UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023

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 001-4078

ELIEM THERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**83-2273741**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
PMB #117 **2801 Centerville Road 1st Floor** **Wilmington, DE**	**19808-1609**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: 1-877-ELIEMTX (354-3689)

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

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

As of June 30, 2023, the market value of voting stock held by non-affiliates of the Registrant was $13.2 million. The calculation of the aggregate market value of voting and non-voting stock excludes certain shares of the Registrant's common stock held by current executive officers, directors and stockholders that the Registrant has concluded are affiliates of the Registrant. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the Registrant or that such person is controlled by or under common control with the Registrant.

As of March 22, 2024, the registrant had 27,719,409 shares of common stock, $0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2024 Annual Meeting of Stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2023, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and the information incorporated herein by reference contain forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future results of operations, financial condition, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as "may," "might," "will," "should," "expect," "plan," "anticipate," "project," "believe," "estimate," "predict," "potential," "intend" or "continue," the negative of these words or other similar terms or expressions. Forward-looking statements in this Annual Report on Form 10-K include, but are not limited to, statements about:

- our plans and expectations regarding our exploration of strategic alternatives focused on maximizing shareholder value, including whether or not such process will result in a strategic transaction on terms satisfactory to us, or other alternatives which increase shareholder value;
- the success, cost and timing of any future product development activities, preclinical studies and clinical trials;
- costs associated with any restructuring activities, as well as any savings benefits we may expect to receive from any restructuring;
- our ability to obtain and maintain regulatory approval of any product candidates we may develop;
- our ability to successfully commercialize any of our products that are approved;
- the rate and degree of market acceptance of our products;
- the size and growth potential of the markets for our product candidates, if approved for commercial use, and our ability to serve those markets;
- our estimates of our expenses, ongoing losses, future revenues, capital requirements and our needs for or ability to obtain additional financing;
- the sufficiency of our capital resources to fund operations for the time periods referenced;
- our ability to obtain and maintain intellectual property protection for our products and product candidates;
- the ability to scale up manufacturing of our product candidates to commercial scale;
- our ability to successfully establish and successfully maintain appropriate collaborations;
- our reliance on third parties to conduct any future clinical trials;
- our reliance on third-party contract manufacturers to manufacture and supply any product candidates we may develop;
- our ability to identify and develop new products and product candidates;
- our ability to enroll patients in any future clinical trials at the pace that we project;
- our ability to obtain funding for our operations, including funding necessary for any future development and commercialization our product candidates;
- our financial performance; and
- developments and projections relating to our competitors or our industry.

You should refer to the section of this Annual Report on Form 10-K titled "Risk Factors" for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. New risk factors may emerge from time to time and it is not possible for our management to predict all risk factors, nor can we 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, or implied by, any forward-looking statements.

You should not rely on forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Annual Report on Form 10-K primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. We undertake no obligation to update any forward-looking statements made in this Annual Report on Form 10-K to reflect events or circumstances after the date of this Annual Report on Form 10-K or to reflect new information or the occurrence of unanticipated events, except as required by law. 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. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments.

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

You should read this Annual Report on Form 10-K with the understanding that our actual future results, levels of activity, performance and achievements may be different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

Risk Factor Summary

Our business is subject to numerous risks and uncertainties. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" under Part I, Item 1A of this Annual Report. These risks include, but are not limited to, the following:

- We may not be successful in identifying and implementing a strategic alternative which increases shareholder value, including any strategic transaction, and any strategic transactions that we may consummate in the future may not be successful. If we are able to complete any such transaction, or if we pursue another strategic alternative, it may not result in additional value to stockholders and may present additional challenges. We may also elect to pursue a dissolution and liquidation of our company instead of a strategic transaction, which may impact the timing and amount of payments to our stockholders.
- We have incurred significant losses since our inception, anticipate that we will incur substantial losses for the foreseeable future, and may never achieve or maintain profitability.
- If we are unable to access capital when needed, it could force us to delay, reduce or terminate our product development programs, commercialization efforts, or other operations.
- We currently have no source of product revenue, and we may never become profitable.
- Our future success is dependent primarily on regulatory approval and commercialization of our future product candidates.
- Even if our future product candidates receive regulatory approval, they may still face future development and regulatory difficulties.
- Preclinical and clinical development involves a lengthy, complex and expensive process with an uncertain outcome. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of any future clinical trials may not satisfy the requirements of the Food and Drug Administration (FDA) or comparable foreign regulatory authorities.
- We have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our products that receive regulatory approval on our own or together with collaborators.
- We face significant competition from other pharmaceutical and biotechnology companies and other research organizations and our operating results will suffer if we fail to compete effectively.
- We rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.
- If we are unable to obtain, maintain and protect sufficient patent and other intellectual property rights for our product candidates and technology, or if the scope of patent and other intellectual property rights obtained is not sufficiently broad, we may not be able to compete effectively in our market.
- We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

PART I

Item 1. Business

Company Overview

We are a biotechnology company focused on developing novel therapies for neuronal excitability disorders to address unmet needs in psychiatry, epilepsy, chronic pain, and other disorders of the peripheral and central nervous systems. These disorders often occur when neurons are overly excited or inhibited, leading to an imbalance, and our focus is on restoring homeostasis. We are focused on developing clinically differentiated product candidates focused on validated mechanisms of action with broad therapeutic potential to deliver improved therapeutics for patients with these disorders.

In February 2023, due to a challenging capital environment and investor sentiment around the $GABA_A$ PAM opportunity in Major Depressive Disorder (MDD), we paused further investment in the development of our clinical-stage program, ETX-155. Additionally, on February 7, 2023, our board of directors approved a restructuring plan (the Restructuring Plan) to conserve financial resources and better align our workforce with current business needs, as a result of the decision to pause development of ETX-155 and focus on our preclinical Kv7.2/3 program. As part of the Restructuring Plan, our workforce was reduced by approximately 55%.

In July 2023, we made the determination to pause further development of our Kv7 program and to conduct a comprehensive exploration of strategic alternatives focused on maximizing stockholder value. As part of that effort, we are exploring a variety of options, including seeking a partner for further development of both Kv7 and ETX-155. We engaged Leerink Partners LLC to act as a financial advisor in this process. We also formed a special committee of independent and disinterested directors (the Special Committee) to oversee our exploration of strategic alternatives.

As a part of this process, our representatives and a development stage private biotechnology company (who we refer to as Tango) that is majority-owned by funds affiliated with RA Capital Management, L.P. (RA Capital) have recently engaged in preliminary discussions in an effort to determine whether a potential transaction between the two companies could be mutually beneficial. On March 14, 2024, Tango submitted a summary of proposed terms (the Non-Binding Term Sheet), which contemplates that we would acquire Tango through a transaction whereby we would issue common stock to Tango's equityholders in exchange for all of the outstanding equity of Tango, and Tango would become our wholly owned subsidiary (the Proposed Transaction). As of March 14, 2024, entities affiliated with RA Capital beneficially owned approximately 47.5% of our outstanding common stock.

The terms of the Non-Binding Term Sheet include, without limitation:

- The proposed exchange ratio would value our company initially at $110 million as of the closing of the Proposed Transaction, while Tango would initially be valued at $20 million;
- In connection with the closing of the Proposed Transaction, a concurrent private placement of our common stock would be effected at or as of immediately after the closing pursuant to binding subscription agreements to be entered into concurrently with the execution of a definitive agreement with respect to the Proposed Transaction (the Concurrent Investment), in an aggregate amount to be mutually determined by the parties. We currently anticipate that funds affiliated with RA Capital would purchase some portion of the securities to be issued in the Concurrent Investment;
- That after giving effect to the closing of the Proposed Transaction (but before giving effect to the Concurrent Investment), (i) the equityholders of Tango immediately prior to the closing (including all options, convertible securities and warrants) would own 15.4% of the equity of our company on a fully diluted basis and (ii) our equityholders (including all outstanding equity awards) would own 84.6% of the equity of our company on a fully diluted basis (calculated via the treasury stock method); and
- The post-closing board of directors of our company would consist of seven directors, the composition of which would satisfy applicable U.S. Securities and Exchange Commission (SEC) and Nasdaq listing requirements, and that the specific composition of the board of directors would be determined by the parties during negotiation of a definitive agreement.

The Non-Binding Term Sheet is non-binding, and there can be no assurance that any definitive agreement will result from the Non-Binding Term Sheet or that any transaction with Tango or any other third party will be consummated. The Non-Binding Term Sheet, and the Proposed Transaction contemplated thereby, are subject to various conditions, including but not limited to, (i) the satisfactory completion of due diligence by both parties, (ii) the negotiation and execution of a definitive agreement and the satisfaction of the conditions negotiated therein, (iii) the approval and recommendation of the Proposed Transaction by the Special Committee, and (iv) a non-waivable condition requiring approval of our stockholders holding a majority of the voting power of the outstanding shares of our company not held by RA Capital or its affiliates. As the parties continue to negotiate the terms of the Proposed Transaction, it is possible that, through these negotiations, the proposed terms of the Proposed Transaction may change, including as a result of the ongoing diligence efforts of both parties, market conditions and other factors. There can be no guarantee that the parties will ever reach a definitive agreement with respect to the Proposed Transaction and either party may determine to abandon the Proposed Transaction at any time for any reason, including the parties' respective beliefs regarding the preferability of the Proposed Transaction to other alternatives that may be available to them, as well as other factors.

There can be no assurance that this strategic review process will result in us continuing to pursue any transaction, including the Proposed Transaction, or that any transaction, if pursued, will be completed on attractive terms or at all. We have not set a timetable for completion of this strategic review process, and our board of directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value or that we will make any additional cash distributions to our stockholders.

Kv7.2/3 Program to Date

Our lead program was a preclinical, next-generation Kv7.2/3 channel opener that was being developed for potential use in multiple neuronal excitability conditions including epilepsy, pain, depression, and others. Kv7.2/3 is a heteromeric voltage-gated potassium channel comprised of Kv7.2 and Kv7.3 subunits (Kv7.2/3) that plays an important role in controlling neuronal excitability by stabilizing the membrane potential and inhibiting action potential firing of neuronal cells. Kv7.2/3 has genetic validation as a target for epilepsy, as loss-of-function mutations in the genes encoding for Kv7.2 and Kv7.3, KCNQ2 and KCNQ3, have been shown to be responsible for a rare epilepsy disorder in newborns that is characterized by impaired gating of the Kv7.2/3 channel and hyperexcitation of neurons.

In addition to its genetic validation, Kv7.2/3 has been clinically validated as a therapeutic target for both epilepsy and pain. The first generation Kv7 channel opener, ezogabine (Potiga), was approved for refractory focal onset seizures in 2011 in both the United States and in Europe (where it was known as retigabine, or Trobalt). Flupirtine (Katadolon), a close analogue of ezogabine/retigabine, was another first generation Kv7.2/3 opener that provided clinical validation of the Kv7 mechanism and has been used in Europe as a treatment for pain since the 1980s. Despite demonstrating compelling efficacy in epilepsy and pain, ezogabine/retigabine and flupirtine were removed from the market in 2017 and 2018, respectively, due to emergent unexpected safety concerns. In the case of ezogabine, an accumulation of blue pigment in the skin and eye was identified, raising concerns of potential vision loss, while flupirtine was associated with severe liver toxicity, including cases of acute liver failure. With both of these first generation Kv7 openers, the safety concerns have been hypothesized to be driven by the chemistry of the molecules, rather than being target-related adverse effects. Xenon Pharmaceuticals has initiated a Phase 3 epilepsy (focal onset seizures) program that includes two Phase 3 clinical trials for its Kv7 targeted agent, XEN1101, an analogue of retigabine, following positive data reported in a Phase 2b study in focal onset seizures in October 2021, providing further clinical validation for this mechanism. XEN1101 is also being evaluated in a Phase 2 clinical trial in patients with MDD.

We used a combination of both ligand-based and structure-based design approaches to develop novel Kv7.2/3 opener compounds that potentially eliminate the toxicity liabilities associated with the first generation Kv7.2/3 openers, while retaining strong activity and selectivity. We designed several lead series based on novel chemistry and selected a lead clinical candidate, ETX-123. The ETX-123 molecule displays potent activation of Kv7.2/3 in vitro with an approximately 0.7 nM EC50, and about 14,000-fold selectivity for Kv7.2/3 subtypes over the Kv7.4 subtype that is predominantly expressed in bladder smooth muscle and cardiac muscle. In addition, in vitro studies of ETX-123 have demonstrated no genotoxicity risk and no significant off-target effects, including no activity at $GABA_A$ receptors which has been previously described for ezogabine/retigabine. We believe the ETX-123 program has the potential to be highly differentiated from previously approved Kv7 openers as well as other Kv7 openers in development, with its novel chemical composition, high potency combined with high selectivity, lack of off-target activity, and reduced potential for metabolic safety liabilities.

Initial preclinical in vivo data for the ETX-123 molecule is provided in Figure 1.

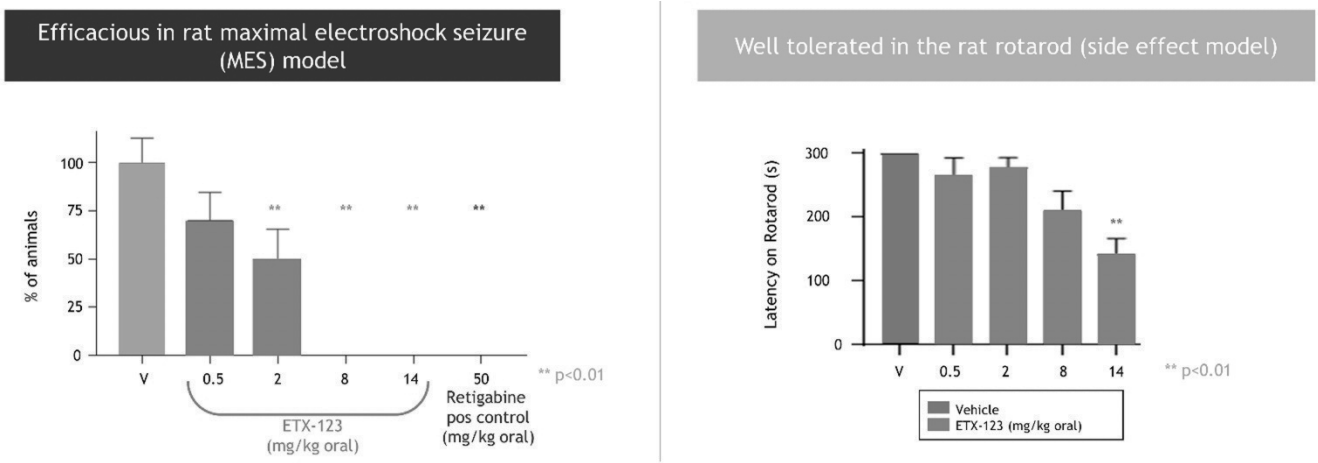

Figure 1. Initial ETX-123 preclinical in vivo data demonstrates a 7-fold separation between the dose that inhibits tonic convulsions in the rat MES model (2 mg/kg) and the dose that induces CNS side effects in the rat rotarod model (14 mg/kg).

