the grant date.

Foreign Currency Transactions

The functional currency for the Company and all of its subsidiaries is the U.S. Dollar. Transactions denominated in foreign currencies are initially measured in U.S. dollars using the exchange rate on the date of the transaction. Foreign currency denominated monetary assets and liabilities are subsequently remeasured at the end of each reporting period using the exchange rate at that date, with the corresponding foreign currency transaction gain or loss recorded in other income (expense), net in the consolidated statements of operations and comprehensive loss.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. The Company's comprehensive loss includes unrealized gains (losses) on available-for-sale securities.

Pre-Funded Warrants

Warrants are accounted for based on the specific terms of the warrant agreements. The Company's pre-funded warrants are indexed to the Company's common stock and meet the criteria to be classified as equity. Proceeds from the issuance of pre-funded warrants are recorded within additional paid-in capital and are not subject to remeasurement. Refer to Note 12 and Note 14 for further information regarding the pre-funded warrants issued by the Company.

Net Loss Per Share Attributable to Common Stockholders

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period. The Company's potentially dilutive securities include convertible promissory notes, redeemable convertible preferred stock, common stock subject to repurchase, unvested restricted stock awards, and stock options. These potentially dilutive securities have been excluded from the computation of diluted net loss per share as their inclusion would be antidilutive.

Basic and diluted net loss per share attributable to common stockholders is presented in conformity with the two-class method required for participating securities as the redeemable convertible preferred stock and common stock subject to repurchase are considered participating securities. The redeemable convertible preferred stock does not have a contractual obligation to share in the Company's losses, and common stock subject to repurchase and unvested restricted stock awards are considered contingently issuable shares for accounting purposes. As such, the net loss is attributed entirely to common stockholders. Because the Company has reported a net loss for the reporting periods presented, the diluted net loss per common share is the same as basic net loss per common share for those periods.

Issued and unexercised pre-funded warrants are classified as a component of equity in the Company's consolidated balance sheet as they are freestanding financial instruments that are immediately exercisable, do not embody an obligation for the Company to repurchase its own shares and permit the holders to receive a fixed number of shares of common stock upon exercise. All shares underlying pre-funded warrants are included in the weighted-average number of shares of common stock used to calculate basic and diluted net loss per common share because the shares may be issued for little or no consideration, are fully vested and are exercisable after the original issuance date of the pre-funded warrants.

Commitments and Contingencies

The Company recognizes a liability with regard to loss contingencies when it believes it is probable a liability has been incurred, and the amount can be reasonably estimated. If some amount within a range of loss appears at the time to be a better estimate than any other amount within the range, the Company accrues that amount. When no amount within the range is a better estimate than any other amount the Company accrues the minimum amount in the range.

Income Taxes

The Company accounts for income taxes using the asset and liability method; under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse.

The Company recognizes deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In evaluating the ability to recover its deferred income tax assets, the Company considers all available positive and negative evidence, including its operating results, ongoing tax planning and forecasts of future taxable income on a jurisdiction-by-jurisdiction basis. In the event the Company determines that it would be able to realize its deferred income tax assets in the future in excess of their net recorded amount, it would make an adjustment to the valuation allowance that would reduce the provision for income taxes. Conversely, if all or part of the net deferred tax assets are determined not to be realizable in the future, an adjustment to the valuation allowance would be charged to the provision of income taxes in the period when such determination is made.

As of December 31, 2025 and 2024, the Company maintained a valuation allowance against its deferred tax assets as the Company concluded it had not met the “more likely than not” to be realized threshold. Changes in the valuation allowance when they are recognized in the provision for income taxes may result in a change in the estimated annual effective tax rate.

Tax benefits related to uncertain tax positions are recognized when it is more likely than not that a tax position will be sustained during an audit. Tax positions that meet the more-likely-than-not threshold are measured at the largest amount of tax benefit that is greater than 50% likely of being realized upon settlement with the taxing authority. Interest and penalties related to unrecognized tax benefits are included within the provision for income tax.

Short-Term Marketable Securities

The Company classifies all investments with an original maturity of less than one year upon purchase as short-term marketable securities. Short-term marketable securities consist of U.S. treasury securities classified as available-for-sale. The Company's short-term marketable securities are classified as available-for-sale as they are available to fund current operations, even if the Company intends to hold the marketable securities to maturity. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in other comprehensive income (loss) until realized. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization or accretion is included in other income (expense), net in the consolidated statements of operations and comprehensive loss. Realized gains and losses are determined using the specific identification method and are included in other income (expense), net in the consolidated statements of operations and comprehensive loss. Interest on available-for-sale securities is included in other income (expense), net in the consolidated statements of operations and comprehensive loss.

Property and Equipment, net

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets. The Company's property and equipment is comprised of furniture and fixtures, and the estimated useful life is five years. Depreciation and amortization begin at the time the asset is placed in service. Repairs or maintenance costs are expensed as incurred. Upon the sale or retirement of property and equipment, the costs and related accumulated depreciation and amortization are eliminated and the resulting gain or loss is reflected in the consolidated statements of operations and comprehensive loss. The property and equipment, net balance is included within other non-current assets in the consolidated balance sheets. Depreciation expense and accumulated depreciation were immaterial as of December 31, 2025.

Leases

The Company accounts for leases in accordance with ASC 842, *Leases* (“ASC 842”). The Company determines whether an arrangement is or contains a lease at the inception of the arrangement and whether such a lease should be classified as a financing lease or operating lease at the commencement date of the lease. The Company does not have any leases classified as financing leases. Operating leases with a term greater than one year are recognized on the consolidated balance sheets as operating right-of-use asset (“ROU asset”) and operating lease liabilities. The Company elected not to recognize the ROU assets and lease liabilities for leases with lease terms of one year or less (short-term leases). Lease liabilities and their corresponding ROU assets are recorded based on the present value of lease payments over the lease term. ROU assets are further adjusted for initial direct costs, prepaid rent, or incentives received, if any. The Company considers the lease term to be the noncancelable period that it has the right to use the underlying asset, together with any periods where it is reasonably certain it will exercise an option to extend (or not terminate) the lease. As the interest rate implicit in the Company’s lease contracts is not readily determinable, the Company utilizes its incremental borrowing rate based on the information available at the commencement date to determine the present value of lease payments.

Operating lease cost is recognized on a straight-line basis over the lease term. The Company has elected not to separate lease and non-lease components for its real estate leases and instead accounts for each separate lease component and the non-lease components associated with that lease component as a single lease component. Variable lease payments are not included in the measurement of ROU assets and lease liabilities, but rather are recognized as incurred. The Company is responsible for additional costs of improvements in excess of the tenant improvement allowance, and recorded excess costs as payments in the measurement of lease liabilities.

Capitalized Software Implementation Costs

The Company incurred costs to implement cloud computing arrangements hosted by third-party vendors. ASC 350-40, *Internal-Use Software*, requires hosting arrangements that are service contracts to follow the guidance of internal-use software to determine which implementation costs can be capitalized. Implementation costs incurred during the application development stage are capitalized until the software is ready for its intended use. The costs are then amortized on a straight-line basis over the term of the associated hosting arrangement and are recognized as an operating expense within the consolidated statement of operations and comprehensive loss. As of December 31, 2025, the Company capitalized $0.2 million in software implementation costs within other non-current assets on the consolidated balance sheets.

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

ASU 2023-09, Income Taxes (Topic 740)

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which includes amendments that further enhance income tax disclosures, primarily through standardization and disaggregation of rate reconciliation categories and income taxes paid by jurisdiction. The amendments are effective for fiscal years beginning after December 15, 2024 for all public entities. An entity may apply the amendments in this ASU prospectively by providing the revised disclosures for the period ending December 31, 2025 and continuing to provide the pre-ASU disclosures for the prior periods, or may apply the amendments retrospectively by providing the revised disclosures for all period presented. As of December 31, 2025, the Company adopted this ASU retrospectively, which only impacts the Company's income tax disclosures with no impact to its operations, cash flows, or financial condition.

Recently Issued Accounting Pronouncements Not Yet Adopted

ASU 2024-03, Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40)

In November 2024, the FASB issued ASU 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement* Expenses to improve financial reporting by requiring that public business entities disclose additional information about specific expense categories in the notes to financial statements at interim and annual reporting periods. The amendments in this ASU do not change or remove current expense disclosure requirements; however, the amendments affect where such information appears in the notes to the financial statements because entities are required to include certain current disclosures in the same tabular format as the other disaggregation requirements in the amendments. This ASU is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact that the updated standard will have on its consolidated financial statement disclosures and financial reporting processes.

ASU 2025-06, Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40)

In September 2025, the FASB issued ASU 2025-06, *Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software* to modernize the accounting for software costs and increase the operability of the recognition guidance considering different methods of software development. The amendments are effective for annual reporting periods beginning after December 15, 2027, and interim reporting periods within those annual reporting periods. Early adoption is permitted as of the beginning of an annual reporting period. The Company is currently evaluating the impact that the updated standard will have on its consolidated financial statement disclosures.

3. Merger with AlloVir

On March 18, 2025, the Merger closed, and, pursuant to the Merger Agreement, Merger Sub merged with and into Legacy Kalaris with Legacy Kalaris continuing as a wholly owned subsidiary of AlloVir and the surviving corporation of the Merger. Upon completion of the Merger, AlloVir changed its name to “Kalaris Therapeutics, Inc.” and Legacy Kalaris was renamed to “Kalaris Tx, Inc.”

Subject to the terms and conditions of the Merger Agreement, at the Effective Time, all issued and outstanding shares of the Legacy Kalaris’ common stock (including common stock issued upon conversion of Legacy Kalaris’ redeemable convertible preferred stock and outstanding convertible promissory notes, other than the AlloVir Note (as defined below)) converted into the right to receive 0.2016 shares of AlloVir’s common stock calculated in accordance with an exchange ratio equal to 1:0.2016 (the “Exchange Ratio”). Each award of restricted shares of Legacy Kalaris’ common stock that was unvested and outstanding was converted into and exchanged for the right to receive a number of restricted shares of AlloVir common stock based on the Exchange Ratio. Each outstanding option to purchase shares of Legacy Kalaris’ common stock under the Legacy Kalaris’ 2019 Equity Incentive Plan (the “2019 Plan”), whether vested or unvested, was converted into an option to acquire a number of shares of AlloVir’s common stock based on the Exchange Ratio. Exercise prices of assumed options were determined as the product of the exercise price immediately prior to the Effective Time multiplied by the reciprocal of the Exchange Ratio, and rounding up to the nearest whole cent. There were no changes to any other terms of such options or restricted share awards.