ETX-123 was being advanced into toxicology studies in 2023, and we were planning to progress into Phase 1 studies in the first half of 2024. In addition to ETX-123, we were exploring several other members of this chemical series to identify potential backup Kv7 candidates which may be developed in the same or different indications as ETX-123. However, in July 2023, we made the determination to pause further development of our Kv7 program.

ETX-155 Program to Date

Our clinical-stage program, ETX-155, is an investigational, oral, neuroactive steroid NCE that is designed to act as a positive allosteric modulator (PAM) of the $GABA_A$ receptor ($GABA_AR$). The $GABA_A$ PAM neuroactive steroid class has been clinically validated in depression and epilepsy, with Sage Therapeutics receiving approval from the United States (U.S.) FDA for the neuroactive steroid, zuranolone (ZURZUVAE®), for the treatment of postpartum depression (PPD) following successful Phase 3 trials, and Marinus Therapeutics receiving approval from the U.S. FDA for its neuroactive steroid, ganaxolone (ZTALMY®) in cyclin-dependent kinase-like 5 deficiency disorder (CDD), a rare pediatric seizure disorder.

ETX-155 was designed to have dual potency at both synaptic and extrasynaptic $GABA_A$ receptors. ETX-155 has also shown differentiated pharmacokinetic properties relative to other neuroactive steroids, including no clinically meaningful food effect, an approximate 40-hour half-life to enable once-a-day dosing, and higher exposures than zuranolone at the 60-milligram dose that had been planned for Phase 2a. Results from our 7-day and 14-day Phase 1 repeat dose clinical trials demonstrated favorable tolerability data at exposure levels that are consistent with dosing levels that achieved robust activity in preclinical models of depression, anxiety and epilepsy. However, in February 2023, we paused further investment in the development of ETX-155.

Based on our preclinical and clinical work to date, ETX-155 has the potential to be pursued in clinical development in MDD, with indication expansion opportunities in epilepsy and anxiety disorders. We have received clearance of our investigational new drug (IND) application filed with the psychiatry division of the FDA to support a potential Phase 2 clinical trial in MDD that may be conducted in the future by Eliem or a strategic partner.

Competition

The biotechnology industry is characterized by rapid technological advancement, significant competition and an emphasis on intellectual property. We face potential competition from many different sources, including major and specialty pharmaceutical, biopharmaceutical, therapeutics and biotechnology companies, academic research institutions, governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with current therapies and new therapies that may become available in the future. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective or more convenient or have fewer or less severe side effects than any products that we may develop. Our competitors also may obtain FDA, European Medicines Agency (EMA) or other regulatory approval for their products more rapidly than we do. We believe that the key competitive factors affecting the success of any of our product candidates will include efficacy, safety profile, convenience, cost, the level of branded and generic competition, market access and reimbursement by payors, level of promotional activity devoted to them and intellectual property protection.

For the treatment of epilepsy, we may face competition from a variety of currently marketed therapies such as generic anticonvulsants, sodium channel modulators and benzodiazepines. Additionally, there are next-generation therapies in development harnessing the previously mentioned mechanisms of action, such as XEN901 being co-developed by Xenon Pharmaceuticals and Neurocrine Biosciences. Furthermore, there are multiple compounds that have been recently approved or are in late-stage development for focal onset seizures, including cenobamate (XCOPRI®), which was developed by SK Life Sciences and was approved by the FDA in November 2019, the Kv7.2/3 openers XEN1101, currently in Phase 3 for focal onset seizures, being developed by Xenon Pharmaceuticals, and BHV-7000, currently in Phase 2, being developed by Biohaven.

We expect to face competition from existing products and products in development. In addition to those described above, there may be other earlier stage clinical programs that, if approved, would compete with our product candidates. Many of our competitors have substantially greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances made in the commercial applicability of technologies and greater availability of capital for investment in these fields. Our success will be based in part on our ability to build and actively manage a portfolio of drugs that addresses unmet medical needs and creates value in patient therapy.

Intellectual Property

Our commercial success will depend in part on our ability to obtain and maintain proprietary protection for our product candidates and any associated novel discoveries, drug development technologies and know-how; to operate without infringing on or otherwise violating the proprietary rights of others; and to prevent others from infringing or otherwise violating our proprietary rights. Our policy is to seek to protect our proprietary position for our product candidates by, among other methods, filing and acquiring U.S. and foreign patents and patent applications related to our products and other proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position.

Our intellectual property estate is designed to provide multiple layers of protection, including: (1) patents and patent applications with claims directed to our product candidates; (2) patent applications with claims directed to methods of treatment using our product candidates; and (3) patent applications with claims directed to innovative formulations.

While we seek to cover our product candidates and their use in our issued patents and pending patent applications, there is always a risk that a modification of the product or its use may allow a competitor to avoid infringement claims. In addition, patents, if granted, expire, and we cannot provide any assurance that any patents will be issued from our pending or any future applications or that any issued patents will adequately protect our products.

Kv7 Program. For our Kv7 program, we have a pending patent application under the Patent Cooperation Treaty (PCT) which includes claims directed to compositions, methods of use, and manufacturing processes for ETX-123 and related compounds.

ETX-155. Our intellectual property portfolio covering ETX-155 includes three issued U.S. patents: a first with method claims covering use of the composition of matter to treat an anxiety disorder, depression, or a seizure disorder; a second with composition claims covering a controlled release formulation of ETX-155; and a third with method claims covering the use of the composition of matter to treat sleep disorders. A continuation application in this family is pending with method claims covering the use of the composition of matter to treat a $GABA_A$ disorder. The first two issued U.S. patents in this family and any future patents claiming priority thereto are expected to expire in September 2039, excluding any patent term extensions or adjustments that may be granted. The third issued U.S. patent in this family, with method claims covering the use of the composition of matter to treat sleep disorders, is expected to expire in early 2040. The portfolio additionally includes: pending U.S. and European Patent Office (EPO) applications with method claims covering use of the composition of matter to treat a female health condition, which claim priority to an international patent application under the PCT, and are expected to expire in June 2041; pending U.S. and EPO applications with method claims covering the use of the composition of matter to treat a central nervous system related disorder, which claim priority to a PCT application, and are expected to expire in September 2041; and pending U.S. and EPO applications with method claims covering use of the composition of matter to treat fibromyalgia, which claim priority to a PCT application, and are expected to also expire in September 2041. The portfolio also includes two unpublished U.S. non-provisional applications and two U.S. provisional applications covering methods of treatment and formulations of ETX-155.

Patent Protection and Terms

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued from regularly filed applications in the United States are granted a term of 20 years from the earliest effective filing date. In addition, in certain instances, a patent term can be adjusted to recapture a portion of the United States Patent and Trademark Office (USPTO), delay in issuing the patent, and extended to recapture a portion of the patent term effectively lost as a result of the FDA regulatory review period of the drug covered by the patent. However, as to the FDA component, the restoration period cannot be longer than five years, the total patent term including the restoration period must not exceed 14 years following FDA approval of the drug, and the extension may only apply to one patent that covers the approved drug (and to only those patent claims covering the approved drug, a method for using it, or a method for manufacturing it). There can be no assurance that any such patent term adjustment or extension will be obtained. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Furthermore, the patent positions of biotechnology and pharmaceutical products and processes like those we may develop and commercialize are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in such patents has emerged to date in the United States. The patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries can diminish our ability to protect our inventions and enforce our intellectual property rights, can make it easier to challenge the validity, enforceability or scope of any patents that may issue, and, more generally, could affect the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

Third-Party Patent Filings

Numerous U.S. and foreign issued patents and patent applications owned by third parties exist in the fields in which we are developing products. In addition, because patent applications can take many years to issue, there may be applications unknown to us, which may later result in issued patents that our products or proprietary technologies may infringe. Moreover, we may be aware of patent applications, but incorrectly predict the likelihood of those applications issuing with claims of relevance to us.

Under U.S. law, a person may be able to patent a discovery of a new way to use a previously known compound, even if such compound itself is patented, provided the newly discovered use is novel and non-obvious. Such a method-of-use patent, however, if valid, only protects the use of a claimed compound for the specified methods claimed in the patent. This type of patent does not prevent persons from using the compound for any previously known use of the compound. Further, this type of patent does not prevent persons from making and marketing the compound for an indication that is outside the scope of the patented method.

Trade Secrets and Other Protections

In addition to the protections afforded by patents and other regulatory protections, we may rely, in some circumstances, on trade secrets to protect our technology. Trade secrets may be useful to protect proprietary know-how that is not patentable or which we elect not to patent. Trade secrets may also be useful for processes or improvements for which patents are difficult to enforce. We also protect our products and proprietary technology through confidentiality agreements with employees, consultants, advisors, contractors and collaborators. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Infringement of Third-Party Proprietary Rights

Our commercial success will depend in part on not infringing upon or otherwise violating the intellectual property and proprietary rights of third parties. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue any future development and marketing of our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could also be forced, including by court order, to cease commercializing the infringing product or technology. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our products or force us to cease some of our business operations. For more information regarding these risks, see the section titled "Risk Factors—Risks Related to Intellectual Property."

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently source all of our nonclinical and clinical compound supply through third-party contract development and manufacturing organizations (CDMOs).

For clinical supply, we have used CDMOs who are obligated to act in accordance with the FDA's current Good Manufacturing Practices (cGMPs), for the manufacture of drug substance and product. To the extent we continue to pursue development of any future product candidate, we expect to rely on third parties for our manufacturing processes and the production of all clinical supply drug substance and drug product and currently expect to continue to do so for commercial supplies for any approved product candidates. We have used additional contract manufacturers to fill, label, package, store and distribute our investigational drug products and currently expect to continue to do so for commercial supplies for any product candidates we may develop, if approved. It is our intent to identify and qualify additional manufacturers to provide active pharmaceutical ingredient and fill-and-finish services prior to submission of an NDA to the FDA for any product candidates that we may develop and complete clinical development.

Government Regulation

The FDA and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements upon companies involved in the clinical development, manufacture, marketing and distribution of prescription drugs, such as those we are developing. These agencies and other federal, state and local entities regulate, among other things, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, distribution, post-approval monitoring and reporting, sampling and export and import of drug products and product candidates. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

U.S. Government Regulation of Drug Products

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act (FDCA) and its implementing regulations. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties brought by the FDA and the Department of Justice (DOJ) or other governmental entities.

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

Completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice (GLP) regulations;

- Submission to the FDA of an IND which must become effective before human clinical trials may begin;
- Approval by an independent institutional review board (IRB) at each clinical site before each trial may be initiated;
- Performance of adequate and well-controlled human clinical trials in accordance with good clinical practice (GCP), requirements to establish the safety and efficacy of the proposed drug product for each indication;
- Submission to the FDA of an NDA;
- Satisfactory completion of an FDA advisory committee review, if applicable;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- Satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- Payment of user fees and securing FDA approval of the NDA, including agreement to compliance with any post-approval requirements; and
- Compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy (REMS), and the potential requirement to conduct post-approval studies.

Preclinical studies

Before testing any drug or biological product candidate, including our product candidates, in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies generally include laboratory evaluation of product chemistry, formulation and stability, as well as animal studies to assess potential toxicity, which support subsequent clinical testing. Prior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. Some preclinical testing may continue even after the IND is submitted. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it initiates at that institution. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health (NIH) for public dissemination on their www.clinicaltrials.gov website. 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. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in some cases for up to two years after the date of completion of the trial.

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

- Phase 1: The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.
- Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA.

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

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points are generally prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor to obtain the FDA's feedback on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the drug or biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidates do not undergo unacceptable deterioration over their shelf life.

Marketing application submission and FDA review and approval

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. Data may come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA. In most cases, the submission of an NDA is subject to a substantial application user fee; a waiver of such fees may be obtained under certain limited circumstances. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act (PDUFA), the FDA has ten months from the date of "filing" of a standard NDA for a new molecular entity in which to complete its initial review and respond to the applicant, and six months from the filing date for priority applications.

The FDA does not always meet its PDUFA goal dates, and the review process can be extended by FDA requests for additional information or clarification and a sponsor's process to respond to such inquiries. This FDA review typically takes twelve months from the date the NDA is submitted to FDA (for a standard review) because the FDA has approximately two months, or 60 days, after submission to make a "filing" decision on whether to accept an NDA for review.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review and informs the sponsor by the 74th day after the FDA's receipt of the submission whether an application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

Additionally, the FDA may refer any application to an advisory committee, including applications for novel drug candidates that present difficult questions of safety or efficacy. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which 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 also may require submission of a risk evaluation and mitigation strategy, or REMS, plan, if it determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks and to assure the safe use of the drug product. The REMS plan could include medication guides, physician communication plans, assessment plans and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS plan is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without a REMS, if required.

In addition, under the Pediatric Research Equity Act of 2003, as amended and reauthorized (PREA), certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug 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. The FDA may, on its own initiative or at the request of the applicant, 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.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue either an approval letter or a complete response letter (CRL). An approval letter authorizes commercial marketing of the drug with specific prescribing information and for specific indications. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the submission and contains a statement of specific conditions that must be met in order to secure final approval of the NDA; it may require additional clinical or preclinical testing and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing in order for FDA to reconsider the application. If a CRL is issued, the applicant may choose to either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. If and when those deficiencies have been addressed to the FDA's satisfaction, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some 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. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

Fast track, breakthrough therapy and priority review designations

The FDA is authorized to designate certain products for expedited development or review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast-track designation, breakthrough-therapy designation and priority-review designation.