Immediately prior to the Effective Time, (i) the outstanding principal and accrued but unpaid interest on convertible promissory notes issued by Legacy Kalaris in January 2025 (other than the AlloVir Note) converted into 794,499 shares of Series B-2 redeemable convertible preferred stock (the “Series B-2 Stock”) at a price of $4.7851 per share, which then converted on a one-for-one basis into shares of Legacy Kalaris common stock, and (ii) the outstanding principal and accrued but unpaid interest on convertible notes issued by Legacy Kalaris in 2024 converted into shares of Legacy Kalaris’ common stock at a price of $6.20 per share.

In January 2025, Legacy Kalaris issued a convertible promissory note in an aggregate principal amount of up to $7.5 million to AlloVir (the “AlloVir Note”) under which AlloVir funded a principal amount of $3.75 million in January 2025. The AlloVir Note accrued interest on the initial advance commencing on the date of such advance, at an interest rate of 8.0% per annum. At the Effective Time, the AlloVir Note was cancelled.

Immediately prior to the Effective Time, each option to purchase shares of AlloVir’s common stock (each, an “AlloVir Option”) that was outstanding immediately prior to the Effective Time, whether vested or unvested, survived the Closing and remains outstanding in accordance with its terms, provided that (i) each unexercised and outstanding AlloVir Option with an exercise price per share equal to or greater than $92.00 was cancelled for no consideration, and (ii) each AlloVir Option that had an exercise price per share less than $92.00, was unvested and unexercised as of the Effective Time, was accelerated in full. Additionally, immediately prior to the Effective Time, each outstanding and unvested AlloVir restricted stock unit was accelerated in full and settled in shares of AlloVir’s common stock.

The aggregate number of shares that AlloVir issued to Legacy Kalaris’ securityholders (including all holders of outstanding convertible notes) at the closing of the Merger was 13,634,744 shares of AlloVir's common stock. Immediately following the Merger, Legacy Kalaris securityholders owned approximately 74.47% of the outstanding shares of the Company’ common stock on a fully-diluted basis and pre-closing AlloVir securityholders owned approximately 25.53% of the outstanding shares of the Company’s common stock on a fully-diluted basis. The number of shares of the Company's common stock issued and outstanding immediately following the closing of the Merger was as follows:

AlloVir’s common stock outstanding	5,043,652
AlloVir’s restricted stock units accelerated and settled in common stock	24,022
Common stock issued to Legacy Kalaris' securityholders at the Effective Time	13,634,744
	18,702,418

The Merger was accounted for as a reverse recapitalization in accordance with GAAP. Under this method of accounting, Legacy Kalaris was deemed to be the accounting acquirer for financial reporting purposes. This determination was primarily based on the fact that, immediately following the Merger: (1) Legacy Kalaris’ stockholders owned a substantial majority of the voting rights of the Company, inclusive of Samsara; (2) Legacy Kalaris designated a majority of the initial members of the board of directors of the Company; and (3) other than with respect to the Company’s chief financial officer, for which the Company had commenced a search for a qualified candidate, the Company's senior management (which are determined by the board of directors of the Company) held all key positions in senior management of the Company. For accounting purposes, the Merger is treated as the equivalent of Legacy Kalaris issuing stock to acquire the net assets of AlloVir. The reported operating results prior to the Merger are those of Legacy Kalaris. The net assets of AlloVir were recorded at their carrying value in the consolidated financial statements of the Company. Historical common stock share, restricted share awards, common stock options and exercise prices data of Legacy Kalaris have been retroactively recast based on the Exchange Ratio.

AlloVir’s net assets acquired included the following: $102.1 million of cash and cash equivalents, $1.7 million of prepaid expenses and other current assets, and $2.6 million of accounts payable and accrued expenses.

The Company recognized approximately $1.5 million related to AlloVir’s directors’ and officers’ insurance and $0.1 million of share-based compensation expense related to the acceleration of vesting of stock options and restricted stock units as general and administrative expenses at the Effective Time. The Company also incurred transaction costs related to the Merger of approximately $5.4 million, which were recorded as a reduction to additional paid-in capital in the consolidated statement of redeemable convertible preferred stock and stockholders’ equity (deficit) for the year ended December 31, 2025.

4. Short-Term Marketable Securities

The following table summarizes the amortized cost and estimated fair value of the Company's U.S. government treasury securities, which are considered to be available-for-sale marketable securities and are included in short-term marketable securities on the consolidated balance sheet as of December 31, 2025 (in thousands):

	December 31, 2025			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term marketable securities:				
U.S. government treasury securities	$ 19,922	$ 6	$ —	$ 19,928
Total short-term marketable securities	$ 19,922	$ 6	$ —	$ 19,928

The Company did not have any short-term marketable securities as of December 31, 2024. Certain short-term debt securities with original maturities of less than three months are included in cash and cash equivalents on the consolidated balance sheets and are not included in the table above. As of December 31, 2025, all marketable securities had contractual maturities within one year.

The Company holds debt securities with high credit quality and has determined that there was no material change in the credit risk of any of its debt securities. There were no securities with an unrealized loss position for less than 12 months as of December 31, 2025.

5. Fair Value Measurements

The Company's fair value hierarchy for its financial instruments measured at fair value on a recurring basis as of December 31, 2025 and December 31, 2024, were as follows (in thousands):

	Fair Value Measurements			
As of December 31, 2025	Total	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 94,394	$ 94,394	$ —	$ —
U.S. government treasury securities	—	—	—	—
Total cash equivalents	$ 94,394	$ 94,394	$ —	$ —
Short-term marketable securities:				
U.S. government treasury securities	$ 19,928	$ 19,928	$ —	$ —
Total short-term marketable securities	$ 19,928	$ 19,928	$ —	$ —

	Fair Value Measurements			
As of December 31, 2024	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds (included in cash equivalents)	$ 1,009	$ 1,009	$ —	$ —
Total fair value of assets	$ 1,009	$ 1,009	$ —	$ —
Liabilities:				
Derivative liabilities (including $995 for a related party)	$ 1,042	$ —	$ —	$ 1,042
Tranche liability (including $331 for a related party)	365	—	—	365
Total fair value of liabilities	$ 1,407	$ —	$ —	$ 1,407

The Company classifies its money market funds and U.S. government treasury securities as Level 1 assets under the fair value hierarchy, as these assets have been valued using quoted market prices in active markets without any valuation adjustment. The Company classifies its derivative liabilities and tranche liability as Level 3 liabilities under the fair value hierarchy as these liabilities have been valued using pricing models with unobservable inputs supported by little or no market activity that are significant to the fair value of the liabilities. The carrying amounts of prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities approximate their fair value due to their short-term maturities. During the periods presented, the Company has not changed the manner in which it values liabilities that are measured at estimated fair value using Level 3 inputs. There were no transfers within the hierarchy for any period presented.

The Company issued the following financial instruments to be accounted for at fair value on a recurring basis: derivative liabilities embedded in convertible promissory notes, and the tranche liability related to the convertible note financing (Note 8).

The Company estimated the fair value of the derivative liabilities embedded in the convertible promissory notes using a with-and-without scenario analysis. The Company estimated that the embedded change of control feature fair values were minimal based on the low probability of the change of control events during the year ended December 31, 2024.

The following assumptions were used to determine the estimated fair value of the derivative liabilities related to the redemption features as of the issuance dates:

	At Issuance Date (January 10, 2025)
Expected term (in years)	0.2 – 0.3
Probability of achievement	0.0% – 80.0%
Discount rate	8.50%

The following assumptions were used to determine the estimated fair value of the derivative liabilities related to the redemption features as of the issuance date and as of December 31, 2024:

	Issuance Dates	December 31, 2024
Expected term (in years)	0.4 – 1.3	0.2 – 0.4
Probability of achievement	0.0% – 90.0%	0.0% – 80.0%
Discount rate	9.5% – 18.7%	9.0%

As all outstanding convertible promissory notes, other than the AlloVir Note, were converted on March 18, 2025, in connection with the closing of the Merger, the derivative liabilities expired and their fair values were immaterial at the time of conversion.

The fair value of the tranche liability related to the convertible promissory notes issued in October and November 2024 was estimated using the probability weighted model with the following Level 3 input assumptions: the timing of issuing convertible notes and notes conversion, probabilities of conversion scenarios, the estimated fair value of the Company's shares into which the note was convertible and a discount rate. The significant assumptions were as follows as of December 31, 2024:

	December 31, 2024
Expected term (in years)	0.2 - 0.4
Probability of achievement	0.0% - 80.0%
Discount rate	9.0%

In March 2025, the Company and other noteholders entered into an acknowledgment of conversion and termination agreement to cancel all unfunded tranches and the tranche liability expired unexercised.

The following table provides a roll-forward of the aggregate fair values of the Company's outstanding Level 3 financial instruments during the years ended December 31, 2025 and 2024 (in thousands):

	Derivative liabilities	Tranche liability
Balance as of December 31, 2023	$ —	$ —
Initial fair value at issuance	3,126	21,377
Change in fair value	(2,084)	(21,012)
Balance as of December 31, 2024	$ 1,042	$ 365
Initial fair value at issuance	187	—
Change in fair value	(1,229)	(365)
Balance as of December 31, 2025	$ —	$ —

6. Balance Sheet Components

Prepaid expenses and other current assets

Prepaid expenses and other current assets as of December 31, 2025 and 2024, consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
Prepaid research and development expenses	$ 323	$ 388
Prepaid insurance	185	54
Prepaid taxes	211	—
Prepaid professional and legal costs	30	525
Other prepaid expenses and other current assets	78	—
Total prepaid expenses and other current assets	$ 827	$ 967

Accrued expenses and other current liabilities

Accrued expenses and other current liabilities as of December 31, 2025 and 2024, consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
Accrued research and development expenses	$ 4,295	$ 659
Accrued compensation expense	1,601	591
Accrued professional and legal costs	442	308
Accrued transaction expenses	1,717	567
Accrued patent reimbursement costs	—	48
Other accrued expenses and other current liabilities	62	22
Total accrued expenses and other current liabilities	$ 8,117	$ 2,195

Property and Equipment, net

The property and equipment, net balance is included within other non-current assets in the consolidated balance sheets. Depreciation expense and accumulated depreciation were immaterial as of December 31, 2025. The Company did not hold property and equipment, net as of December 31, 2024.

7. Significant Agreements

License Agreement with the University of California, San Diego

In April 2021, the Company entered into a license agreement with UCSD (as amended, the "UCSD Agreement") pursuant to which the Company obtained (i) an exclusive license under the patent rights to make, use, sell, offer for sale, and import licensed products and (ii) a non-exclusive license to use the technology with a right to sublicense, each (i) and (ii) related to new anti-VEGF agents and novel long-acting VEGF inhibitors for intraocular neovascularization for the treatment of patients with retinal pathologies. As partial consideration for the license, the Company agreed to pay UCSD $0.2 million and was obligated to issue shares of its common stock to UCSD equal to 5% of the fully diluted issued and outstanding securities of the Company until such time as an aggregate of $5.0 million in gross proceeds from the sale of equity securities had been raised by the Company. In June 2022, after the closing of the Series A financing, the Company issued 137,234 shares of its common stock to UCSD. The Company was also obligated to pay $0.1 million of patent costs incurred prior to the effective date and is required to reimburse future patent expenses incurred by UCSD during the term of the UCSD Agreement. Under the UCSD Agreement, the Company is required to make annual license maintenance payments of $10,000 during the first four anniversaries and $15,000 on the fifth and every subsequent anniversary of the effective date. The Company is obligated to pay an aggregate of up to $4.6 million upon the achievement of various development and regulatory milestones and low single-digit royalties on net sales of licensed products. The royalty is payable, on a licensed product-by-licensed product and country-by country basis, until expiration of the last-to-expire issued patent of the applicable licensed product in the country of sale or the manufacture. If the Company enters into a sublicensing agreement, it is required to pay UCSD a sublicense fee as a percentage of the fair market value of any sublicense fee received that is not earned royalties for each sublicense granted. The sublicense fee percentage ranges from 50% if the applicable sublicense agreement is entered into within one year from the UCSD Agreement effective date and decreases to 10% if the applicable sublicense agreement is entered into after the first dosing of a patient for a phase 2 clinical trial.

In case of a closing of a merger, or sale of at least 50% of the voting stock of the Company or the sale by the Company of all or substantially all of its assets (collectively referred to as "Liquidity Event"), the Company is obligated to make a one-time cash milestone payment to UCSD ranging from $0.1 million to $1.0 million based on the valuation of the Company's outstanding shares at the Liquidity Event closing date. The Merger did not meet the definition of the Liquidity Event.

The UCSD Agreement is effective until the expiration date of the longest-lived patent rights or last to be abandoned patent or future patent of the licensed products, whichever is later. The Company can terminate the agreement upon 60 days written notice. UCSD can terminate the agreement in the event of an uncured material breach, such as a failure to make payments due, or to perform under the UCSD Agreement or a violation of any other material term of the UCSD Agreement, that is not cured by the Company within 60 days after a written breach notice provided by UCSD.

The acquisition of the license under the UCSD Agreement, including patent rights and know-how, was accounted for as an asset acquisition. As the acquired technology did not have an alternative future use, the Company recognized the $0.2 million initial cash consideration, $0.1 million patent reimbursement costs incurred prior to the effective date, and $0.2 million related to the obligation to issue shares of the Company's common stock as research and development expenses. The obligation to issue shares of common stock included two components, the initial shares obligation and the additional shares obligation. The fair value of the initial share obligation was estimated as $0.1 million based on the fair value of 55,440 shares of common stock, which represented 5% of the outstanding fully diluted equity at the effective date. As the initial share obligation was indexed to the Company's own stock, it was recorded as additional paid-in capital. The additional shares obligation was recognized when the next round of financing closed in March 2022. The Company estimated the fair value of an additional 81,794 shares of common stock as $0.2 million and recognized it as research and development expenses and additional paid-in capital in March 2022. The Company concluded that the contingent payment upon the closing of the Liquidity Event is a derivative liability and should be accounted for at fair value and re-measured until its settlement or expiration. The Company recognized $0.2 million and $0.1 million in patent reimbursement costs for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025 and 2024, the Company recognized $0.03 million and $0.2 million related to the UCSD Agreement in accrued expenses and other current liabilities in the consolidated balance sheet. Over the life of the agreement through December 31, 2025, development milestones totaling $0.1 million have been achieved by the Company and incurred as research and development expenses. The Company did not achieve any development milestones and did not incur any related milestone expense during the year ended December 31, 2025. The Company achieved the first development milestone in August 2024 and incurred $0.1 million as research and development expense during the year ended December 31, 2024. The assignment fee derivative liability fair value was estimated to be zero as of December 31, 2025 and 2024, as the probability of the Liquidity Event was estimated to be zero.

Royalty Agreement with Samsara – Related Party

In July 2024, the Company entered into a royalty agreement (the "Royalty Agreement") with Samsara, the majority stockholder of the Company and a related party. Under the Royalty Agreement, the Company redeemed 10,080 shares of its common stock issued to Samsara under a restricted stock purchase agreement in exchange for the Company's agreement to pay Samsara a low single-digit percentage tiered royalty on net sales, if any, of the Company's products developed using the technology licensed under the UCSD Agreement. Such royalties are payable on a product-by-product and country-by-country basis until the later of (i) ten years after the first commercial sale of such product in such country and (ii) the expiration of the last-to-expire issued claim of the Company's patents for such product in such country.

The Company identified two elements in the Royalty Agreement: repurchased shares, and future royalty payments to Samsara. The repurchase of shares was accounted at an estimated fair value of $32,000 as a reduction of common stock and additional paid-in-capital in the consolidated balance sheet and the statement of redeemable convertible preferred stock and shareholders' deficit. The Company recorded $32.1 million as a long-term liability related to the obligation to make royalty payments to Samsara. The fair value of the royalty obligation was estimated using a risk-adjusted net present value model, based on the contractual royalty rates applied to the future net sales forecast, adjusted by the probability of success of product development and discounted to the effective date of the Royalty Agreement using a 25.0% discount rate. The excess of the royalty liability over the fair value of the repurchased shares of $32.0 million was recorded as a research and development expense in July 2024. Once royalty payments to Samsara are deemed probable and estimable, and if such amounts exceed the initially recorded royalty obligation balance, the Company will impute interest to accrete the liability on a prospective basis based on such estimates. If and when the Company makes royalty payments under the Royalty Agreement, the royalty obligation balance will be reduced.

From July 2024 through December 31, 2025, royalty payments were not probable and estimable and, therefore, no interest expense was recognized for the royalty liability.

8. Convertible Promissory Notes

2024 Convertible Promissory Note

In March 2024, the Company issued a convertible promissory note to Samsara (the "2024 Note") for total proceeds of up to $10.0 million. The 2024 Note was payable in two advances at Samsara's discretion, carried an annual interest rate of 10%, and had an original maturity date of March 2025. In March and May 2024, Samsara advanced to the Company $5.0 million for an aggregate advance of $10.0 million under the 2024 Note. All unpaid interest and principal were due and payable upon request of Samsara on or after maturity, or in the event of default. The Company could not prepay the principal amount and accrued interest at any time before maturity without the consent of Samsara.

In the event that the Company issued and sold shares of its redeemable convertible preferred stock to investors following the issuance date of the 2024 Note in a single transaction or a series of related transactions that resulted in either (i) gross proceeds of at least $10.0 million (excluding conversion of the (a) 2024 Note and any other convertible notes or convertible securities issued by the Company and then outstanding and (b) aggregate gross proceeds to the Company yielded by any cash investment by Samsara, or (ii) designated as a qualified financing by Samsara (a "2024 Note Qualified Financing")), then the outstanding principal amount of the 2024 Note and any unpaid accrued interest would automatically convert into shares of redeemable convertible preferred stock issued in the 2024 Note Qualified Financing at a conversion price equal to 80% of the per share price paid by investors for the redeemable convertible preferred stock in the 2024 Note Qualified Financing.

Upon a change in control, the 2024 Note, at the election of Samsara, would either (i) become due and payable in cash upon the closing of such change in control, in an amount equal to twice the outstanding principal amount plus any unpaid accrued interest, or (ii) convert into shares of the Company's Series B-2 Stock. The conversion would have been based on a price equal to 100% of the total aggregate consideration paid for each share of the Company's capital stock on an as-converted to common stock basis (including any earn-out amounts).

Unless earlier converted or repaid in connection with the 2024 Note Qualified Financing or a change in control on or prior to the maturity date, or at any time at Samsara's option, Samsara could have elected to convert the 2024 Note and any unpaid accrued interest into the Company's common stock at a conversion price equal to the Series B-2 Stock conversion price then in effect.

The 2024 Note contained customary representations and warranties and event of default provisions. Upon any event of default, Samsara could declare the principal and unpaid accrued interest under the 2024 Note immediately due and payable.

The 2024 Note was issued to Samsara at the estimated fair value of $12.1 million at the issuance date. Since the convertible promissory notes were issued to a related party and considered not at arm's length, the total premium of $2.1 million, which was the difference between the fair value at the issuance date and the principal amount of the note, was recognized as a loss on issuance of convertible promissory notes – related party in the consolidated statement of operations and comprehensive loss and as additional paid-in-capital in the consolidated statement of redeemable convertible preferred stock and stockholders' equity (deficit) in March and May 2024 when amounts were advanced under the 2024 Note. The Company recognized a $0.2 million loss on extinguishment and on issuance of convertible promissory notes to a related party for the year ended December 31, 2025. The Company recognized a $38.0 million loss on extinguishment and on issuance of convertible promissory notes, of which $34.7 million was to a related party for the year ended December 31, 2024. The fair value of convertible promissory notes at issuance was estimated using the probability weighted settlements scenarios model discounted to present value with the following range of assumptions: expected term of 0.4 – 1.3 years, probabilities of scenario achievement of 0.0% – 90.0% and discount rates of 12.3% – 18.7%.