To be eligible for a fast-track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for the condition. Fast track designation provides opportunities for more frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the NDA for a fast-track product on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable and the sponsor pays any required user fees upon submission of the first section of the application. The sponsor can request the FDA to designate the product for fast-track status any time before receiving NDA approval, but ideally no later than the pre-NDA meeting. Fast track designation may be withdrawn by the sponsor or rescinded by the FDA if the designation is no longer supported by data emerging in the clinical trial process.

In addition, with the enactment of the Food and Drug Administration Safety and Innovation Act (FDASIA) in 2012, Congress created a new regulatory program for product candidates designated by FDA as "breakthrough therapies" upon a request made by IND sponsors. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment. Breakthrough therapy designation comes with all of the benefits of fast-track designation, which means that the sponsor may file sections of the NDA for review on a rolling basis if certain conditions are satisfied, including an agreement with the FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review. Finally, the FDA may designate a product for priority review if it is a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines at the time that the marketing application is submitted, on a case-by-case basis, whether the proposed drug represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications and to shorten the FDA's goal for taking action on a marketing application from ten months to six months for an NDA for a new molecular entity from the date of filing. If criteria are not met for priority review, the application for a new molecular entity is subject to the standard FDA review period of ten months after FDA accepts the application for filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

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

U.S. marketing and data exclusivity

Market exclusivity provisions under the FDCA can delay the submission or the approval of certain follow-on drug applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an Abbreviated New Drug Application (ANDA) or a 505(b)(2) NDA submitted by another company for a generic or follow-on version of the protected drug product, respectively, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The FDCA also provides three years of data exclusivity when an NDA or a supplement to an existing NDA, includes new clinical investigations, other than bioavailability studies, conducted or sponsored by the applicant that are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs or follow-on 505(b)(2) NDAs if the protected clinical data are not referenced. Five-year and three-year exclusivity will not delay the submission or approval of a stand-alone NDA submitted under section 505(b)(1) of the FDCA. However, an applicant submitting a stand-alone NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness, if applicable.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing regulatory exclusivity periods. This six-month exclusivity may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial. The issuance of a written request does not require the sponsor to undertake the described clinical trials.

Post-approval requirements

Following approval of a new prescription drug product, the manufacturer and the approved drug are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to monitoring and recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs must be promoted by a manufacturer and any third parties acting on behalf of a manufacturer only for the approved indications and in a manner consistent with the approved label for the product. The FDA and other agencies enforce the laws and regulations prohibiting the promotion of off-label uses and a company found to have improperly promoted one may be subject to significant liability. After approval, most changes to the approved product, such as adding new indications or other labeling claims or changes to the manufacturing processes or facilities, are subject to prior FDA review and approval. There are continuing, annual user fee requirements for any marketed products and the establishments where such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval of a drug 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 mandatory 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 other enforcement-related letters or clinical holds on post-approval clinical trials;
- Refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- Product seizure or detention, or refusal to permit the import or export of products;
- Consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- Mandated modification of promotional materials and labeling and the issuance of corrective information;
- Issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- Injunctions or the imposition of civil or criminal penalties.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and may require the implementation of other risk management measures.

Other healthcare laws and regulations

Healthcare providers, including physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any drug products for which we obtain marketing approval. Our current and future arrangements with third-party payors, customers, healthcare providers, physicians and others, in connection with the clinical research, sales, marketing and promotion of products, once approved, and related activities, may expose a pharmaceutical manufacturer to broadly applicable fraud and abuse and other healthcare laws and regulations. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services and certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business or financial arrangements. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the U.S. federal Anti-Kickback Statute, which makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual, or the purchase, lease, order, arrangement, or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. The term remuneration has been interpreted broadly to include anything of value. Further, courts have found that if "one purpose" of renumeration is to induce referrals, the federal Anti-Kickback statute is violated. Violations are subject to significant civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment and exclusion from government healthcare programs. The Anti-Kickback Statute has been interpreted to apply to arrangements between biopharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers, among others, on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;
- the U.S. federal civil and criminal false claims laws, including the False Claims Act (FCA), which can be enforced through "qui tam" or "whistleblower" actions, and civil monetary penalty laws, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal health care programs that are false, fictitious or fraudulent; knowingly making, using, or causing to be made or used, a false record or statement material to a false, fictitious or fraudulent claim or an obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing such an obligation. to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. In addition, a claim submitted for payment to any federal healthcare program that includes items or services that were made as a result of a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (*e.g.*, public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA fraud provisions without actual knowledge of the statute or specific intent to violate it;
- the U.S. federal Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the Centers for Medicare and Medicaid Services (CMS), an agency within the U.S. Department of Health and Human Services (HHS), under the Open Payments Program, information related to direct or indirect payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals, (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by the physicians and their immediate family members.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, also imposes obligations, including mandatory contractual terms, on "covered entities," including certain healthcare providers, health plans, healthcare clearinghouses, and their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, as well as analogous state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.
- U.S. federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous U.S. state, local and foreign laws and regulations, such as U.S. state anti-kickback, false claims and laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and other relevant compliance guidance promulgated by the federal government that otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Efforts to ensure that business arrangements comply with applicable healthcare laws involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting its rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, imprisonment, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reporting obligations and oversight if we become subject to integrity and oversight agreements to resolve allegations of non-compliance, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and the results of operations. In addition, commercialization of any drug product outside the United States will also likely be subject to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business with are found to be not in compliance with applicable laws, they may be subject to similar penalties.

Data privacy and security laws

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, health information privacy laws, including HIPAA, and federal and state consumer protection laws (*e.g.*, Section 5 of the Federal Trade Commission Act) that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our partners. For example, the California Consumer Protection Act (CCPA) came into effect on January 1, 2020 and provides data privacy rights for consumers and operational requirements for companies. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA provides civil penalties for violations and a private right of action for data breaches that is expected to increase data breach litigation. Further, the California Privacy Rights Act (CPRA), was recently voted into law by California residents. The CPRA significantly amends the CCPA, and imposes additional data protection obligations on covered companies doing business in California, including additional consumer rights processes and opt outs for certain uses of sensitive data. It also creates a new California data protection agency specifically tasked to enforce the law, which would likely result in increased regulatory scrutiny of California businesses in the areas of data protection and security. The substantive requirements for businesses subject to the CPRA went into effect on January 1, 2023 and became enforceable on July 1, 2023. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the European Economic Area (EEA), including personal health data, is subject to the European Union (EU) General Data Protection Regulation (EU GDPR), which became effective in May 2018, and the equivalent law in the U.K. (UK GDPR), which became effective on January 1, 2021 (together, the GDPR). 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 imposes strict rules on the transfer of personal data to countries outside the EEA, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions, as well as fines of up to 20 million euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR, or, in each case, 4% of annual global revenue, 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.

Current and future healthcare reform legislation

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and devices and to spur innovation, but its ultimate implementation is uncertain. More recently, in August 2017, the FDA Reauthorization Act was signed into law to reauthorize the FDA's user fee programs and included additional drug and device provisions that build on the Cures Act.

In addition, in both the United States and certain foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes regarding the health care system directed at broadening the availability of healthcare, improving the quality of healthcare and containing or lowering the cost of healthcare. For example, in March 2010 the Patient Protection and Affordable Care Act (ACA) was enacted, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjected biological products to potential competition by lower-cost biosimilars; expanded the types of entities eligible for the 340B drug discount program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations; established annual fees and taxes on manufacturers of certain branded prescription drugs; and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018 (BBA), effective as of January 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been judicial, administrative, executive and legislative challenges to certain aspects of the ACA. 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. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a newly established manufacturer discount program. The ACA may be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden administration with impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and, due to subsequent legislative amendments, will remain in effect until 2031, unless additional Congressional action is taken. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. There also has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent U.S. Congressional inquiries, Presidential executive orders, and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services (HHS) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare Part B and Part D that have been approved by the FDA for at least 7 years for drugs, and 11 years for biologics; and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. Drugs and biologics are selected for negotiation two years prior to the negotiated price taking effect. Therefore, small-molecule drug manufacturers and biologic manufacturers are afforded at least 9 years and 13 years, respectively, before they must sell their product at the negotiated price under Medicare Part B and Part D, as applicable. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within ninety (90) days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries.

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

In the European Union and in other foreign jurisdictions, similar political, economic and regulatory developments may affect our ability to profitably commercialize our products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or EU member state level may result in significant additional requirements or obstacles that may increase our operating costs.

Legislative and regulatory proposals, and enactment of laws at the foreign, federal and state levels, directed at containing or lowering the cost of healthcare, will likely continue.

Rest of world regulation

For other countries outside of the European Union and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing product development, the conduct of clinical trials, manufacturing, distribution, marketing approval, advertising and promotion, product licensing, pricing and reimbursement vary from country to country. Additionally, clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

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

Additionally, to the extent that any of our product candidates, once approved, are sold in a foreign country, we may be subject to applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals.

Additional laws and regulations governing international operations

If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act (FCPA) prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered by U.S. authorities that enforce the FCPA, including DOJ, to be foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Coverage, pricing and reimbursement

Significant uncertainty exists as to the coverage, pricing and reimbursement status of any products seeking regulatory approval. Successful commercialization of new drug products depends in part on the extent to which coverage and reimbursement for those drug products will be available from government health administration authorities, private health insurers and other organizations. The availability of coverage and extent of reimbursement depend substantially, both domestically and abroad, on the extent to which the costs of drugs products are paid for by third-party payors, such as government health care programs (*e.g.*, Medicare, Medicaid), health maintenance organizations, managed care providers, pharmacy benefit and similar healthcare management organizations, private health coverage insurers and other third-party payors. These third-party payors decide which medications they will pay for and will establish reimbursement levels.

In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors and coverage and reimbursement levels for drug products can differ significantly from payor to payor. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Moreover, the process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. 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. Third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all FDA-approved products for a particular indication.

Increasing efforts by third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or comparable regulatory approvals. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Our product candidates, if approved, may nonetheless not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. We expect to experience pricing pressures from third-party payors in connection with the potential sale of any of our product candidates.

Outside of the United States, the pricing of pharmaceutical products and medical devices is subject to governmental control in many countries. For example, 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 a particular therapy's cost effectiveness to currently available therapies or so-called health technology assessments, to obtain reimbursement or pricing approval. Other countries may allow companies to fix their own prices for products but monitor and control product volumes and issue guidance to physicians to limit prescriptions. Efforts to control prices and utilization of pharmaceutical products and medical devices will likely continue as countries attempt to manage healthcare expenditures. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Employees and Human Capital

As of December 31, 2023, we had 9 full-time employees and 2 part-time employees. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

We are committed to a work environment that is welcoming, inclusive and encouraging. To achieve our plans and goals, it is imperative that we attract and retain top talent. In order to do so, we aim to have a safe and encouraging workplace, with opportunities for our employees to grow and develop professionally, supported by strong compensation, benefits, and other incentives. In addition to competitive base salaries, we offer our employees discretionary cash-based performance bonuses and, in addition, may utilize our equity incentive plan to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards.

Corporate Information

We were incorporated under the laws of the state of Delaware in October 2018. Our principal mailing address is PMB #117, 2801 Centerville Road 1st Floor, Wilmington, DE 19808-1609. Our telephone number is 1-877-ELIEMTX (354-3689). Our website is www.eliemtx.com. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports are available free of charge on our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission.

Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to the other information contained in this Annual Report on Form 10-K, including the section of this report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes. If any of the events described in the following risk factors and the risks described elsewhere in this report occurs, or if any other risks of which we are not presently aware occurs, our business, operating results and financial condition could be seriously harmed. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements due to factors described below and elsewhere in this report.

Risks Related to Strategic Process and Potential Strategic Transaction

We may not be successful in identifying and implementing any strategic transaction and any strategic transactions that we may consummate in the future may not be successful.

In July 2023, we made the strategic decision to pause further development of our Kv7 program and to conduct a comprehensive exploration of strategic alternatives focused on maximizing stockholder value. As part of this process we expect to explore potential strategic alternatives that may include, but are not limited to, an acquisition, merger, business combination, or other transaction.

For example, in connection with this process, on March 14, 2024 we received a Non-Binding Term Sheet from Tango, a development stage private biotechnology company which is majority-owned by funds affiliated with RA Capital. The Non-Binding Term Sheet contemplates that we would acquire Tango through a transaction whereby we would issue common stock to Tango's equityholders in exchange for all of the outstanding equity of Tango, and Tango would become our wholly owned subsidiary, as described in Part I, Item 1 of this Annual Report on form 10-K.

However, there can be no assurance that we will be able to successfully consummate any particular strategic transaction, including the Proposed Transaction. In addition, the Non-Binding Term Sheet is non-binding, and there can be no assurance that any definitive agreement will result from the Non-Binding Term Sheet or that any transaction with Tango or any other third party will be consummated. The Non-Binding Term Sheet, and the Proposed Transaction contemplated thereby, are subject to various conditions, including but not limited to, (i) the satisfactory completion of due diligence by both parties, (ii) the negotiation and execution of a definitive agreement and the satisfaction of the conditions negotiated therein, (iii) the approval and recommendation of the Proposed Transaction by the Special Committee, and (iv) a non-waivable condition requiring approval of our stockholders holding a majority of the voting power of the outstanding shares of our company not held by RA Capital or its affiliates. As the parties continue to negotiate the terms of the Proposed Transaction, it is possible that, through these negotiations, the proposed terms of the Proposed Transaction may change, including as a result of the ongoing diligence efforts of both parties, market conditions and other factors. There can be no guarantee that the parties will ever reach a definitive agreement with respect to the Proposed Transaction and either party may determine to abandon the Proposed Transaction at any time for any reason, including the parties' respective beliefs regarding the preferability of the Proposed Transaction to other alternatives that may be available to them, as well as other factors.