The 2024 Note contained embedded features that provided Samsara the right to receive cash or a variable number of shares upon a change in control or the completion of a capital raising transaction by the Company. These embedded features were required to be bifurcated and accounted for separately as a compound derivative instrument. The embedded features were initially and subsequently measured at fair value, with changes in the fair value recorded as a change in fair value of derivative liabilities – related party in the consolidated statements of operations and comprehensive loss. The total fair value at issuance of the derivative instrument issued with the 2024 Note was $2.1 million, including $1.1 million for the convertible promissory note issued in March 2024. The derivative liability created a discount on the advances under the 2024 Note that was amortized using the effective interest rate method over the term of the respective advance and recorded as a non-cash interest expense.

The Company recognized a change in the fair value of derivative liability of $0.5 million for the year ended December 31, 2025. The Company recognized a change in the fair value of derivative liability of $1.6 million for the year ended December 31, 2024. The 2024 Note was converted into shares of common stock, and the derivative liability expired in connection with the closing of the Merger on March 18, 2025.

For the year ended December 31, 2025, interest expense for the 2024 Note was $0.8 million, consisting of $0.2 million of contractual interest expense and $0.6 million in amortization of debt discount arising from the separation of the derivative instrument. For the year ended December 31, 2024, interest expense for the 2024 Note was $2.3 million, including $0.7 million of contractual interest expense and $1.6 million in amortization of debt discount arising from the separation of the derivative instrument. In connection with the closing of the Merger, the $10.0 million aggregate outstanding principal amount and $0.9 million accrued interest of the 2024 Note were converted into 1,757,951 shares of Legacy Kalaris common stock at a conversion price of $6.20 per share. The 2024 Note was no longer outstanding as of December 31, 2025.

2024 and 2025 Bridge Notes

In October 2024, the Company entered into a convertible note purchase agreement with Samsara to sell and issue convertible promissory notes for an aggregate principal amount of up to $25.0 million. In November 2024, the Company amended the agreement and other existing preferred stockholders of the Company joined the agreement. In October 2024, the Company issued to Samsara a convertible promissory note with an aggregate principal amount of approximately $9.0 million (the "October 2024 Note"). In November 2024, the Company issued additional notes with an aggregate principal amount of approximately $1.0 million to Samsara and other investors (the "November 2024 Notes", and together with the October 2024 Note, the "2024 Bridge Notes"). The October and November 2024 issuance of convertible notes is referred to as the "First Tranche Closing". The Company had the right to draw up to an additional $15.0 million in three subsequent tranche closings of up to a maximum aggregate principal amount of $5.0 million in each such closing (each, the "Subsequent Tranche Closing"). The 2024 Bridge Notes carried an annual interest rate of 8%, and had an original maturity date of May 2025.

In the event that the Company issued and sold shares of its redeemable convertible preferred stock to investors following the respective issuance date of the 2024 Bridge Notes in a single transaction or a series of related transactions that results in either (i) gross proceeds of at least $10.0 million (excluding conversion of the (a) 2024 Bridge Notes and any other convertible notes or convertible securities issued by the Company and then outstanding and (b) aggregate gross proceeds to the Company yielded by any cash investment by Samsara), or (ii) designated as a qualified financing by Samsara (a "2024 Bridge Notes Qualified Financing"), then the outstanding principal amount of the 2024 Bridge Notes and any unpaid accrued interest would automatically convert into shares of redeemable convertible preferred stock issued in the 2024 Bridge Notes Qualified Financing at a conversion price equal to 80% of the per share price paid by investors for the redeemable convertible preferred stock in the 2024 Bridge Notes Qualified Financing.

Upon a change in control, the 2024 Bridge Notes, at the election of Samsara, would either (i) become due and payable in cash upon the closing of such change in control, in an amount equal to twice the outstanding principal amount plus any unpaid accrued interest, or (ii) convert into shares of the Company's Series B-2 Stock at a price equal to 100% of the total aggregate consideration to be paid for each share of the Company's capital stock on an as-converted to common stock basis (including any earn-out amounts) as determined by the board of directors of the Company in its sole discretion, provided that if the conversion occurred due to the closing of the Merger, only clause (ii) would apply to such conversion.

Unless earlier converted or repaid in connection with the 2024 Bridge Notes Qualified Financing or a change in control on or prior to the maturity date, or at any time at Samsara's option, Samsara could have elected to convert the 2024 Bridge Notes and any unpaid accrued interest into the Company's common stock at a conversion price equal to the Series B-2 Stock conversion price then in effect (the "2024 Bridge Notes Optional Conversion").

The 2024 Bridge Notes contained customary representations and warranties and event of default provisions. Upon any event of default, Samsara could declare the principal and unpaid accrued interest under the 2024 Bridge Notes immediately due and payable.

The Company determined that the investors' right to receive additional convertible promissory notes at a predetermined conversion price under each of the Subsequent Tranche Closing represented freestanding instruments that should be accounted for separately as liabilities, initially recorded and subsequently remeasured at fair value until their exercise or expiration (the "Tranche Liability"). The Tranche Liability was initially recorded at $21.4 million. The change in the fair value of the Tranche Liability was $21.0 million for the year ended December 31, 2024. As of December 31, 2024, the Tranche Liability fair value was $0.4 million. The decrease in fair value was a result of modification of tranche amounts and parties agreeing to convert each of the subsequent Tranche Closings at a price per share equal to the Company Value Per Share, as defined in the Merger Agreement. The fair value of the Tranche Liability was estimated using the probability weighted scenario analysis discounted to the current period (Note 5).

The 2024 Bridge Notes were issued to Samsara and other existing preferred stockholders of the Company at the estimated fair value of $24.5 million at the issuance dates. The premium of $14.5 million, which was the difference between the fair value at the issuance date and the principal amount of the notes, was recognized as additional paid-in-capital in the consolidated statement of redeemable convertible preferred stock and stockholders' equity (deficit) at the issuance date. The fair value of the notes at issuance was estimated using the probability weighted settlements scenarios model discounted to present value with the following range of assumptions: expected term of 0.4 - 0.6 years, probabilities of scenario achievement of 0% - 60% and a discount rate of 9.5%. The aggregate estimated fair value of the 2024 Bridge Notes and the Tranche Liability was $45.9 million as of the issuance date. The

Company recognized the excess of the aggregated fair value over net cash proceeds received as non-pro rata distribution to the stockholders, resulting in a loss of $35.9 million at the issuance date, which was recorded as a loss on issuance of convertible promissory notes in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2024.

The 2024 Bridge Notes contained embedded features that provided Samsara and other stockholders the right to receive cash or a variable number of shares upon a change in control or the completion of a capital raising transaction by the Company. These embedded features were required to be bifurcated and accounted for separately as a compound derivative instrument. The embedded features were initially and subsequently measured at fair value with changes in the fair value recorded as a change in fair value of derivative liabilities in the consolidated statements of operations and comprehensive loss. The fair value at issuance of the derivative instrument issued with the 2024 Bridge Notes was $1.0 million. The derivative liabilities created a discount on the advances under the 2024 Bridge Notes that were amortized using the effective interest rate method over the term of the respective advance and recorded as a non-cash interest expense. The change in the fair value of derivative liabilities related to the 2024 Bridge Notes was $0.5 million for the year ended December 31, 2025. The 2024 Bridge Notes were converted into shares of common stock and the derivative liability expired in connection with the closing of the Merger on the Closing Date.

Pursuant to the Merger Agreement, the Company was permitted to enter into a series of financings to fund its operations prior to the closing of the Merger in an amount not to exceed $15.0 million in the aggregate on a to be converted post-money basis, with up to $7.5 million to be provided by AlloVir and up to $7.5 million to be provided by Legacy Kalaris' stockholders.

In January 2025, the Company amended its 2024 Bridge Notes agreement and changed the amounts of Subsequent Tranche Closings from $5.0 million for each tranche to $3.75 million for the first two tranches and $7.5 million for the third tranche. No other changes were made to the terms of the 2024 Bridge Notes. In January 2025, Samsara and other investors funded an aggregate principal amount of $3.75 million in convertible promissory notes (the "2025 Bridge Notes"). The 2025 Bridge Notes' terms were similar to the 2024 Note's terms. Samsara and other investors agreed that the 2025 Bridge Notes would convert into shares of Series B-2 Stock at a price per share equal to the Company Value Per Share, as defined in the Merger Agreement, at the closing of the Merger.

The 2025 Bridge Notes were issued to Samsara and other existing preferred stockholders of the Company at the estimated fair value of $3.9 million at the issuance dates. The premium of $0.2 million, which was the difference between the fair value at the issuance date and the principal amount of the notes, was recognized as additional paid-in-capital in the consolidated statement of redeemable convertible preferred stock and stockholders' equity (deficit) at the issuance date. The fair value of the notes at issuance was estimated using the probability weighted settlements scenarios model discounted to present value with the following range of assumptions: expected term of 0.2 - 0.3 years, probabilities of scenario achievement of 20% - 80% and a discount rate of 8.5%. The 2025 Bridge Notes contained embedded features that provided Samsara and other stockholders the right to receive cash or a variable number of shares upon a change in control or the completion of a capital raising transaction by the Company. These embedded features were required to be bifurcated and accounted for separately as a compound derivative instrument. The embedded features were initially and subsequently measured at fair value, with changes in the fair value recorded as a change in fair value of derivative liabilities in the consolidated statements of operations and comprehensive loss. The fair value at issuance of the derivative instrument issued with the 2025 Bridge Notes was $0.2 million. The derivative liabilities created a discount on the advances under the 2025 Bridge Notes that were amortized using the effective interest rate method over the term of the respective advance and recorded as a non-cash interest expense. The change in the fair value of derivative liabilities related to the 2025 Bridge Notes was $0.2 million for the year ended December 31, 2025. The 2025 Bridge Notes were converted into shares of Series B-2 Stock and the derivative liability expired in connection with the closing of the Merger on the Closing Date.

The total interest expense for the 2024 Bridge Notes and 2025 Bridge Notes was $0.6 million for the year ended December 31, 2025. For the year ended December 31, 2025, total interest expense consisted of $0.2 million of contractual interest expense and $0.4 million in amortization of debt discount arising from the separation of the derivative instrument. The total interest expense for the 2024 Bridge Notes and 2025 Bridge Notes was $0.4 million for the year ended December 31, 2024. For the year ended December 31, 2024, total interest expense consisted of $0.1 million of contractual interest expense and $0.3 million in amortization of debt discount arising from the separation of the derivative instrument.

In connection with the closing of the Merger, the $10.0 million aggregate outstanding principal amount and $0.3 million accrued interest of the 2024 Bridge Notes converted into 1,660,888 shares of Legacy Kalaris common stock at a conversion price of $6.20 per share and the 2024 Bridge Notes were no longer outstanding as of December 31, 2025. In connection with the closing of the Merger, the $3.75 million aggregate outstanding principal amount and $0.1 million accrued interest of the 2025 Bridge Notes converted into 794,499 shares of Series B-2 Stock at a price of $4.7851 per share, which then converted on a one-for-one basis into shares of Legacy Kalaris common stock, and subsequently into 160,165 shares of AlloVir common stock.

In March 2025, the Company and other noteholders entered into an acknowledgment of conversion and termination agreement to cancel all unfunded tranches included in the 2024 Bridge Notes. The Company recognized a gain of $0.4 million in the change in fair value of the tranche liability for the year ended December 31, 2025.

January 2025 AlloVir Convertible Promissory Note

In January 2025, the Company issued the AlloVir Note under which AlloVir funded a principal amount of $3.75 million. At the closing of the Merger on March 18, 2025, the AlloVir Note was cancelled in accordance with its terms.

As of December 31, 2025, the Company does not have any outstanding convertible promissory notes, derivative liabilities or the tranche liability.

9. Leases

In February 2025, the Company entered into an operating lease agreement for office space in Berkeley Heights, New Jersey. In accordance with ASC 842, the Company has determined the lease commencement occurred in September 2025 upon substantial completion of lessor-owned improvements. The lease is expected to terminate in December 2031, however, the Company has the option to extend the lease term twice for an additional three years. As of December 31, 2025, it is not reasonably certain that the Company will exercise this option to extend. The Company can terminate the lease after four years and four months after the lease commencement date with a termination penalty of $0.3 million. In addition to the base rent, the Company will pay its share of operating expenses and taxes. The lessor provided a tenant improvement allowance of up to $0.4 million, which the Company fully utilized as of December 31, 2025. The Company is responsible for additional improvement expense incurred in excess of the tenant improvement allowance and has incurred $0.1 million of excess costs as of December 31, 2025. The Company records excess costs as payments in the measurement of lease liabilities.

In connection with the signing of the lease, the Company secured a letter of credit in favor of the lessor in the amount of $0.5 million, which will be reduced to $0.2 million over five years. The letter of credit is recorded as restricted cash in the consolidated balance sheet as of December 31, 2025.

The following table summarizes the presentation of the Company's operating lease on its consolidated balance sheet as of December 31, 2025 (in thousands):

Leases	Balance sheet classification	December 31, 2025
Assets:		
Operating lease assets	Operating lease right-of-use assets	$ 1,475
Total lease assets		$ 1,475
Liabilities:		
Current:		
Operating lease liabilities	Operating lease liability, current	$ 316
Noncurrent:		
Operating lease liabilities	Operating lease liability, long-term	1,132
Total lease liabilities		$ 1,448

The components of lease cost under ASC 842 included within general and administrative expenses in the Company’s consolidated statements of operations and comprehensive loss were as follows for the year ended December 31, 2025 (in thousands):

Lease cost	Year Ended December 31, 2025
Operating lease cost	$ 117
Variable lease cost	6
Total lease cost	$ 123

As of December 31, 2025, the weighted-average remaining lease term for the operating lease was 6.0 years, and the weighted-average discount rate was 13.12%. Cash paid for amounts included in the measurement of lease liabilities was $0.1 million for the year ended December 31, 2025.

Future minimum annual lease commitments under the Company's non-cancelable operating lease as of December 31, 2025 was as follows (in thousands):

Year ended December 31,	Amount
2026	$ 335
2027	342
2028	349
2029	356
2030	363
Thereafter	338
Total lease payments	2,083
Less: interest	(635)
Present value of operating lease liabilities	$ 1,448

10. Commitments and Contingencies

Leases

The Company's commitments under its operating leases are described in Note 9.

Research and Development Agreements

The Company enters into various agreements in the ordinary course of business, such as those with suppliers, contract development and manufacturing organizations, clinical research organizations, and other research and development vendors. These agreements provide for termination at the request of either party, generally with less than one year’s notice. Therefore, they are cancellable contracts and, if canceled, are not expected to have a material effect on the Company’s financial condition, results of operations, or cash flows.

License and Royalty Agreements

The Company is required to pay certain milestone payments contingent upon the achievement of specific development and regulatory events in accordance with the UCSD Agreement (Note 7). Over the life of the agreement through December 31, 2025, the Company achieved development milestones totaling $0.1 million, which were recorded as research and development expenses. No other milestones were achieved or probable as of December 31, 2025 and 2024. The Company is required to pay royalties on commercial sales of products developed under the UCSD Agreement. The Company’s product candidate was in clinical development as of December 31, 2025, and no such royalties were due.

The Company is obligated to pay royalties to Samsara under the Royalty Agreement (Note 7). The Company recognized an initial royalty obligation liability in the amount of $32.1 million, which was based on its estimated fair value at the effective date of the Royalty Agreement. Once royalty payments to Samsara are deemed probable and estimable, and if such amounts exceed the royalty liability balance, the Company will impute interest to accrete the royalty obligation on a prospective basis based on such estimates. As of December 31, 2025, these royalties were not probable and estimable.

Legal Contingencies

The Company, from time to time, may be a party to litigation arising in the ordinary course of business. If the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount is reasonably estimable, the Company will accrue a liability for the estimated loss.

Litigation Related to the Merger

Two complaints have been filed by purported AlloVir stockholders as individual actions against AlloVir and the members of its board of directors in the Supreme Court of the State of New York, New York County, captioned Keller v. AlloVir, Inc. et al., No. 650989/2025 (N.Y. Sup. Ct. Feb. 20, 2025), and Morgan v. AlloVir, Inc. et al., No. 650965/2025 (N.Y. Sup. Ct. Feb. 19, 2025) (the “Complaints”). The Complaints allege that the proxy statement/prospectus describing the transaction between Legacy Kalaris and AlloVir misrepresented and/or omitted certain purportedly material information, and assert claims for negligent misrepresentation and concealment and negligence under New York common law. The Complaints seek various remedies including, among other things, an order enjoining the consummation of the merger, requiring the defendants to file an amended proxy statement/prospectus, rescinding the merger or granting rescissory damages, and awarding costs, including plaintiff’s attorneys’ fees and experts’ fees, and other relief the court may deem just and proper. AlloVir and Legacy Kalaris deny the allegations in the Complaints and deny that any further

disclosure beyond that already contained in the proxy statement/prospectus was required under applicable law. The Company has not recorded any liabilities in connection with the Complaints.

Litigation Related to Legacy Operations of AlloVir

On January 19, 2024, a purported stockholder of AlloVir filed a lawsuit, captioned Zerbato v. AlloVir, Inc. et al., No. 1:24-cv-10152 (D. Mass.) (the "Securities Class Action"), in the U.S. District Court for the District of Massachusetts (the "Court") against AlloVir and two of its officers purportedly on behalf of a putative class of stockholders. On April 16, 2024, the Court appointed stockholders Harry Levin and Julio Maurice Bueno as lead plaintiffs and their counsel as lead counsel in the action. On June 17, 2024, lead plaintiffs filed their amended complaint. In the amended complaint, lead plaintiffs asserted claims purportedly on behalf of a putative class of stockholders consisting of persons who purchased or otherwise acquired AlloVir securities between January 11, 2023 and December 21, 2023, inclusive. The amended complaint asserted claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and the related regulations, alleging that the defendants made false and misleading statements and omissions to investors relating to AlloVir's three Phase 3 studies of posoleucel. The complaint sought, among other things, damages, prejudgment and post-judgment interest, and attorneys' fees, expert fees and other costs. On April 14, 2025, the parties executed a definitive stipulation and agreement of settlement resolving the claims in the Securities Class Action for $1.0 million. On July 30, 2025, the Court entered an order granting final approval of the settlement and dismissing the Securities Class Action with prejudice.

On October 21, 2024, a purported AlloVir stockholder filed a derivative lawsuit, captioned Lister v. Brainard et al., No. 1:24-cv-12658 (D. Mass.), in the U.S. District Court for the District of Massachusetts against certain of AlloVir's officers and directors and naming AlloVir as a nominal defendant. The derivative complaint alleged, purportedly on behalf of AlloVir, violations of Section 14(a) of the Securities Exchange Act of 1934, breach of fiduciary duties, unjust enrichment, waste of corporate assets, gross mismanagement, and abuse of control against the individual defendants and contribution under Sections 10(b) and 21D of the Securities Exchange Act of 1934 against Dr. Brainard and Mr. Sinha. These claims were based on substantially identical allegations as the complaint in the above-listed Securities Class Action. The lawsuit sought, among other things, an award of damages and restitution in favor of AlloVir, certain changes to AlloVir's corporate governance, and attorneys' fees and costs. On August 1, 2025, the plaintiff filed a notice voluntarily dismissing the derivative lawsuit without prejudice.

Guarantees and Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of December 31, 2025 and December 31, 2024, the Company does not have any material indemnification claims that were probable or reasonably possible.

11. Redeemable Convertible Preferred Stock

In January 2024, the Company issued 1,280,000 shares of Series B-2 Stock at a price of $1.25 per share for gross cash proceeds of $1.6 million.