Continuing to evaluate these strategic options may be very costly, time-consuming and complex and we may incur significant costs related to this continued evaluation. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented, or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business and may diminish or delay any future distributions to our stockholders. In addition, we may not be able to adequately limit or avoid future liabilities, including future costs relating to the lease on our headquarters, which may impair the value of any potential transaction or present additional challenges to completing a strategic transaction.

There can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated, lead to increased stockholder value, or achieve the anticipated results. Any failure of such potential transaction to achieve the anticipated results could significantly impair our ability to enter into any future strategic transactions and may significantly reduce or delay any future distributions to our stockholders.

We may not realize any additional value in a strategic transaction.

The market capitalization of our company is below the value of our current cash, cash equivalents and marketable securities. Potential counterparties in a strategic transaction involving our company may place minimal or no value on our assets, including ETX-123 and ETX-155. Further, the development and any potential commercialization of our product candidates would require substantial additional cash to fund the costs associated with conducting the necessary preclinical and clinical testing and obtaining regulatory approval. Consequently, any potential counterparty in a strategic transaction involving our company may choose not to spend the additional resources necessary to continue developing our product candidates and may attribute little or no value, in such a transaction, to those product candidates.

If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks.

Although there can be no assurance that a transaction will result from the process we have undertaken to assess strategic options, the negotiation and consummation of any such transaction will require significant time on the part of our management, and the diversion of management's attention may disrupt the orderly operation of our company. The negotiation and consummation of any such transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including:

- increased near-term and long-term expenditures;
- exposure to unknown liabilities;
- higher than expected acquisition, disposition or integration costs;
- incurrence of substantial debt or dilutive issuances of equity securities to fund future operations;
- write-downs of assets or incurrence of non-recurring, impairment or other charges;
- difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership;
- inability to retain key employees of our company or any acquired business; and
- possibility of future litigation.

Our Board may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that a strategic transaction will be completed and, whether or not such strategic transaction is completed, our Board may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our Board were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our Board, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up.

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

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

Risks Related to our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception and anticipate that we will incur substantial losses for the foreseeable future and may never achieve or maintain profitability.

We are a biotechnology company with a limited operating history. Our efforts have focused primarily on developing novel therapies for neuronal excitability disorders to address unmet needs in psychiatry, epilepsy, chronic pain, and other disorders of the peripheral and central nervous system. To date, we have not received regulatory approvals for any of our product candidates or generated any revenue from the sale of products, and we do not expect to generate any revenue in the foreseeable future. All of our product candidates are in early stages of research and development and we have paused further development of our programs while we focus on evaluating strategic alternatives. As a result, we are not profitable and we have incurred significant operating losses since inception. Our net losses were $35.1 million and $45.2 million for the years ended December 31, 2023 and 2022, respectively. We had an accumulated deficit of $156.0 million as of December 31, 2023.

While we have taken measures to reduce our expenses in the near term, we continue to incur significant expenses related to our ongoing operations, including expenses relating to the wind down of ETX-123 and ETX-155 and expenses related to our ongoing corporate restructuring, and are not currently moving any of our existing product candidates toward commercialization. We therefore expect to continue to have operating losses for the foreseeable future. If we are able to complete a strategic transaction that will allow us to continue development of our programs, we may resume our work to identify, acquire, and conduct research and development of future product candidates, and potentially begin to commercialize any future products that may achieve regulatory approval. We may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our financial condition. 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 revenues. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our financial condition. If we are unable to bring any of our product candidates or future product candidates through full clinical trials for any reason, or if such product candidates or future product candidates do not gain regulatory approval, or if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

If we are unable to access capital when needed, it could force us to delay, reduce or terminate our product development programs, commercialization efforts, or other operations.

While we expect to have adequate capital to fund our operations through the process we have undertaken to assess strategic options, our future capital requirements and the period during which we expect to complete this process may vary significantly from what we expect, and we may have to seek an alternate resolution to the process. If a strategic transaction is not consummated and/or if product development is resumed, we will require substantial additional funding to support our continuing operations. In addition, even if we are successful in completing a strategic transaction, we may still need to raise additional funds for any research and development or clinical programs we may choose to pursue in the future. Because the length of time and activities associated with successful research and development of our product candidates is highly uncertain, and because we have paused further development of our programs while we pursue strategic alternatives, we are unable to estimate the actual funds we will require for development and any marketing and commercialization activities for any product candidates that ultimately may be approved for sale. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- our ability to complete a strategic transaction in a timely manner and on acceptable terms;
- the timing, cost and progress of research and preclinical, and clinical development activities;
- the number and scope of development, preclinical and clinical programs we decide to pursue;

- the terms of any collaborations and/or research and development agreements we may enter into, which may impact the cost, timing and development plans of one or more of our product candidate programs;
- the costs involved in prosecuting and enforcing patent and other intellectual property claims;
- the costs of manufacturing our product candidates by third parties;
- the cost of regulatory requirements, regulatory submissions and timing of regulatory approvals;
- the potential delays in our preclinical studies, our development programs and our ongoing and planned clinical trial activities due to the effects of global events, including macroeconomic conditions and continued supply chain disruptions;
- the impact of inflationary pressures on salaries and wages, and costs of goods and transportation expenses, among other things;
- the cost of commercialization activities if any future product candidates are approved for sale, including marketing, sales and distribution costs; and
- our efforts to enhance operational systems and hire personnel to support development of any future product candidates.

If we are unable to obtain funding on a timely basis or on acceptable terms, we may have to pursue less advantageous strategic opportunities, limit future research and development, or dissolve the Company and liquidate our assets.

We may seek the additional funding we will need to continue operating in the future through collaborations and/or licensing agreements, public or private equity offerings or debt financings, credit or loan facilities, or a combination of one or more of these funding sources. If we raise additional funds by issuing equity securities, our stockholders will suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. If we are able to raise additional funds through future debt financings, the terms of such financings are likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. We also could be required to seek collaborators for product candidates at an earlier stage than otherwise would be desirable or relinquish some or all of our rights to certain product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. Failure to obtain capital when needed on acceptable terms may force us to delay, limit or terminate our product development and commercialization of our current or future product candidates, which could have a material and adverse effect on our business, financial condition, results of operations, and prospects.

If we are unable to successfully develop and commercialize product candidates or experience significant delays in doing so, our business may be harmed.

Drug development is a highly uncertain undertaking and involves a substantial degree of risk. For example, we have paused or discontinued the development of all of our remaining product candidates, which are still in drug discovery stages, and we may not ever obtain regulatory approval for any future product candidates.

To date, we have not initiated or completed a pivotal clinical trial, obtained marketing approval for any product candidates, manufactured a commercial scale product or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Our short operating history as a company makes any assessment of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage biotechnology companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully overcome such risks and difficulties. If we do not address these risks and difficulties successfully, our business may be harmed.

We currently have no source of product revenue and may never become profitable.

We have paused further development of our programs and to date, we have not generated any revenues from commercial product sales, or otherwise. Our ability to generate revenue from product sales and achieve profitability will depend upon our ability, alone or with any future collaborators, to successfully commercialize any products that we may develop, in-license or acquire in the future. Even if we are able to successfully achieve regulatory approval for any future product candidates, we do not know when any of these products will generate revenue from product sales for us, if at all. Our ability to generate revenue from any of our future product candidates also depends on a number of additional factors, including our or any future collaborators' ability to:

- complete development activities, including the necessary clinical trials;
- complete and submit new drug applications, or NDAs, to the U.S. Food and Drug Administration, or FDA, and obtain regulatory approval for indications for which there is a commercial market;
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;
- set a commercially viable price for our products;
- establish and maintain supply and manufacturing relationships with third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- develop a commercial organization capable of sales, marketing and distribution for any products for which we obtain marketing approval and intend to sell ourselves in the markets in which we choose to commercialize on our own;
- find suitable distribution partners to help us market, sell and distribute our approved products in other markets;
- obtain coverage and adequate reimbursement from third-party payors, including government and private payors;
- achieve market acceptance for our products, if any;
- establish, maintain and protect our intellectual property rights; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with pharmaceutical product development, any future product candidates may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide, or are required by the FDA or foreign regulatory authorities, to perform studies or trials in addition to those that we currently anticipate. Even if we can complete the development and regulatory process for any future product candidates, we anticipate incurring significant costs associated with commercializing these products.

Even if we can generate revenues from the sale of any future product candidates that may be approved, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

Risks Related to our Business and the Development of our Product Candidates

Our future success is dependent primarily on the regulatory approval and commercialization of our future product candidates.

We do not have any products that have gained regulatory approval. As a result, our prospects, including our ability to finance our operations and generate revenue, are substantially dependent on our ability to obtain regulatory approval for, and, if approved, to successfully commercialize any future product candidates. We cannot commercialize our future product candidates in the United States without first obtaining regulatory approval for the product from the FDA; similarly, we cannot commercialize our future product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. The FDA review process for an NDA typically takes more than a year to complete and approval is never guaranteed. Before obtaining regulatory approvals for the commercial sale of our future product candidates for a target indication, we must demonstrate with substantial evidence gathered in preclinical and well-controlled clinical trials, generally including at least two well-controlled Phase 3 trials, and, with respect to approval in the United States, to the satisfaction of the FDA, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate.

Obtaining regulatory approval for marketing of our future product candidates in one country does not ensure we will be able to obtain regulatory approval in other countries but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries.

Even if our future product candidates were to successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, gender or subpopulation of target indication, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of any of our future product candidate that we may discover, in-license, develop or acquire in the future. Also, any regulatory approval of any of our future product candidates, once obtained, may be withdrawn. Furthermore, even if we obtain regulatory approval for any of our future product candidates, their commercial success will depend on a number of factors, including the following:

- development of a commercial organization or establishment of a commercial collaboration with a commercial infrastructure;
- establishment of commercially viable pricing and adequate reimbursement from third-party and government payors;
- the ability of our third-party manufacturers to manufacture quantities of our products in commercially sufficient processes and at a scale sufficient to meet anticipated demand and enable us to reduce our cost of manufacturing;
- our success in educating physicians and patients about the benefits, administration and use of our products;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- the effectiveness of our own or our potential strategic collaborators' marketing, sales and distribution strategy and operations;
- acceptance of our products as safe and effective by patients and the medical community; and
- a continued acceptable safety profile of our products following approval.

Many of these factors are beyond our control. If we, or our potential commercialization collaborators, are unable to successfully commercialize our product candidates, we may not be able to earn sufficient revenues to continue our business.

Even if our future product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for a future product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any future product candidate, they may require labeling changes or establishment of a Risk Evaluation and Mitigation Strategy (REMS) or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practice (cGMP), requirements and other regulations. If we or a regulatory agency discover 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, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates, fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- impose restrictions on the marketing or manufacturing of the product candidates;

- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us or any future collaborator to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific remediation actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize any future product candidates and generate revenue.

The FDA strictly regulates the advertising and promotion of drug products, and drug products may only be marketed or promoted for their FDA approved uses, consistent with the product's approved labeling. Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the DOJ, the Office of Inspector General of the Department of Health and Human Services, state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil, criminal and/or administrative sanctions by the FDA and other enforcement authorities. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by relevant foreign regulatory authorities.

In the United States, engaging in impermissible promotion of our future products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to numerous actions, including civil, criminal and/or administrative penalties and fines and agreements that materially restrict the manner in which we promote or distribute our drug products. These false claims statutes include the federal False Claims Act, which allows the federal government, or any individual relator or whistleblower on behalf of the federal government to bring a lawsuit against a pharmaceutical company alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual relator may share in any fines or settlement funds. Since 2004, these False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements based on certain sales practices promoting off-label drug uses. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from the Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our products once they have received regulatory approval, we may become subject to such litigation and, if we are not successful in defending against such actions, those actions could have a material adverse effect our business, results of operations, financial condition and cash flows and future prospects.

Existing government regulations may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of any future product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and/or be subject to fines or enhanced government oversight and reporting obligations, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Preclinical and clinical development involves a lengthy, complex and expensive process with an uncertain outcome. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities.

To obtain the requisite regulatory approvals to commercialize any future product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans to the satisfaction of FDA. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. In particular, in the United States, the general approach for FDA approval of a new drug is dispositive data from two well-controlled, Phase 3 clinical trials of the relevant drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds to thousands of patients, have significant costs and take years to complete. A product candidate can fail at any stage of testing, even after observing promising signs of activity in earlier preclinical studies or clinical trials, as demonstrated by the failure of ETX-810 to achieve statistically significant separation from placebo on the primary endpoint in either of our Phase 2a clinical trials in DPNP and LSRP, respectively. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. For example, preclinical models evaluating product candidates for pain are notoriously unreliable and, as such, the therapies face substantial translational risk. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or emergence of unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved and there can be no assurance that any of our future clinical trials will ultimately be successful or support further preclinical or clinical development of ETX-123, ETX-155 or any of our other product candidates. The commencement and rate of completion of preclinical studies and clinical trials may be delayed by many factors, including:

- inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical studies;
- preclinical studies or clinical trials may show the product candidates to be less effective than expected (e.g., a clinical trial could fail to meet its primary endpoint(s)) or to have unacceptable side effects or toxicities;
- failure to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- delays in reaching agreement on acceptable terms with prospective CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials;
- delays in recruiting suitable patients to participate in our clinical trials;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing;
- insufficient or inadequate supply or quality of product candidates or other materials necessary for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- imposition of a temporary or permanent clinical hold by regulatory authorities;
- developments on trials conducted by competitors for related technology that raises FDA or foreign regulatory authority concerns about risk to patients of the technology broadly, or if the FDA or a foreign regulatory authority finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in recruiting, screening and enrolling patients and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical trial protocols;
- failure to perform in accordance with the FDA's or any other regulatory authority's good clinical practice requirements (GCPs) or applicable regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, or occurrence of adverse events in trial of the same class of agents conducted by other companies;

- the cost of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates;
- transfer of manufacturing processes to larger-scale facilities operated by a third-party contract development and manufacturing organization (CDMO) and delays or failure by our CDMOs or us to make any necessary changes to such manufacturing process; and
- third parties being unwilling or unable to satisfy their contractual obligations to us.