Upon the closing of the Merger on March 18, 2025, all outstanding shares of redeemable convertible preferred stock were automatically converted into shares of common stock and no redeemable convertible preferred stock was outstanding as of December 31, 2025.

Redeemable convertible preferred stock as of December 31, 2024, consisted of the following (in thousands, except shares):

	December 31, 2024			
	Shares Authorized	Shares Issued and Outstanding	Aggregate Liquidation Preference	Net Carrying Value
Series A	25,194,245	25,194,245	$ 25,194	$ 24,965
Series B-1	9,957,095	9,957,095	9,957	11,222
Series B-2	40,000,000	8,000,000	10,000	9,812
Total redeemable convertible preferred stock	75,151,340	43,151,340	$ 45,151	$ 45,999

The holders of the Company's redeemable convertible preferred stock had the following rights and preferences prior to the conversion of the redeemable convertible preferred stock into common stock upon the closing of the Merger:

Liquidation Preference

In the event of any liquidation, dissolution, or winding up of the Company, or a deemed liquidation event, including a merger or consolidation, or a sale or other disposition of all or substantially all of the Company's assets, the holders of shares of Series A redeemable convertible preferred stock (the "Series A Stock"), Series B-1 redeemable convertible preferred stock (the "Series B-1 Stock") and Series B-2 Stock were entitled to receive, before any payments are made to the holders of common stock, an amount per share equal to the Series A Stock, Series B-1 Stock and Series B-2 Stock original issuance price of $1.00, $1.00 and $1.25 per share, respectively, plus any dividends declared but unpaid. If the Company's legally available assets were insufficient to satisfy the Series A Stock, Series B-1 Stock and Series B-2 Stock liquidation preference, then proceeds would be distributed with equal priority and pro rata among the holders of the Series A Stock, Series B-1 Stock and Series B-2 Stock in proportion to the preferential amount each holder was otherwise entitled to receive.

After the payment of the full liquidation preference of the redeemable convertible preferred stock, the Company's remaining assets legally available for distribution, if any, would be distributed ratably to the holders of common stock and redeemable convertible preferred stock on an as-if-converted basis.

Conversion

Shares of redeemable convertible preferred stock were convertible into common stock at the option of the holder at a conversion ratio that equaled the original issue price for such series, adjusted for any anti-dilution adjustments, divided by the conversion price for such series, in effect on the date of the conversion. The initial conversion price per share for convertible preferred stock was the original issuance price. The conversion ratios were one-for-4.9603 for each series of redeemable convertible preferred stock as of March 18, 2025 and December 31, 2024, as adjusted for the Exchange Ratio.

Each share of redeemable convertible preferred stock was automatically convertible into shares of common stock at the then-effective conversion ratio immediately upon (i) the vote or written consent of the holders of at least the majority of the outstanding shares of redeemable convertible preferred stock, (ii) the closing of a firm-commitment underwritten public offering with gross proceeds to the Company of at least $75.0 million and a public offering price which is at least $3.75 per share, adjusted for any anti-dilution adjustments, or (iii) closing of a special purpose acquisition company (a "SPAC") transaction. A SPAC transaction is any business combination pursuant to which the Company was merged into, or otherwise combined with a SPAC listed on a national securities exchange, or a subsidiary of such SPAC, and the shares of capital stock of the Company outstanding immediately prior to such transaction continued to represent, immediately following such combination, a majority, by voting power, of the capital stock of the surviving or resulting corporation.

Dividends

The Company could not pay any dividends on common stock of the Company unless the holders of redeemable convertible preferred stock then outstanding first or simultaneously received dividends at the same rate as dividends paid with respect to common stock or any class or series that was not convertible into common stock, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to redeemable convertible preferred stock. If the Company declared, paid or set aside, a dividend on shares of more than one class or series of capital stock of the Company, the dividend payable to the holders of each series of redeemable convertible preferred stock was calculated based upon the dividend on the class or series of capital stock that would have resulted in the highest dividend for such series of preferred stock. Through March 18, 2025, no dividends had been declared or paid.

Voting Rights

Each holder of redeemable convertible preferred stock was entitled to the number of votes equal to the number of shares of common stock into which such shares of preferred stock held by such holder could then be converted. The holders of redeemable convertible preferred stock voted together with the holders of common stock as a single class and on an as-converted to common stock basis.

The holders of shares of the Series A Stock, voting as a separate class, were entitled to elect three members of the board of directors. The holders of the shares of common stock, voting as a separate class, were entitled to elect one director of the Company. The holders of common stock and redeemable convertible preferred stock, voting together as a single class on an as-converted basis, were entitled to elect all remaining members of the board of directors, if any.

Redemption

The Company's redeemable convertible preferred stock was classified as temporary equity in the accompanying consolidated balance sheets in accordance with authoritative guidance for the classification and measurement of potentially redeemable securities whose redemption was based upon deemed liquidation events not solely within the Company's control, including a merger or consolidation, or, a sale or other disposition of all or substantially all of the Company's assets. The Company determined not to adjust the carrying values of the redeemable convertible preferred stock to the liquidation preferences of such shares because of the uncertainty of whether or when such events would occur.

12. Stockholders' Equity (Deficit)

As of December 31, 2025 the Company's certificate of incorporation authorized the Company to issue 300,000,000 shares of common stock, par value $0.0001 per share. As of December 31, 2024, Legacy Kalaris's certificate of incorporation authorized Legacy Kalaris to issue 86,000,000 shares of common stock, par value $0.00001 per share. The voting, dividend and liquidation rights of the holders of the Company's common stock are subject to and qualified by the rights, powers and preferences of the holders of preferred stock.

The holders of the Company's common stock are entitled to one vote for each share of common stock held on all matters submitted to a vote of the stockholders, and the holders of our common stock do not have any cumulative voting rights. The number of authorized shares of common stock may from time to time be increased or decreased (but not below the number of shares of such class outstanding) by the affirmative vote of the holders of a majority in voting power of the outstanding shares of capital stock of the Company.

2025 Private Placement

On December 17, 2025, the Company entered into a Securities Purchase Agreement (the "2025 Securities Purchase Agreement") with certain institutional investors (the "PIPE Investors") named therein. Pursuant to the 2025 Securities Purchase Agreement, the Company issued and sold to the PIPE Investors in a private placement (the "2025 Private Placement") an aggregate of (i) 4,200,000 shares of the Company's common stock at a purchase price of $10.00 per share, for aggregate gross processed of $42.0 million, and (ii) pre-funded warrants ("Pre-Funded Warrants") to purchase up to an aggregate of 800,000 shares of the Company's common stock at a purchase price of $9.9999 per Pre-Funded Warrant, which represents the per share purchase price of the Company's common stock less the $0.0001 per share exercise price for each Pre-Funded Warrant, for total aggregate proceeds of $8.0 million. The Pre-Funded Warrants are exercisable at any time after the date of issuance and will be exercisable until the Pre-Funded Warrant is exercised in full. The 2025 Private Placement closed on December 22, 2025, for aggregate gross proceeds of $50.0 million, before deducting placement agent fees and offering expenses of $3.4 million, for net proceeds of $46.6 million.

Under the terms of the Pre-Funded Warrants, the Company may not effect the exercise of any portion of such Pre-Funded Warrant, and a holder of will not be entitled to exercise any portion of such Pre-Funded Warrant, if, upon giving effect to such exercise, the holder, together with its affiliates, would beneficially own more than 4.99% or 9.99%, at the option of the holder, of the number of shares of common stock outstanding immediately after giving effect to such exercise. The holders of Pre-Funded Warrants may increase or decrease such percentage by providing at least 61 days' prior notice to the Company, provided that such percentage may in no event exceed 19.99%. The Pre-Funded Warrants are indexed to the Company's common stock and none of the provisions of the warrant would require a cash settlement. Therefore, the Pre-Funded Warrants were classified as a component of equity in the Company's consolidated balance sheet as they are freestanding financial instruments that are immediately exercisable, do not embody an obligation for the Company to repurchase its own shares and permit the holders to receive a fixed number of shares of common stock upon exercise. As of December 31, 2025, no Pre-Funded Warrants were exercised.

Common Stock

As of December 31, 2025 and 2024, shares of common stock reserved for future issuance were as follows:

	December 31, 2025	December 31, 2024
Redeemable convertible preferred stock, as converted	—	8,699,309
Outstanding stock option awards	2,142,278	1,144,690
Pre-funded warrants to purchase common stock	800,000	—
Shares available for future options grants under the Equity Plans	1,310,403	222,724
Shares available for grant under the 2020 ESPP	119,326	—
Total shares reserved for future issuance	4,372,007	10,066,723

13. Stock-Based Compensation

Equity Plans

At the closing of the Merger, the Company assumed the 2019 Plan.

In connection with the Merger, AlloVir's stockholders approved an amendment to AlloVir's 2020 Stock Option and Grant Plan (as amended, the "2020 Plan" and together with the 2019 Plan, the "Equity Plans") to increase the number of shares reserved for future issuance under the 2020 Plan, which is subject to an annual increase on January 1 of each year from 2026 and thereafter, such that the number of shares of common stock reserved and available for issuance under the 2020 Plan is cumulatively increased by 5% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, or such lesser number of shares as approved by the plan administrator; to establish the maximum aggregate number of shares of stock that may be issued in the form of incentive stock options ("ISOs") shall not exceed 15,250,000 and to extend the term of the 2020 Plan to the tenth anniversary of the closing of the Merger.

Under the Equity Plans, the Company may grant ISOs, nonqualified stock options ("NSO"), restricted stock awards ("RSAs"), restricted stock unit awards and other stock awards to the Company's employees, officers, non-employee directors, consultants, and advisors. Options to purchase common stock may be granted at a price not less than the fair market value as established by the board of directors in the case of both NSOs and ISOs. Stock option grants under the Equity Plans generally vest over four years. All options expire no later than ten years from the date of grant. The exercise price of ISOs granted to an employee who owns more than 10% of the voting power of all classes of stock of the Company shall be no less than 110% of the estimated fair market value of the underlying common stock on the grant date, and the contractual term is no longer than five years.