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

Further, clinical trials that we may undertake in the future will likely contain endpoints that require subjective assessments and subject us to a substantial risk of "placebo effect" which is a well-known risk in clinical trials evaluating therapeutics for pain as well as depression. While a product candidate may show clinical activity or therapeutic benefit, a high placebo effect in a clinical trial will make it difficult to ascertain that benefit or to show statistically significant effect of the product candidate as compared to the control arm and may ultimately cause a clinical trial to fail.

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 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.

Delays in the completion of any preclinical studies or clinical trials of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate product revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Any delays to our preclinical studies or clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

If we seek to conduct clinical trials in foreign countries or pursue marketing approvals in foreign jurisdictions, we must comply with numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and jurisdictions and may include all of the risks associated with FDA approval described above and risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ jurisdiction-to-jurisdiction from that required to obtain FDA approval. Approval by foreign regulatory authorities does not ensure approval by the FDA and, similarly, approval by the FDA does not ensure approval by regulatory authorities outside the United States.

Successful completion of clinical trials is a prerequisite to submitting a marketing application to foreign regulatory authorities or the FDA, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates. We may experience negative or inconclusive results, or regulators may be unwilling to accept preclinical or clinical data obtained in foreign jurisdictions, which may result in our deciding, or our being required by regulators, to conduct additional clinical studies or trials or abandon some or all of our product development programs, which could harm our business.

Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. 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.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital to properly capitalize and continue our operations.

Our future product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any marketing approval.

Undesirable side effects caused by our future product candidates could cause us or regulatory authorities to interrupt, delay or pause clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. If undesirable side effects do occur in our future clinical trials they could cause delay or even discontinuance of further development of future product candidates, which would impair our ability to generate revenues and would have a material adverse effect on our business, results of operations, financial condition and cash flows and prospects.

As a result of undesirable side effects or further safety issues that we may experience in our clinical trials in the future, we may not receive approval to market any future product candidates, which could prevent us from ever generating revenues or achieving profitability. Results of our trials could reveal an unacceptably high severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may have a material adverse effect on our business, results of operations, financial condition and cash flows and prospects.

Additionally, if any of our future product candidates receives marketing approval, and we, or others, later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- we may be forced to suspend marketing of such product;
- regulatory authorities may withdraw their approvals of such product;
- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such products;
- the FDA or other regulatory bodies may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- the FDA may require the establishment or modification of a REMS or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of our products and impose burdensome implementation requirements on us;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to subjects or patients;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved.

If we encounter difficulties enrolling and/or retaining patients in our future clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

If we are able to move any of our product candidates to the clinical trial stage, we may not be able to initiate or continue our planned clinical trials on a timely basis or at all for our product candidates if we are unable to recruit and enroll a sufficient number of eligible patients to participate in these trials through completion of such trials as required by the FDA or other comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. Our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. There may be limited patient pools from which to draw for clinical studies. The eligibility criteria of our clinical studies will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a study. Patient enrollment for our current or any future clinical trials may be affected by other factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- the availability and efficacy of approved drugs for the disease under investigation;
- perceived risks and benefits of the product candidate under study;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications that we are investigating;
- clinicians' willingness to screen their patients for biomarkers to indicate which patients may be eligible for enrollment in our clinical trials;
- our ability to obtain and maintain patient consents;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition would reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site.

Our inability to enroll enough patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials. Delays in patient enrollment may result in increased costs, affect the timing or outcome of the planned clinical trials, product candidate development and approval process and jeopardize our ability to seek and obtain the regulatory approval required to commence product sales and generate revenue, which could prevent completion of these trials, adversely affect our ability to advance the development of our product candidates, cause the value of our company to decline and limit our ability to obtain additional financing if needed. Furthermore, even if we can enroll enough patients for our clinical trials, we may have difficulty maintaining participation in our clinical trials through the treatment and any follow-up periods.

We are also required to register certain clinical trials and post the results of completed clinical trials on a government-sponsored database, such as www.ClinicalTrials.gov in the United States, within certain time frames. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

We could be subject to product liability lawsuits based on the use of our product candidates in clinical testing or, if obtained, following our products' marketing approval and commercialization. Product liability lawsuits brought against us or any of our future collaborators could divert our resources and attention, require us to cease clinical testing, cause us to incur substantial liabilities or limit commercialization of our product candidates.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of biotechnology products. Currently, we have no products that have been approved for commercial sale; however, the use of our product candidates by us and any collaborators in clinical trials may expose us to liability claims. We will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us or our partners if any product candidate we develop allegedly causes injury or is found to be otherwise unsuitable for human use during product testing, manufacturing, marketing or sale. Any such product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. Such claims could be made by participants enrolled in our clinical trials, patients, health care providers, biotechnology companies, our collaborators or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources.

Regardless of the merits or eventual outcome, product liability claims may result in:

- decreased demand for any of our future approved products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- significant litigation costs;
- substantial monetary awards to, or costly settlements with, patients or other claimants;
- product recalls or a change in the indications for which any approved drug products may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, clinical development does not always fully characterize the safety and efficacy profile of a new medicine, and it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If our product candidates were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity associated with illness or other adverse effects resulting from physicians' or patients' use or misuse of our products or any similar products distributed by other companies.

Although we maintain product liability insurance coverage including clinical trial liability, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if we commercialize any product that receives regulatory approval. In addition, insurance coverage is becoming increasingly expensive. If we are unable to maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product candidates, which could harm our business.

Risks Related to Legal and Regulatory Compliance

Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval and commercialize our product candidates and may affect the prices we may charge for such product candidates.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act (ACA), was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. There have been executive, judicial and congressional challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is unclear how any additional challenges or future healthcare reform measures of the Biden administration will impact the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011 was signed into law, which, among other things, included aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments including the Infrastructure Investment and Jobs Act and the Consolidated Appropriations Act of 2023, will stay in effect until 2032 unless Congress takes additional action.

Recently, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. presidential executive orders, congressional inquiries and legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. At the federal level, the Biden administration used several means to propose or implement drug pricing reform, including through executive orders and policy initiatives. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, U.S. Department of Health and Human Services (HHS) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare Part B and Part D that have been approved by the FDA for at least 7 years for drugs, and 11 years for biologics; and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. Drugs and biologics are selected for negotiation two years prior to the negotiated price taking effect. Therefore, if selected for price negotiations, small-molecule drug manufacturers and biologic manufacturers are afforded at least 9 years and 13 years, respectively, before they must sell their product at the negotiated price under Medicare Part B and Part D, as applicable. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs as implemented. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare & Medicaid Services (CMS) Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. On December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control costs for pharmaceutical and biological products.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Our business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors and customers will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Although we do not currently have any products on the market, our operations may be, directly or indirectly through our prescribers, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations. These laws may impact, among other things, our current business operations, including our clinical research activities and proposed sales, marketing and education programs and constrain the business of financial arrangements and relationships with healthcare providers and other parties through which we may market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual, or the purchase, lease, order, arrangement, or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal civil and criminal false claims laws, including the False Claims Act (FCA), which can be enforced through "qui tam" or "whistleblower" actions, and civil monetary penalty law, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal health care programs that are false, fictitious or fraudulent; knowingly making, using, or causing to be made or used, a false record or statement material to a false, fictitious or fraudulent claim or an obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing such an obligation to pay money to the federal government. In addition, a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the FCA;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA fraud provisions without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, also imposes obligations, including mandatory contractual terms, on "covered entities," including certain healthcare providers, health plans, healthcare clearinghouses, and their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, as well as analogous state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

- the U.S. federal Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the CMS, an agency within the HHS under the Open Payments Program, information related to direct or indirect payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members;
- U.S. federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous U.S. state laws and regulations, including state anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and other relevant compliance guidance promulgated by the federal government that otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance 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 the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the delay, reduction, termination or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

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

We process personal data and other sensitive data (including health data we collect about study or trial participants in connection with our preclinical studies or clinical trials); proprietary and confidential business data; trade secrets; intellectual property; and sensitive third-party data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws. These privacy laws include, without limitation, the following laws and regulations: Section 5 of the Federal Trade Commission Act, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) (which imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information) and the California Consumer Privacy Act of 2018 (CCPA). The CCPA applies to personal information of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights.

The CCPA provides for civil penalties of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. In addition, the CPRA amended the CCPA and expanded the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law. Other states, such as Virginia and Colorado, have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. If we are or were to become subject to these laws and/or new or amended data privacy laws, the risk of enforcement actions against us could increase because we may be subject to obligations under applicable regulatory frameworks and the number of individuals or entities that could initiate actions against us may increase (including individuals via a private right of action), in addition to further complicating our compliance efforts.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation (EU GDPR) and the equivalent law in the U.K. (UK GDPR) (together, the GDPR), impose strict requirements for processing the personal data of individuals, including sensitive data that we may process such as health data. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions, as well as fines of up to 20 million euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR, or, in each case, 4% of annual global revenue, whichever is greater. Further, individuals may initiate litigation related to our processing of their personal data. Additionally, under various privacy laws and other obligations, we may be required to obtain certain consents to process personal data. Our inability or failure to do so could result in adverse consequences.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. The EEA, the U.K. and certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws. In particular, the EEA and the U.K. have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and U.K. to the United States in compliance with law, such as the EEA standard contractual clauses, the U.K. International Data Transfer Agreement, and the EU-U.S. Data Privacy Framework (which allows for transfers for relevant United States-based organizations who self-certify compliance and participate in the Framework, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the U.K. or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and U.K. to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the EU GDPR's cross-border data transfer limitations.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CCPA, require our customers to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparation for and compliance with these obligations requires us to devote significant resources. These obligations may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

Although we try to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived as having failed). Despite our efforts, our personnel or third parties upon whom we rely on may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the third-party providers (such as research institutions) who share this information with us, may contractually limit our ability to use and disclose the information.

If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including our clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our product candidates; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

Risks Related to our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We rely on third parties in winding down our development of our former clinical product candidates, and we expect to rely on third-party CROs to conduct, supervise, and monitor our future preclinical and studies and clinical trials for our product candidates and do not currently plan to independently conduct preclinical studies or future clinical trials of any other potential product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators to conduct our future preclinical studies and clinical trials. While we have agreements governing their activities, we have limited influence over their actual performance and control only certain aspects of their activities. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may not obtain marketing approval for or commercialize our product candidates in a timely manner or at all. Moreover, these agreements might terminate for various reasons, including a failure to perform by the third parties; if we need to enter into alternative arrangements, that will delay our product development activities and harm our business.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies and clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory 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 and for ensuring that our preclinical studies are conducted in accordance with good laboratory practice (GLP) as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with standards, commonly referred to as good clinical practices (GCPs), for conducting, monitoring, 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. As a clinical trial sponsor, we will also have regulatory requirements that directly apply to us. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators, and trial sites. If we or any of our CROs fail to comply with applicable GCPs, we or our CROs may be subject to enforcement or other legal actions, 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.

In addition, once we have an approved product, we will be required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA and comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who previously served or currently serve as scientific advisors or consultants to us from time to time and receive cash compensation in connection with such services or otherwise receive compensation from us that could be deemed to impact study outcome, proprietary interests in a product candidate, certain company equity interests or significant payments of other sorts.

We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product candidates that were produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified time frames. Failure to do so can result in enforcement actions and adverse publicity.

Our CROs may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, non-clinical, and preclinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may 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 commercialize our product candidates, or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be harmed.

If any of our relationships with these third-party CROs terminates, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Switching or adding additional CROs 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 could occur, which could compromise our ability to meet our desired development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not harm our business.

If we are not able to establish future collaborations, we may have to alter some of our future development and commercialization plans.

Our product development programs and the potential commercialization of our product candidates will require substantial additional capital to fund expenses. While currently we have no plans to do so, we may decide to collaborate for the future development and potential commercialization of our product candidates. Furthermore, we may find that our programs require the use of proprietary rights held by third parties, and the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. We cannot predict the success of any collaboration that we have entered into or will enter into.

We face significant competition in seeking appropriate collaborators, and many more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we may 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, European Medicines Agency (EMA), the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) or similar foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, 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, 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 and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate further collaborations on a timely basis, on acceptable terms, or at all. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us. Our existing collaboration partners may not prioritize our product candidates or otherwise not effectively pursue the development of our product candidates which may delay, reduce or terminate the development of such product candidate, reduce or delay its development program or delay its potential commercialization. Further if we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to delay, reduce or terminate the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. Doing so will likely harm our ability to execute our business plans. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Risks Related to Intellectual Property

If we are unable to obtain, maintain and protect sufficient patent and other intellectual property rights for our product candidates and technology, or if the scope of patent and other intellectual property rights obtained is not sufficiently broad, we may not be able to compete effectively in our market.

Our success depends in significant part on our ability and the ability of future licensors, licensees or collaborators to obtain, maintain, enforce and defend patents and other intellectual property rights with respect to our product candidates and technology and to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others. A U.S. provisional patent application is not eligible to become an issued patent until, among other things, we file non-provisional patent application within 12 months of filing of the provisional patent application. With regard to such U.S. provisional patent applications, if we do not timely file any non-provisional patent applications, we may lose our priority dates with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.

The patent prosecution process is expensive and time-consuming. We and our future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our future licensors will fail to identify patentable aspects of our research and development output in time to obtain patent protection or fail to file patent applications covering inventions made in the course of development and commercialization activities before a competitor or another third party files a patent application covering, or publishes information disclosing, a similar, independently-developed invention. Such competitor's or other third party's patent application may pose obstacles to our ability to obtain patent protection or limit the scope of the patent protection we may obtain.

Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, CROs, CDMOs, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our future licensors were the first to make the inventions claimed in our owned or any future licensed patents or pending patent applications or were the first to file for patent protection of such inventions.

The patent position of biotechnology and pharmaceutical companies generally is uncertain, involves complex legal and factual questions and is the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors' patent rights are uncertain. Our and our future licensors' pending, and future patent applications may not result in patents being issued that protect our technology or product candidates, in whole or in part, or which effectively exclude others from commercializing competitive technologies and product candidates. The patent examination process may require us or our future licensors to narrow the scope of the claims of our pending and future patent applications, and therefore, even if such patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage.

Our and our licensors' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover such technology. Any patents that we hold or in-license in the future may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Any of the foregoing could impair our competitive position and harm our business.

The patent protection we obtain for our product candidates and technologies may be challenged and rendered invalid and/or unenforceable.

Even if our owned patent applications issue as patents, the issuance of any such patents is not conclusive as to their inventorship, scope, validity or enforceability, and such patents may be challenged, invalidated, narrowed or held to be unenforceable, including in the courts or patent offices in the United States and abroad, or circumvented. We may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office (USPTO), or equivalent foreign bodies, or become involved in opposition, derivation, revocation, re-examination, post-grant and inter partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or 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. Moreover, we may have to participate in interference or derivation proceedings declared by the USPTO to determine priority or ownership of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such proceedings and any other patent challenges may result in loss of patent rights, loss of exclusivity, loss of priority or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Moreover, there could be public announcements of the results of hearings, motions or other developments related to any of the foregoing proceedings. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline. Any of the foregoing could harm our business.

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

Because we will rely on third parties to develop and manufacture our future product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite these contractual agreements with third parties, sharing trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may harm our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our 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 harm our business.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful, and issued patents covering our technology and product candidates could be found invalid or unenforceable if challenged.

Competitors and other third parties may infringe, misappropriate or otherwise violate our issued patents or other intellectual property. In addition, our patents may become involved in inventorship or priority disputes. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. To counter infringement or other unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or that our patents are invalid or unenforceable. In a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. We may find it impractical or undesirable to enforce our intellectual property against some third parties.

In patent litigation in the United States, defendant counterclaims alleging invalidity 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, non-enablement or insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO or an equivalent foreign body, even outside the context of litigation. Potential proceedings include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our technology or any product candidates that we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. 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 the applicable product candidates or technology covered by the patent rendered invalid or unenforceable. Such a loss of patent protection would harm our business.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the ownership or priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Such licenses may not be available on commercially reasonable terms, or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of one or more of the product candidates we may develop. In addition, if we or any future licensors are unsuccessful in any inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights, such as exclusive ownership of, or the exclusive right to use, our owned or any future in-licensed patents. The loss of exclusivity or the narrowing of such patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could harm our business. Even if we are successful in any of the foregoing disputes, it could result in substantial costs and be a distraction to management and other employees. 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 or proceeding.

Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or otherwise violating our intellectual property. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims could result in substantial costs and diversion of management resources, which could harm our business. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to initiate anticipated clinical trials, continue our internal research programs or in-license needed technology or other product candidates. There could also be public announcements of the results of the hearing, motions or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline. Any of the foregoing events could harm our business.

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

Filing, prosecuting, maintaining, defending and enforcing patents and other intellectual property rights on our product candidates in all countries 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. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection or other intellectual property rights to develop their own products and may export otherwise infringing, misappropriating or violating products to territories where we have patent or other intellectual property protection, but enforcement rights are not as strong as those in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property rights, which could make it difficult for us to stop the infringement, misappropriation or other violation of our intellectual property rights generally. Proceedings to enforce our intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly 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.

Many countries, including EU countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. 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, which could harm our business.

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 product candidates.

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 patent application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, U.S. patent applications filed before November 29, 2000, and certain U.S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are 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. Therefore, patent applications covering our product candidates could have been filed by third parties without our knowledge. Additionally, 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 their use. 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 product candidates. 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, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

If we fail to identify and correctly interpret relevant patents or if we are unable to obtain licenses to relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, which may be significant, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could harm our business.

If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. The licensing or acquisition of third-party 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. If we are unable to license such technology, or if we are forced to license such technology, on unfavorable terms, our business could be harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Even if we can obtain a license, it may be non-exclusive, giving our competitors access to the same technologies licensed to us.

Moreover, some of our patents and patent applications in the future may be co-owned with third parties. If we are unable to obtain an exclusive license to any such co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, who could market competing products and technology. In addition, we may need the cooperation of any such co-owners to enforce such patents against third parties, and such cooperation may not be provided to us.

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

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

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and one or more of our foreign patents may be eligible for patent term extension under similar legislation, for example, in the EU. In the United States, the Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, there are no assurances that the FDA or any comparable foreign regulatory authority or national patent office will grant such extensions, in whole or in part. For example, 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. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened, and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced.

Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position and business could be harmed.

Changes in patent law could diminish the value of our patents, thereby impairing our ability to protect our product candidates.

Obtaining and enforcing patents in the pharmaceutical industry is inherently uncertain, due in part to ongoing changes in the patent laws. Depending on decisions by Congress, the federal courts, and the USPTO and equivalent institutions in other jurisdictions, the laws and regulations governing patents, and interpretation thereof, could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce existing or future patents. For example, the U.S. 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. Therefore, there is increased uncertainty with regard to our ability to obtain patents in the future, as well as uncertainty with respect to the value of patents once obtained.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the Leahy-Smith Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications are prosecuted and may also affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, particularly the first inventor-to-file provisions. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on any issued patents and applications are required to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent. In certain circumstances, we may rely on our future licensors to pay these fees. The USPTO and various foreign patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar requirements during the patent application and prosecution process.

Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official communications within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. 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 non-compliance can result in irrevocable abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we or any future licensors or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market with similar or identical products or technology, which would harm our business.

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

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including re-examination, interference, post-grant review, inter partes review or derivation proceedings before the USPTO or an equivalent foreign body. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. In the event that any of these patents were asserted against us, we believe that we would have defenses against any such action, including that such patents are not valid or that we would be able to replace such technology with alternative, non-infringing technology. However, if any such patents were to be asserted against us and our defenses to such assertion were unsuccessful and such alternative technology was not available or technologically or commercially practical, unless we obtain a license to such patents, we could be liable for damages, which could be significant and include treble damages and attorneys' fees if we are found to willfully infringe such patents, and we could be precluded from commercializing any product candidates that were ultimately held to infringe such patents. Any potential future legal proceedings relating to these patents could cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. If we are unsuccessful in our challenges to these patents and become subject to litigation or are unable to obtain a license on commercially reasonable terms with respect to these patents, it could harm our business.

Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that third-party patents asserted against us are valid, enforceable and infringed, which could adversely affect our ability to commercialize any product candidates we may develop, and any other product candidates or technologies covered by the asserted third- party patents. To successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, and we are unsuccessful in demonstrating that such rights are invalid or unenforceable, we could be required to obtain a license from such a third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease commercializing the infringing technology or product candidates. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties and other fees, redesign our infringing drug or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Any of the foregoing events would harm our business.

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

Many of our employees were previously employed at other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. Litigation may be necessary to defend against these claims.

In addition, we or our future licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or any future in-licensed patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives, develops or reduces to practice intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs, delay development of our product candidates and be a distraction to management. Any of the foregoing events would harm our business.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to initiate anticipated clinical trials, continue our research programs, license necessary technology from third parties or enter into development collaborations that would help us commercialize our product candidates, if approved. Any of the foregoing events would harm our business.

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

We rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information and to maintain our competitive position. Trade secrets and know-how can be difficult to protect. We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed.

We may not be able to protect and enforce our trademarks and trade names, or build name recognition in our markets of interest thereby harming our competitive position.

We intend to rely on both registered and common law rights for our trademarks. We plan to apply to register these trademarks with the USPTO and may in the future seek to register additional trademarks in the United States and other countries. Our trademark applications may not be allowed for registration in a timely fashion or at all, and our future registered trademarks may not be maintained or enforced. In addition, any registered or unregistered trademarks or trade names that we own or will own may be challenged, infringed, circumvented, declared generic, lapsed or determined to be infringing on or dilutive of other marks. We may not be able to protect our rights in these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. In addition, third parties have filed, and may in the future file, for registration of trademarks similar or identical to our trademarks, thereby impeding our ability to build brand identity and possibly leading to market confusion. If they succeed in registering or developing common law rights in such trademarks, and if we are not successful in challenging such rights, we may not be able to use these trademarks to develop brand recognition of our technologies, products or services. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names.

During the trademark registration process, we may receive Office Actions from the USPTO or from comparable agencies in foreign jurisdictions objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. 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/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may in the future be filed against our trademark applications or registrations, and our trademark applications or registrations may not survive such proceedings. In addition, third parties may file first for our trademarks in certain countries. If they succeed in registering such trademarks, and if we are not successful in challenging such third-party rights, we may not be able to use these trademarks to market our products in those countries. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, which could harm our business.

Intellectual property rights do not necessarily address all potential threats.

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

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

Should any of these events occur, they could harm our business.

Risks Related to our Business Operations and Employee Matters

In 2023, we reduced the size of our organization, and we may encounter difficulties in managing this restructuring, which could disrupt our operations.

In February 2023, we commenced certain restructuring actions (the Restructuring Plan) to conserve financial resources and better align our workforce with current business needs, as a result of the decision to pause development of ETX-155 and focus on our preclinical Kv7.2/3 program. In July 2023, we made the determination to pause further development of our Kv7 program and to conduct a comprehensive exploration of strategic alternatives focused on maximizing stockholder value. In October 2023, we reduced our workforce by an additional 10 employees.

The workforce reduction that accompanied our strategic realignment has resulted in the loss of longer-term employees, the loss of institutional knowledge and expertise and the reallocation and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations. The restructuring and possible additional cost containment measures may yield unintended consequences, such as attrition beyond our intended workforce reduction and reduced employee morale. In addition, we may not achieve anticipated benefits from the workforce reduction. Due to our limited resources, we may not be able to effectively manage our operations or recruit and retain qualified personnel, which may result in weaknesses in our infrastructure and operations, risks that we may not be able to comply with legal and regulatory requirements, and loss of employees and reduced productivity among remaining employees. If our management is unable to effectively manage this transition and workforce reduction and additional cost containment measures, our expenses may be more than expected and we may not be able to implement our business strategy. As a result, our future financial performance and our ability to commercialize our future product candidates successfully would be negatively affected.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or unauthorized activities that violates (1) the laws and regulations of the FDA, the EMA, the MHRA and other similar regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, (3) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad and (4) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product candidates, which could result in regulatory sanctions and harm our reputation.

We have adopted a code of business conduct and ethics, but 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 or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm and the delay, reduction, termination or restructuring of our operations.

Our international operations in the U.K. may expose us to business, regulatory, political, operational, financial, pricing and reimbursement risks associated with doing business outside of the United States.

Our business is subject to risks associated with conducting business internationally. Some of our suppliers, industry partners and clinical study centers are located outside of the United States. Furthermore, our business strategy incorporates potential international expansion as we seek to obtain regulatory approval for, and commercialize, our product candidates in patient populations outside the United States. If approved, we may hire sales representatives and conduct physician and patient association outreach activities outside of the United States. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations, including those related to Brexit related changes, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries; rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- delays or interruptions in the supply of clinical trial materials resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- additional potentially relevant third-party patent and other intellectual property rights;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our product candidates and exposure to foreign currency exchange rate fluctuations;
- currency exchange rate fluctuations and the resulting effect on our revenue and expenses and the cost and risk of entering into hedging transactions if we chose to do so in the future;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, including related public health guidance measures, boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel and insurance; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or its anti- bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries.

Any of these factors could harm our future international expansion and operations and, consequently, our results of operations.

We may not be able to utilize a significant portion of our net operating loss carryforwards.

As of December 31, 2023, we had net operating loss carryforwards of approximately $13.1 million for federal income tax purposes, $55.5 million for foreign income tax purposes and $8.3 million for state income tax purposes. The federal net operating loss may be used up to 80% of future taxable income while the state and foreign losses may be used to offset up to 100% of future taxable income. The federal net operating loss carryforward can be carried forward indefinitely while the state net operating loss carryforward will begin to expire in varying amounts in 2038. The net operating loss carryforwards subject to expiration could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Cuts and Jobs Act (Tax Act), as modified by the Coronavirus Aid, Relief and Economic Security Act (CARES Act), federal net operating losses incurred in taxable years beginning after December 31, 2017 and in future taxable years may be carried forward indefinitely, but the deductibility of such federal net operating losses in taxable years beginning after December 31, 2020 is limited.

Separately, under Section 382 of the Internal Revenue Code of 1986, as amended, (Internal Revenue Code), and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50 percentage point change, by value, in its equity ownership by certain stockholders over a rolling three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. The completion of our IPO, together with private placements and other transactions that have occurred since our inception, may trigger such an ownership change pursuant to Section 382 of the Internal Revenue Code. We have not completed a Section 382 analysis, and therefore, there can be no assurances that the NOLs carryforward are not already limited.

In addition, we may experience ownership changes due to subsequent shifts in our stock ownership, some of which may be out of our control. If an ownership change occurs and our ability to use our NOL carryforwards is materially limited, it could harm our future operating results by effectively increasing our future tax obligations.

We may seek to grow our business through acquisitions or investments in new or complementary businesses, products or technologies, through the licensing of products or technologies from third parties or other strategic alliances, and the failure to manage acquisitions, investments, licenses or other strategic alliances, or the failure to integrate them with our existing business, could have a material adverse effect on our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing clinician and patients' needs, competitive technologies and market pressures. Accordingly, from time to time we may consider opportunities to acquire, make investments in or license other technologies, products and businesses that may enhance our capabilities, complement our existing products and technologies or expand the breadth of our markets or customer base. Potential and completed acquisitions, strategic investments, licenses and other alliances involve numerous risks, including:

- difficulty assimilating or integrating acquired or licensed technologies, products, employees or business operations; issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions or strategic alliances, including the assumption of unknown or contingent liabilities and the incurrence of debt or future write-offs of intangible assets or goodwill;
- diversion of management's attention from our core business and disruption of ongoing operations;
- adverse effects on existing business relationships with suppliers, sales agents, health care facilities, surgeons and other health care providers;
- risks associated with entering new markets in which we have limited or no experience;
- potential losses related to investments in other companies;
- potential loss of key employees of acquired businesses; and
- increased legal and accounting compliance costs.