As of December 31, 2025, 1,588,703 shares of common stock had been authorized for issuance and 396,646 shares were available for future grants under the 2019 Plan and 2,269,474 shares of common stock had been authorized for issuance and 913,757 shares were available for future grants under the 2020 Plan.

Stock Options

The Company has granted stock options with service-based vesting conditions. Stock options typically vest over four years and have a maximum term of ten years. The Company typically grants stock options to employees and non-employees at exercise prices deemed to be equal to the fair value of the common stock at the time of grant.

The Black-Scholes-option pricing model, used to estimate the fair value of stock-based awards, requires the use of the following assumptions:

- *Fair Value of Common Stock.* Prior to the Merger, the fair market value of Legacy Kalaris' common stock was determined by the board of directors of Legacy Kalaris with assistance from management of Legacy Kalaris and external valuation experts. The approach to estimating the fair market value of common stock is consistent with the methods outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately- Held-Company Equity Securities Issued as Compensation* (the "Practice Aid"). After the closing of the Merger, the fair value of common stock is the Company's closing price per share on the Nasdaq Global Market on the grant date.
- *Expected Term.* The expected term of options granted represents the period of time that the options are expected to be outstanding. Due to the lack of historical exercise history, the expected term of the Company's employee and non-employee stock options has been determined by calculating the midpoint of the contractual term of the options and the weighted-average vesting period.
- *Expected Volatility*. The expected stock price volatility assumption was determined by examining the historical volatilities for comparable public companies, as the Company did not have any trading history for the common stock.
- *Risk-Free Interest Rate.* The risk-free interest rate assumption is based on the U.S. Treasury zero-coupon issued in effect at the time of grant for periods corresponding with the expected term of the option.
- *Dividends.* The Company has not paid any dividends on its common stock since inception and does not anticipate paying any dividends in the foreseeable future. Consequently, an expected dividend yield of zero was used.

The assumptions that the Company used in the Black-Scholes option-pricing model to determine the grant date fair value of stock options granted during the years ended December 31, 2025 and 2024 were as follows:

	Year Ended December 31,	
	2025	2024
Expected term (in years)	5.52-6.12	5.18 - 6.06
Expected volatility	98.69% - 100.96%	103.18% - 104.88%
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	3.66% - 4.09%	3.48% - 4.56%
Fair value of common stock range	$2.95-$5.88	$2.88-$11.29

A summary of option activity under the Equity Plans for the year ended December 31, 2025 is as follows:

	Outstanding Awards			
	Number of Shares Underlying Outstanding Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2024	1,144,690	$ 0.81		
Options granted	1,208,719	$ 6.51		
Options cancelled	(211,131)	$ 1.27		
Outstanding, December 31, 2025	2,142,278	$ 3.98	8.88	9,552
Shares exercisable December 31, 2025	611,902	$ 1.46	8.16	4,274
Vested and expected to vest, December 31, 2025	2,142,278	$ 3.98	8.88	9,552

Aggregate intrinsic value represents the difference between the fair value of the underlying common stock and the exercise price as of December 31, 2025. No options were exercised during the year ended December 31, 2025. The weighted-average fair value of options exercised during years ended December 31, 2025 and 2024 was immaterial. The aggregate intrinsic value of options exercised during the years ended December 31, 2025 and 2024 was immaterial.

The total fair value of options that vested during the years ended December 31, 2025 and 2024 was $1.4 million and $0.4 million, respectively. The weighted-average grant date fair value of options granted for the years ended December 31, 2025 and 2024 was $5.23 and $0.60 per option, respectively. As of December 31, 2025, the total unrecognized stock-based compensation expense was $6.2 million, which is expected to be recognized over a weighted-average period of 2.9 years.

RSAs

In February 2022, the Company issued RSAs to its former president for 203,670 shares and a consultant for 13,577 shares, in each case, at a purchase price of $0.005 per share under the 2019 Plan. The shares related to the former president’s award vest monthly over four years starting from January 2021, while the shares related to the consultant’s award vest monthly over six years starting from January 2020. If and when an RSA vests, the Company will issue one share of common stock for each whole RSA that has vested, subject to satisfaction of the employee's tax withholding obligations. The unvested RSAs are subject to the Company’s right of repurchase upon termination of services at a repurchase price equal to their original purchase price. Shares purchased pursuant to these awards participate in dividends and voting, are legally outstanding, and are presented as outstanding shares; however, for accounting purposes, shares purchased by employees pursuant to RSAs are not considered issued until they vest according to their respective vesting schedules. Unvested awards are excluded from the calculation of net loss attributable to common stockholders as these are considered contingently issuable shares and require services to be performed as these shares continue to vest. Proceeds received from the issuance of RSAs are recorded as a share repurchase liability within accrued expenses and other current liabilities on the consolidated balance sheet and reclassified to additional paid-in capital as such awards vest.

A summary of RSAs activity under the 2019 Plan for the year ended December 31, 2025 is as follows:

	Restricted Stock Awards	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2024	1,839	$ 1.71
Vested	(1,698)	1.74
Unvested as of December 31, 2025	141	$ 1.74

No RSAs were granted during the years ended December 31, 2025 and 2024. The total fair value of RSAs vested during the years ended December 31, 2025 and 2024 was immaterial. No RSAs were repurchased or cancelled during the years ended December 31, 2025 and 2024.

2020 Employee Stock Purchase Plan

The Company can issue common stock shares to its employees under the 2020 Employee Stock Purchase Plan (the "2020 ESPP"). The number of shares of common stock reserved and available for issuance under the 2020 ESPP is cumulatively increased on each January 1 by the lesser of (i) 53,161 shares of common stock, (ii) 1% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, and (iii) such number of shares of common stock as determined by the plan administrator. On December 31, 2025, there was an aggregate of 119,326 shares reserved for future issuance under the 2020 ESPP.

The ESPP allows eligible employees to authorize payroll deductions of up to 15% of their base salary or wages up to $25,000 annually to be applied toward the purchase of shares of the Company's common stock on the last trading day of the offering period. Participating employees will purchase shares of the Company's common stock at a discount of up to 15% on the lesser of the closing price of the Company's common stock on the Nasdaq Global Market (i) on the first trading day of the offering period or (ii) the last day of any offering period. The Company utilizes the Black Scholes option pricing model to compute the fair market value of the shares and stock-based compensation expense is recognized over the offering period. Six-month offering periods commence each January 1 and July 1 during the term of the plan, with the plan administrator having the right to establish different offering periods.

The Company did not issue shares of common stock under the 2020 ESPP during the year ended December 31, 2025.

Stock-Based Compensation Expense

Stock-based compensation expense included in the Company's consolidated statements of operations and comprehensive loss for the years ended December 31, 2025 and 2024 is as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development expenses	$ 530	$ 333
General and administrative expenses	1,406	562
Total stock-based compensation expense	$ 1,936	$ 895

14. Net Loss Per Share Attributable to Common Stockholders

Basic and diluted net loss per share attributable to common stockholders for the years ended December 31, 2025 and 2024 was calculated as follows (in thousands, except share and per share data):

	Year Ended December 31,	
	2025	2024
Numerator:		
Net loss attributable to common stockholders, basic and diluted	$ (43,438)	$ (69,167)
Denominator:		
Weighted average common shares outstanding	15,268,733	1,358,586
Less: Weighted-average common shares subject to repurchase	(916)	(22,661)
Weighted-average shares outstanding, basic and diluted	15,267,817	1,335,925
Net loss per share attributable to common stockholders, basic and diluted	$ (2.85)	$ (51.77)

As described in Note 12, the Pre-Funded Warrants to purchase up to an aggregate of 800,000 shares of the Company's common stock at a purchase price of $9.9999 per Pre-Funded Warrant were classified as a component of equity in the Company's consolidated balance sheet as they are freestanding financial instruments that are immediately exercisable, do not embody an obligation for the Company to repurchase its own shares and permit the holders to receive a fixed number of shares of common stock upon exercise. All of the shares underlying the Pre-Funded Warrants have been included in the weighted-average number of shares of common stock used to calculate basic and diluted net loss per common share for the year ended December 31, 2025, because the shares may be issued for little or no consideration, are fully vested, and are exercisable after the original issuance date of the Pre-Funded Warrants.

The potential shares of common stock were excluded from the computation of diluted net loss per share attributable to common stockholders as of December 31, 2025 and 2024 because including them would have had an anti-dilutive effect. The excluded shares were as follows:

	December 31,	
	2025	2024
Redeemable convertible preferred stock, as converted	—	8,699,309
Outstanding options to purchase common stock	2,142,278	1,144,690
Unvested restricted stock awards	141	1,839
2024 Note[1]	—	3,360,787
Total	2,142,419	13,206,625

[1] As of December 31, 2024, the conversion of the 2024 Note into common stock or redeemable convertible preferred stock was dependent on the price of shares that may be issued in connection with the 2024 Note Qualified Financing. The number of shares herein is calculated based on the conversion of the 2024 Note's outstanding principal and accrued and unpaid interest as of December 31, 2024 into the Company's preferred stock at the price of $6.20 per share.

15. Income Taxes

Loss before provision for income taxes for the years ended December 31, 2025 and 2024 consisted of the following (in thousands):

	Year Ended December 31,	
	2025	2024
Federal	$ (43,438)	$ (69,167)
Foreign	—	—
Loss before provision for income taxes	$ (43,438)	$ (69,167)

The provision for income taxes for the years ended December 31, 2025 and 2024 consisted of the following (in thousands):

	December 31,	
	2025	2024
Current income tax (benefit) expense:		
Federal	$ —	$ —
State	—	—
Foreign	—	—
Total current income tax benefit	—	—
Deferred income tax (benefit) expense:	—	—
Federal	—	—
State	—	—
Foreign	—	—
Total deferred income tax benefit	—	—
Total income tax expense (benefit):	$ —	$ —

The reconciliation of the effective tax rate for income taxes from the federal statutory rate for the years ended December 31, 2025 and 2024 was as follows (in thousands):

	Year Ended December 31,			
	2025		2024	
Income tax computed at federal statutory rate	$ (9,122)	21.0%	$ (14,525)	21.0%
State taxes	—	0.0%	—	0.0%
Tax credits - research and development tax credits	375	-0.9%	(378)	0.5%
Change in valuation allowance	8,545	-19.6%	11,642	-16.8%
Nontaxable or nondeductible items				
Loss on extinguishment and on issuance of convertible promissory notes	—	0.0%	3,571	-5.2%
Other	202	-0.5%	(310)	0.5%
Effective income tax rate	$ —	0.0%	$ —	0.0%

The Company's effective tax rate differs from the statutory rate primarily due to continued losses and the maintenance of a full valuation allowance on deferred tax assets, resulting in zero income tax expense for the period.