We do not know if we will be able to identify acquisitions or strategic relationships we deem suitable, whether we will be able to successfully complete any such transactions on favorable terms, if at all, or whether we will be able to successfully integrate any acquired business, product or technology into our business or retain any key personnel, suppliers, sales agent, health care facilities, physicians or other health care providers. Our ability to successfully grow through strategic transactions depends upon our ability to identify, negotiate, complete and integrate suitable target businesses, technologies or products and to obtain any necessary financing. These efforts could be expensive and time-consuming and may disrupt our ongoing business and prevent management from focusing on our operations.

If we pursue any foreign acquisitions, they typically involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures, languages and legal and regulatory environments, currency risks and the particular economic, political and regulatory risks associated with specific countries.

To finance any acquisitions, investments or strategic alliances, we may choose to issue shares of our common stock as consideration, which could dilute the ownership of our stockholders. For example, in connection with the closing of the Proposed Transaction, a concurrent private placement of our common stock would be effected at or as of immediately after the closing of the Proposed Transaction pursuant to binding subscription agreements to be entered into concurrently with the execution of a definitive agreement with respect to the Proposed Transaction, in an aggregate amount to be mutually determined by the parties.

If the price of our common stock is low or volatile, we may be unable to consummate any acquisitions, investments or strategic alliances using our common stock as consideration. Additional funds may not be available on terms favorable to us, or at all.

Risks Related to our Common Stock

The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could incur substantial losses.

Our stock price has been volatile, fluctuating from a high trading price of $29.69 per share in August 2021 to a low trading price of $2.21 in February 2023. The stock market in general and the market for biotechnology companies in particular have also experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may continue to be volatile in the future and may be influenced by many factors, including:

- adverse regulatory decisions;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- the commencement, enrollment or results of any future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results from, delays in or termination of our clinical trials or those of our competitors;
- unanticipated serious safety concerns related to the use of our product candidates;
- lower than expected market acceptance of our product candidates following approval for commercialization;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the pharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of strategic transactions, significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- actions by institutional or activist investors;
- changes to our business, including pipeline reprioritizations and restructurings;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;

- disputes or other developments relating to intellectual property rights, including patents, litigation matters and our ability to obtain, maintain, defend, protect and enforce patent and other intellectual property rights for our technologies;
- threats of or actual significant lawsuits, including patent or stockholder litigation;
- proposed changes to healthcare laws in the United States or foreign jurisdictions, or speculation regarding such changes;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock, in particular following significant drops in stock price. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business. In addition, in the current volatile market for biotechnology stocks, in particular where shares are trading below cash balances, certain biotechnology investors have advocated for increases in short-term stockholder value through proposed corporate actions such as financial restructurings, special dividends, stock repurchases, mergers, other business combinations or sales of assets. Any such proposals directed at us could cause us to incur substantial costs and divert management's attention and resources from our business.

A significant portion of our common stock may be sold into the market, which could cause the market price of our common stock to drop significantly.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

We have registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. In connection with the Restructuring Plan, we accelerated vesting of certain outstanding and unvested equity awards held by terminated employees, including our former chief executive officer and other executives. As a result, a greater number of shares of common stock will be available for sale in the public market earlier than would have been the case if the Restructuring Plan had not been implemented.

Additionally, the holders of an aggregate of 15.7 million shares of our common stock, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market without limitation. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of our company more difficult, limit attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as currently in effect, may have the effect of delaying or preventing a change of control or changes in our management. Our amended and restated certificate of incorporation and amended and restated bylaws include provisions that:

- provide for a classified board of directors whose members serve staggered terms;
- authorize our board of directors to issue, without further action by the stockholders, shares of undesignated preferred stock with terms, rights and preferences determined by our board of directors that may be senior to our common stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, the chairperson of our board of directors or our chief executive officer;

- establish an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors;
- prohibit cumulative voting in the election of directors;
- provide that our directors may be removed for cause only upon the vote of the holders of at least 66 2/3% of our outstanding shares of common stock;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; and
- require the approval of our board of directors or the holders of at least 66 2/3% of our outstanding shares of common stock to amend our bylaws and certain provisions of our certificate of incorporation.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (DGCL), which generally, subject to certain exceptions, prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder. Any delay or prevention of a change of control transaction or changes in our management could cause the market price of our common stock to decline.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.

We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions and also reduces the public float for our common stock.

Based upon our common stock outstanding as of December 31, 2023, our executive officers, directors and current beneficial owners of 5% or more of our common stock, in the aggregate, beneficially own approximately 89.2% of our outstanding common stock. These stockholders, acting together, are able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. The interests of this group of stockholders may not coincide with the interests of other stockholders.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the price at which shares were sold in the IPO and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

In addition, as a result of this concentration of ownership, there is a limited number of number of shares of our common stock that are not held by officers, directors and controlling stockholders (which is referred to as our public float), thereby adversely impacting the liquidity of our common stock and potentially depressing the price at which you may be able to sell shares of common stock.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

Prior to the completion of the IPO, we were a private company with limited accounting personnel to adequately execute our accounting processes and other supervisory resources with which to address our internal control over financial reporting. In connection with the preparation of our consolidated financial statements for the year ended December 31, 2020, we identified material weaknesses in our internal control over financial reporting, two of which remain unremediated as of December 31, 2023. The unremediated material weaknesses, and our remediation plan, are disclosed in Item 9A of this Annual Report on Form 10-K.

We believe we have made substantial progress toward achieving the effectiveness of our internal control over financial reporting and disclosure controls and procedures. The actions that have been taken are subject to continued review and testing by management as well as oversight by the audit committee of our board of directors. We will not be able to conclude whether the steps we have taken will fully remediate these material weaknesses in our internal control over financial reporting until we have completed our remediation efforts and subsequent evaluation of their effectiveness.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (Exchange Act), the Sarbanes-Oxley Act and the rules and regulations of the Nasdaq Stock Market. Section 302 of the Sarbanes-Oxley Act requires, among other things, that we report on the effectiveness of our disclosure controls and procedures in our quarterly and annual reports and Section 404 of the Sarbanes-Oxley Act requires that we perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Form 10-K filings.

We cannot assure you that the measures we have taken to date, and are continuing to implement, or any measures we may take in the future, will be sufficient to identify or prevent future material weaknesses. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting in our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company or a smaller reporting company with less than $100 million in revenue.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the Nasdaq Stock Market, the SEC or other regulatory authorities. In addition, our common stock may not be able to remain listed on the Nasdaq Stock Market or any other securities exchange.

Our amended and restated certificate of incorporation designates the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America as the exclusive forums for substantially all disputes between us and our stockholders, which restricts our stockholders' ability to choose the judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of claims or causes of action under Delaware statutory or common law: any derivative claims or causes of action brought on our behalf; any claims or causes of action asserting a breach of a fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. In addition, our amended and restated certificate of incorporation provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. These choice of forum provisions will not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Such provisions are intended to benefit and may be enforced by us, our officers and directors, employees and agents, including the underwriters for any offering giving rise to such complaint and any other professional or entity who has prepared or certified any part of the document underlying the offering and may result in increased costs for stockholders to bring a claim.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits with respect to such claims or make such lawsuits more costly for stockholders, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find either choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

General Risk Factors

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

Unless and until we can generate a substantial amount of revenue from our product candidates, we may finance our future cash needs through public or private equity offerings, debt financings, collaborations, licensing arrangements or other sources, or any combination of the foregoing. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, your ownership interest may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a common stockholder. In addition, debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business.

In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates. Additional capital may not be available to us, or even if it is, the cost of such capital may be high. We may be forced to obtain additional capital before reaching clinical or regulatory milestones, when our stock price or trading volume or both are low, or when the general market for life sciences companies is weak. Raising capital under any of these or similar scenarios, if we can raise any at all, may lead to significant dilution to our existing stockholders.

If we raise additional funds through collaborations or marketing, distribution, licensing and royalty arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may 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.

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. As a newly public company, we may have limited equity analyst coverage. 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 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 our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

Unfavorable global economic conditions could adversely affect our business, financial condition, stock price, and results of operations.

The global credit and financial markets have experienced extreme volatility and disruptions (including as a result of actual or perceived changes in interest rates, inflation and macroeconomic uncertainties), which has included severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, high inflation, uncertainty about economic stability, and increases in unemployment rates. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine and Israel and Hamas, terrorism, or other geopolitical events. Sanctions imposed by the U.S. and other countries in response to such conflicts, including the one in Ukraine, may also continue to adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including a decrease in the demand for our drug candidates and in our ability to raise additional capital when needed on acceptable terms, if at all. In addition, current inflationary trends in the global economy may impact salaries and wages, costs of goods and transportation expenses, among other things, and recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures may create market and economic instability. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business.

If our information technology systems or data, or those of third parties upon which we rely, such as CROs, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.

In the ordinary course of our business, we may collect, store, use, transmit, disclose, or otherwise process proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and trade secrets.

Cyberattacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity and availability of our data and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to increase, and are becoming increasingly difficult to detect. These threats come from a variety of sources. In addition to traditional computer "hackers," threat actors, "hacktivists", organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors now engage in attacks. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties upon which we rely, such as CROs, may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may become increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, geopolitical developments, earthquakes, fires, floods, and other similar threats. Ransomware attacks are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

We may rely upon third-party service providers and technologies to operate critical business systems to process confidential information and personal data in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email and other functions. Our ability to monitor these third parties' cybersecurity practices is limited, and these third parties may not have adequate information security measures in place. We may share or receive sensitive data with or from third parties, and if they experience a security incident or other interruption, we could experience adverse consequences. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been affected. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

Our remote workforce poses increased risks to our information technology systems and data, as more of our personnel work from home, utilizing network connections outside our premises. Future business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our data or our information technology systems, or those of the third parties upon whom we rely. If such an event were to occur, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also harm our business.

We may expend significant resources or modify our business activities (including future clinical trial activities) to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and data. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps to detect and remediate vulnerabilities but we may be unable in the future to detect and remediate vulnerabilities because such threats and techniques change frequently, are often sophisticated in nature, and therefore may not be detected until after a security incident has occurred. These vulnerabilities therefore may pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary expenditures; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause delays in the development of our product candidates and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient of protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

We are an "emerging growth company" and a "smaller reporting company," and as a result of the reduced reporting requirements applicable to "emerging growth companies" and "smaller reporting companies," our common stock may be less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an "emerging growth company," we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We may take advantage of these exemptions until we are no longer an "emerging growth company." We could be an "emerging growth company" for up to five years, although circumstances could cause us to lose that status earlier, including if the aggregate market value of our common stock held by non-affiliates exceeds $700 million as of any June 30 (the end of our second fiscal quarter) before that time, in which case we would no longer be an "emerging growth company" as of the following December 31 (our fiscal year-end).

We are also a "smaller reporting company," as defined in the Exchange Act. Even after we no longer qualify as an "emerging growth company," we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements. We cannot predict if investors will find our common stock less attractive because we may 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 the price of our common stock may be more volatile.

We may be unable to maintain adequate insurance coverage.

We presently have general liability, workers' compensation, directors' and officers' and product liability insurance coverage. Although we believe we will be able to maintain such coverage for a reasonable cost and obtain any additional coverages that our business may require, no assurances can be made that we will be able to do so.

Changes in tax laws or regulations that are applied adversely to us may seriously harm our business.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of any of our future domestic and foreign earnings. Any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us.

In addition, we are a "small or medium-sized enterprise" (SME) as defined under U.K. corporate tax regulations. We may continue to rely on U.K. research and development tax credits and incentives that are available to SMEs as a source of capital for our business. Changes in the SME eligibility criteria by the U.K. government or changes in our business could prevent us from being eligible for these tax credits in the future. Further, in November 2022, the U.K. government announced changes to the research and development tax credit program; these changes, which included a reduction in tax credit rates for SMEs, were effective on April 1, 2023. Changes such as these reduce the amount of capital we obtain from recoverable U.K. research and development tax credits, which could also harm our business.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity

Risk Management and Strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and data related to participants in preclinical studies and clinical trials involving certain of our product candidates. (Information Systems and Data).

Members of our management team, with the assistance of third-party technical advisors, help identify, assess and manage our cybersecurity threats and risks. Our third-party technical advisors include consultants with over 20 years of experience in IT leadership as well as subject matter experts in cybersecurity that have extensive experience managing cybersecurity programs.

We manage, identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment and risk profile using various methods including, for example: through the use of automated tools, including but not limited to tools for monitoring, remote wiping, threat detection, intrusion detection and prevention; conducting (through third parties) regular audits and threat assessments for internal and external threats; subscribing to reports and services that identify cybersecurity threats; analyzing reports of threats and actors; conducting vulnerability assessments to identify vulnerabilities; evaluating our and our industry's risk profile; and evaluating threats reported to us.

Depending on the environment, we implement and maintain various processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: risk assessments, implementation of security standards and certifications, encryption of data in transit and at rest, network security controls, data segregation, access controls, systems monitoring, vendor risk management program, employee training and penetration testing.

As part of our cybersecurity risk management program, we maintain processes to assess and review the cybersecurity practices of third-party vendors and suppliers. Prior to engaging key third-party vendors and suppliers, we conduct a security assessment and, as appropriate, include security requirements in contracts.

We, like other companies in our industry, face cybersecurity risks in connection with our business. However, our business strategy, results of operations, and financial condition have not, to date, been materially affected by risks from cybersecurity threats. For more information on our cybersecurity related risks, see "Risk Factors" under Part I, Item 1A of this Annual Report.

Governance

Our board of directors considers cybersecurity risk management as part of its general oversight function. The audit committee of our board of directors is responsible for overseeing our cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our management team provides periodic updates to the audit committee regarding our cybersecurity program, including information about cyber risk management governance and status updates on various projects intended to enhance the overall cybersecurity posture of the Company.

Item 2. Properties.

We lease office space in the U.S. and U.K. under non-cancelable operating leases.

In May 2021, we entered into an agreement for office space in Cambridge, U.K. The term of this lease is for a period of 24 months, which commenced on July 1, 2021. In March 2023, we agreed to extend this lease until June 30, 2024.

In November 2021, we entered into an agreement to lease approximately 5,000 square feet of office space in Bellevue, Washington. The term of this lease is 39 months, which commenced on November 1, 2021. In July 2023, we entered into a non-cancellable sublease agreement for the Bellevue office space, which commenced in July 2023 and ends concurrently with the original lease in January 2025.