The following table presents significant components of the Company's deferred tax assets and liabilities as of December 31, 2025 and 2024 (in thousands):

	December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 24,990	$ 7,360
Capitalized R&D expenditures	24,869	5,115
Research credits	1,851	2,226
Accrued expenses and reserves	1,561	1,472
Other	—	3
R&D funding arrangement	9,037	7,291
Total deferred tax assets	62,308	23,467
Less valuation allowance	(62,308)	(23,467)
Net deferred tax assets	$ —	$ —

A valuation allowance is required to be established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain. The Company has reviewed its positive and negative evidence and has concluded that it is more likely than not that the net deferred tax assets will not be realized; therefore, the Company continues to maintain a valuation allowance. The valuation allowance increased by $13.5 million and $12.2 million during the years ended December 31, 2025 and 2024, respectively, primarily due to the generation of

net operating losses, and capitalized R&D expenditures. In addition, there was $25.3 million of change in valuation allowance as a result of purchase accounting adjustments related to the transaction, resulting in a total increase of $38.8 million for the year ended December 31, 2025.

The Company has net operating loss carryforwards for federal and state income tax purposes of $103.3 million and $46.8 million, respectively, as of December 31, 2025. The federal net operating loss carryforwards are not subject to expiration but are limited to 80% of the taxable income in the year the carryforward is used. State net operating loss carryforwards, if not utilized, will expire beginning in 2039.

As of December 31, 2025, the Company has federal and state research and development credit carryforwards of $1.7 million and $0.9 million, respectively. The federal credits will expire beginning in 2040 and the state credits will expire beginning in 2028.

Under Section 382 of the Tax Code, the ability to utilize net operating losses carryforwards or other tax attributes, such as research tax credits, in any taxable year may be limited if the Company has experienced an “ownership change.” Generally, Section 382 ownership change occurs if there is a cumulative increase of more than 50 percentage points in the stock ownership of one or more stockholders or groups of stockholders who own at least 5% of a corporation’s stock within a specified testing period. Similar rules may apply under state tax laws. The Company has completed the Section 382 analysis from inception through the year ended December 31, 2024. The Company experienced an ownership change in March 2022 related to the redeemable convertible preferred stock financing. Net operating loss of $3.6 million generated prior to the 2022 change in ownership will be permanently limited for California tax purposes. Net federal operating losses are not limited as they can be carried forward indefinitely. The Company has not performed a Section 382 study as of the year ended December 31, 2025. During this time, the Company may experience ownership changes as a result of future financing or other changes in stock ownership.

For tax years beginning after December 31, 2024, the One Big Beautiful Bill Act (“OBBBA”) enacted a new rule under Section 174A allowing companies to immediately expense any domestic research and developmental (“R&D”) expenditures. For domestic R&D, companies may either immediately expense or elect to capitalize and amortize over at least 60 months under Section 174A. However, foreign R&D continues to require capitalization subject to the mandatory 15-year amortization period under Section 174. The Company has elected to continue amortizing the previously capitalized costs over their remaining life and will immediately expense any domestic R&D expenditures. Any foreign R&D costs will continue to be capitalized and amortized over 15 years in accordance with the requirements of Section 174.

The Company provides for U.S. federal, state, and applicable foreign income and withholding taxes on the financial reporting basis over the tax basis of its foreign subsidiary investment because the Company does not have the intentions and ability to indefinitely reinvest the undistributed earnings of its foreign subsidiaries. As a result, deferred taxes have not been recorded for the outside basis differences in its foreign subsidiary as of December 31, 2025 to the extent such differences are expected to result in future taxable income upon repatriation. The Company reviews its ability and intentions to indefinitely reinvest its foreign earnings at each balance sheet.

The following summarizes the Company's income taxes paid (net of refunds received) for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Federal	$ —	$ —
State	—	—
Foreign	—	—
Total	$ —	$ —

Uncertain Tax Positions

A reconciliation of the beginning and ending balances of the unrecognized tax benefits during the years ended December 31, 2025 and 2024, is as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Beginning Balance	$ 680	$ 514
Increase (decrease) based on current year tax positions	—	166
Increase (decrease) for prior year tax positions	(125)	—
Ending Balance	$ 555	$ 680

The entire amount of the unrecognized tax benefits would not impact on the Company's effective tax rate if recognized, due to the valuation allowance. The Company has elected to include interest and penalties as a component of tax expense. During the years ended December 31, 2025 and 2024, the Company did not recognize accrued interest and penalties related to unrecognized tax benefits.

The Company files tax returns in the U.S. and other various states where it has activity. The Company is currently not under examination in any of these jurisdictions and all its tax years remain effectively open to examination due to net operating loss carryforwards.

16. Related Parties

Samsara BioCapital L.P. and Affiliates

Since the Company's inception, Samsara has provided in-kind research and development and general and administrative services to the Company. From April 2022, Samsara also began to provide general and administrative services for cash consideration related to (i) accounting and controllership, (ii) human resources, and (iii) executive assistance. In July 2023, the Company and Samsara entered into a Business Services Agreement (the "BSA") that governs the provision of such services. The BSA has a term of five years and may be terminated upon 15 days written notice by either party.

The Company recognized $0.3 million and $0.2 million for the years ended December 31, 2025 and 2024, respectively, as general and administrative expenses, related to the services provided by Samsara under the BSA. The Company recognized immaterial amounts for the years ended December 31, 2025 and 2024, as research and development expenses, related to the services provided by Samsara under the BSA.

In-kind services of $0.1 million were estimated at fair value and recognized as capital contributions to additional paid-in capital for the year ended December 31, 2024. Samsara stopped providing in-kind services in July 2024.

As of December 31, 2025 and 2024, the Company recognized $0.1 million and $0.1 million in accrued expenses and other current liabilities in the consolidated balance sheets related to the services provided by Samsara under the BSA. As of December 31, 2025 and 2024, the Company recognized immaterial amounts in accounts payable in the consolidated balance sheets related to the services provided by Samsara under the BSA. The Company recognized a $32.1 million royalty obligation - related party, as a long-term liability, under the Royalty Agreement as of December 31, 2025 and 2024.

The Company issued Samsara convertible promissory notes (Note 8), redeemable convertible preferred stock and common stock. In July 2024, the Company entered into a Royalty Agreement with Samsara (Note 7).

Members of the Company's management and board of directors received $0.1 million and $0.1 million in consulting fees for each of the years ended December 31, 2025 and 2024.

17. Defined Contribution plan

The Company sponsors a 401(k) plan (the "401(k) Plan"), which is designed to be qualified under Section 401(k) of the Internal Revenue Code of 1986, as amended. Eligible employees can elect to contribute to the 401(k) Plan, subject to certain limitations on eligible compensation. The Company may match employee contributions in amounts to be determined at the Company's sole discretion. The Company's matching contributions during each of the years ended December 31, 2025 and 2024 were immaterial.

18. Segment Reporting

The Company operates and manages its business as one reportable and operating segment. The CODM regularly reviews and evaluates net loss, as reported in the consolidated statements of operations and comprehensive loss, for purposes of assessing performance, making operating decisions, allocating resources, and planning and forecasting for future periods on an aggregate basis. The CODM does not review assets at a different level or category than the amounts disclosed in the consolidated balance sheets as total assets. All of the Company's long-lived assets are located in the United States.

The following is the Company's summary of segment loss, including significant segment expenses for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
External research and development expenses:		
CDMO, CRO and other third-party preclinical studies, clinical trials and consulting costs	$ 25,108	$ 10,324
License fees, milestone payments, and annual maintenance fees related to acquired technologies	10	32,099
Internal research and development personnel expenses	5,244	2,490
Other research and development costs	391	129
General and administrative personnel expenses	4,447	1,940
Other general and administrative expenses	10,952	4,750
Interest expense	1,443	2,701
Other segment items[1]	(4,157)	14,734
Net loss	$ (43,438)	$ (69,167)

[1] *Other segment items include change in fair value of tranche liability, change in fair value of derivative liabilities, loss on extinguishment and on issuance of convertible promissory notes and other income, net.*

BOARD OF DIRECTORS

Andrew Oxtoby
President, Chief Executive Officer and Director

David Hallal
Board Chairman
Chairman & CEO, Scholar Rock
Executive Chairman, ElevateBio

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Ex-Global Head of Ophthalmology, Immunology and Infectious Disease, Genentech / Roche; Co-founder and Former CSO of Eyetech

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Founder and Managing General Partner, Samsara

Michael Dybbs, Ph.D.
Partner, Samsara

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Distinguished Professor of Ophthalmology and Pathology, UC San Diego School of Medicine

Morana Jovan-Embiricos, Ph.D.
Managing Partner, F2 Ventures

Leone Patterson
Former Executive Vice President, Chief Business Officer, and Chief Financial Officer, Zymeworks

EXECUTIVE OFFICERS AND KEY EMPLOYEES

Andrew Oxtoby
President, Chief Executive Officer and Director

Matthew Feinsod, M.D.
Chief Medical Officer

Brett Hagen
Chief Accounting Officer

CORPORATE HEADQUARTERS

400 Connell Drive, Suite 5500
Berkeley Heights, NJ 07922

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Deloitte & Touche LLP
San Francisco, CA

TRANSFER AGENT

Computershare Trust Company, N.A.
Attn: Kalaris Therapeutics, Inc.
150 Royall Street
Canton, MA 02021

INVESTOR RELATIONS

ir@kalaristx.com

ANNUAL MEETING

Our 2026 Annual Meeting of Stockholders will be held exclusively via the Internet in a virtual meeting format at www.proxydocs.com/KLRS on Wednesday, June 3, 2026 at 11:30 a.m. Eastern Time.