We believe that our facility arrangements are sufficient for our current needs.

Item 3. Legal Proceedings.

As of the date of this Annual Report on Form 10-K, we are not party to any material legal matters or claims. We may become party to legal matters and claims arising in the ordinary course of business. We cannot predict the outcome of any such legal matters or claims, and despite the potential outcomes, the existence thereof may have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

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 listed on the Nasdaq Global Market under the symbol "ELYM" since August 10, 2021. Prior to that date, there was no public market for our common stock.

Holders of Common Stock

As of March 22, 2024, there were 27,719,409 shares of common stock issued and held by approximately 15 stockholders of record. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about securities authorized for issuance under our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Recent Sales of Unregistered Securities.

None.

Use of Proceeds

On August 9, 2021 our Registration Statement on Form S-1, as amended (File No. 333-257980), was declared effective in connection with our initial public offering (IPO), pursuant to which we sold an aggregate of 7,360,000 shares of our common stock, including the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $12.50 per share.

The IPO closed on August 12, 2021, and the aggregate net proceeds were $83.1 million. In connection with our IPO, no payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates or to our affiliates. We intend to use the proceeds from our IPO to fund working capital and other general corporate activities, although the specific use of proceeds will depend in part on the outcome of our process exploring strategic alternatives.

Issuer Purchases of Equity Securities

Not applicable.

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 together with our consolidated financial statements and related notes included in "Item 8. Financial Statements and Supplementary Data." in this Annual Report on Form 10-K. The following discussion contains forward-looking statements that involve risks and uncertainties. For a complete discussion of forward-looking statements, see the section above titled "Special Note Regarding Forward Looking Statements." Our actual results could differ materially from those expressed or implied in any forward-looking statements as a result of various factors, including those set forth under the caption "Item 1A. Risk Factors."

Overview

We are a biotechnology company focused on developing novel therapies for neuronal excitability disorders to address unmet needs in psychiatry, epilepsy, chronic pain, and other disorders of the peripheral and central nervous systems.

Prior to July 2023, our lead program was ETX-123, a Kv7.2/3 potassium channel opener. ETX-123 is designed to harness the efficacy of the Kv7.2/3 channel mechanism while attempting to improve the safety and tolerability relative to earlier molecules, based on our insights into the mechanisms of toxicity and the potency and selectivity profile.

In July 2023, we made the determination to pause further development of our Kv7 program and to conduct a comprehensive exploration of strategic alternatives focused on maximizing stockholder value. As part of that effort, we are exploring a variety of options, including seeking a partner for further development of both Kv7 and ETX-155. We formed a Special Committee of independent and disinterested directors to oversee our exploration of strategic alternatives.

As a part of this process, our representatives and a development stage private biotechnology company (who we refer to as Tango), which is majority-owned by funds affiliated with RA Capital, have recently engaged in preliminary discussions in an effort to determine whether a potential transaction between the two companies could be mutually beneficial. On March 14, 2024, Tango submitted a Non-Binding Term Sheet, which contemplates that we would acquire Tango through a transaction whereby we would issue common stock to Tango's equityholders in exchange for all of the outstanding equity of Tango, and Tango would become our wholly owned subsidiary. As of March 14, 2024, entities affiliated with RA Capital beneficially owned approximately 47.5% of our outstanding common stock.

The terms of the Non-Binding Term Sheet include, without limitation:

- The proposed exchange ratio would value our company initially at $110 million as of the closing of the Proposed Transaction, while Tango would initially be valued at $20 million;
- In connection with the closing of the Proposed Transaction, a concurrent private placement of our common stock would be effected at or as of immediately after the closing pursuant to binding subscription agreements to be entered into concurrently with the execution of a definitive agreement with respect to the Proposed Transaction in an aggregate amount to be mutually determined by the parties. We currently anticipate that funds affiliated with RA Capital would purchase some portion of the securities to be issued in the Concurrent Investment;
- That after giving effect to the closing of the Proposed Transaction (but before giving effect to the Concurrent Investment), (i) the equityholders of Tango immediately prior to the closing (including all options, convertible securities and warrants) would own 15.4% of the equity of our company on a fully diluted basis and (ii) our equityholders (including all outstanding equity awards) would own 84.6% of the equity of our company on a fully diluted basis (calculated via the treasury stock method); and
- The post-closing board of directors of our company would consist of seven directors, the composition of which would satisfy applicable U.S. Securities and Exchange Commission (SEC) and Nasdaq listing requirements, and that the specific composition of the board of directors would be determined by the parties during negotiation of a definitive agreement.

The Non-Binding Term Sheet is non-binding, and there can be no assurance that any definitive agreement will result from the Non-Binding Term Sheet or that any transaction with Tango or any other third party will be consummated. The Non-Binding Term Sheet, and the Proposed Transaction contemplated thereby, are subject to various conditions, including but not limited to, (i) the satisfactory completion of due diligence by both parties, (ii) the negotiation and execution of a definitive agreement and the satisfaction of the conditions negotiated therein, (iii) the approval and recommendation of the Proposed Transaction by the Special Committee, and (iv) a non-waivable condition requiring approval of our stockholders holding a majority of the voting power of the outstanding shares of our company not held by RA Capital or its affiliates. As the parties continue to negotiate the terms of the Proposed Transaction, it is possible that, through these negotiations, the proposed terms of the Proposed Transaction may change, including as a result of the ongoing diligence efforts of both parties, market conditions and other factors. There can be no guarantee that the parties will ever reach a definitive agreement with respect to the Proposed Transaction and either party may determine to abandon the Proposed Transaction at any time for any reason, including the parties' respective beliefs regarding the preferability of the Proposed Transaction to other alternatives that may be available to them, as well as other factors.

There can be no assurance that this strategic review process will result in us continuing to pursue any transaction, including the Proposed Transaction, or that any transaction, if pursued, will be completed on attractive terms or at all. We have not set a timetable for completion of this strategic review process, and our board of directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value or that we will make any additional cash distributions to our stockholders.

In February 2023, we paused further investment in the development of our clinical-stage program, ETX-155. Based on our preclinical and clinical work to date, ETX-155 has the potential to be pursued for the treatment of major depressive disorder (MDD), epilepsy and anxiety disorders. We have received clearance of our IND application filed with the psychiatry division of the FDA to support a potential Phase 2 clinical trial in MDD that may be conducted in the future by Eliem or a strategic partner.

We have incurred significant operating losses since inception, as we have devoted substantially all of our resources to organizing and staffing our company, identifying potential product candidates, business planning, raising capital, undertaking research, executing preclinical studies and clinical development trials, and providing general and administrative support for business activities. We incurred net losses of $35.1 million and $45.2 million for the years ended December 31, 2023 and 2022, respectively. We had an accumulated deficit of $156.0 million and $120.9 million as of December 31, 2023 and December 31, 2022, respectively.

Since our inception, we have primarily funded our operations with an aggregate of $208.3 million in net proceeds from the sale and issuance of shares of our redeemable convertible preferred stock and our initial public offering of our common stock, and to a lesser extent from cash received pursuant to U.K. research and development tax credits and incentives. We had cash, cash equivalents and marketable securities of $106.8 million and $123.6 million as of December 31, 2023 and December 31, 2022, respectively. Based on our current operating plan, we estimate that our cash, cash equivalents and marketable securities will be sufficient to fund our planned operations through at least 12 months following the date of this filing.

If a strategic transaction is not consummated and/or if product development is resumed, we will require substantial additional funding to support our continuing operations. Until such time as we can generate significant revenue from product sales, if ever, we may finance our operations through the sale of equity, debt financings or other capital sources, which could include income from collaborations, strategic partnerships or other strategic arrangements. Adequate funding may not be available when needed or on terms acceptable to us, or at all. If we are unable to raise additional capital as needed, we may have to significantly delay, scale back or discontinue any future development of our product candidates. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide, resulting from increased volatility in the trading prices for shares in the biopharmaceutical industry, the ongoing pandemic, or otherwise. In addition, our ability to continue to benefit from research and development tax credits and incentives will depend on our ability to continue meet the applicable requirements for them. If we fail to obtain necessary capital when needed on acceptable terms, or at all, it could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose.

We do not have any products approved for sale and have not generated any revenue from product sales since our inception. To the extent we continue to pursue clinical development of any future product candidate, our ability to generate product revenue will depend on the successful development, regulatory approval and eventual commercialization of one or more of our product candidates, if approved. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities. We expect to continue to incur operating losses for the foreseeable future as we continue to explore strategic alternatives.

Restructuring Costs

On February 7, 2023, our board of directors approved a restructuring plan (the Restructuring Plan) to conserve financial resources and better align our workforce with current business needs, as a result of the decision to pause development of ETX-155 and focus on our preclinical Kv7.2/3 program. As part of the Restructuring Plan, our workforce was reduced by approximately 55%, with substantially all of the reduction in personnel completed in the first half of 2023.

We further reduced our workforce by 10 employees in October 2023. We incurred additional restructuring costs of $2.0 million in the fourth quarter of 2023 associated with this reduction.

During the year ended December 31, 2023, we recorded restructuring costs of $18.8 million, which is comprised of the following:

	Year Ended December 31, 2023			
	ROU Asset Impairment	Severance and Benefits Costs	Stock-based Compensation	Total Restructuring Cost Recorded
General and administrative expense	$ 180	$ 6,089	8,707	$ 14,976
Research and development expense	—	2,894	939	3,833
Total restructuring costs	$ 180	$ 8,983	$ 9,646	$ 18,809

We expect to incur aggregate restructuring costs of approximately $18.9 million. The remaining costs of $0.1 million are expected to be recognized in the first quarter of 2024.

Components of Operating Results

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and Development

Our research and development expenses consist primarily of direct and indirect costs incurred in connection with our discovery efforts, preclinical studies, and clinical trial activities related to our pipeline, including our recently paused product candidates ETX-123 and ETX-155, as well as our discontinued product candidate ETX-810.

Our direct research and development costs include:

- expenses incurred in connection with research, laboratory consumables and preclinical and clinical trial activities;
- the cost to manufacture drug products for use in our preclinical studies and clinical trials; and
- consulting fees

Our indirect research and development costs include:

- personnel-related expenses such as salaries, bonuses, benefits, stock-based compensation expense, and termination benefits, for our scientific personnel performing research and development activities; and
- facility rent.

Total direct costs and indirect costs are as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Direct costs	$ 6,125	$ 24,471
Indirect costs	11,257	8,426
Research and development tax credits	(1,971)	(6,683)
Total research and development expenses	$ 15,411	$ 26,214

We expense research and development costs as incurred. Non-refundable advance payments for goods and services that will be used over time for research and development are capitalized and recognized as goods are delivered or as the related services are performed.

We categorize costs by stage of development clinical or preclinical. Given our stage of development and the utilization of our resources across our various programs, we have not historically tracked our research and development costs by program. Research and development expenses are presented net of refundable research and development tax credits from the U.K. government.

Research and development costs by stage of development are as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Clinical	$ 5,971	$ 22,199
Preclinical	$ 7,578	10,698
Restructuring costs	$ 3,833	—
Research and development tax credits	$ (1,971)	(6,683)
Total research and development expenses	$ 15,411	$ 26,214

General and Administrative

Our general and administrative expenses consist primarily of personnel-related expenses such as salaries, bonuses, benefits, stock-based compensation, and termination benefits, for our personnel in executive, finance and accounting, human resources, business development and other administrative functions. Other significant general and administrative expenses include legal fees relating to intellectual property and corporate matters, professional fees for accounting, audit, regulatory, tax and consulting services, insurance costs, as well as investor and public relations costs.

Other Income (Expense)

Foreign Currency Gain (Loss)

Our foreign currency gain (loss) consists of foreign exchange losses resulting from remeasurement and foreign currency transactions between the British Pound and the U.S. Dollar.

Interest Income, net

Our interest income consists of interest earned on our cash, cash equivalents and short-term investments and adjustments related to amortization of purchase premiums and accretion of discounts of marketable securities.

Results of Operations

The following table summarizes our results of operations for the years ended December 31, 2023 and 2022 (dollars in thousands):

	Year Ended December 31,		Change	
	2023	2022	$	%
Operating expenses:				
Research and development	$ 15,411	$ 26,214	$ (10,803)	(41.2)%
General and administrative	24,864	18,921	5,943	31.4%
Total operating expenses	40,275	45,135	(4,860)	(10.8)%
Loss from operations	(40,275)	(45,135)	4,860	(10.8)%
Other income (expense):				
Foreign currency gain (loss)	536	(1,484)	2,020	(136.1)%
Interest income, net	4,620	1,375	3,245	236.0%
Total other income (expense)	5,156	(109)	5,265	*
Net loss	$ (35,119)	$ (45,244)	$ 10,125	(22.4)%

* - % Not meaningful

Comparison of the Years Ended December 31, 2023 and 2022

Operating Expenses

Research and Development

Research and development expenses decreased 41.2% from $26.2 million for the year ended December 31, 2022 to $15.4 million for the year ended December 31, 2023. The decrease was driven by an $18.3 million decrease in direct clinical and preclinical expenses, primarily due to the pause of ETX-155 in February 2023 and the discontinuation of ETX-810 in August 2022. This decrease was partially offset by (i) a $2.8 million increase in personnel-related expenses, primarily driven by restructuring costs of $3.8 million, partially offset by a decrease of $1.0 million from reduced headcount and (ii) a $4.7 million decrease in the U.K. refundable research and development tax credits due to the overall reduction in qualifying research and development expenses and a reduction in tax credit rates.

General and Administrative

General and administrative expenses increased 31.4% from $18.9 million for the year ended December 31, 2022 to $24.9 million for the year ended December 31, 2023. This increase was driven by restructuring costs of $15.0 million, partially offset by (i) a decrease of $6.3 million in personnel-related expenses from reduced headcount and (ii) a $2.7 million overall decrease in other general and administrative expense, largely due to a reduction in consulting fees, legal expenses, insurance, and human resource costs.

Other Income (Expense)

Foreign Currency Gain (Loss)

Foreign currency gain (loss) increased from a $1.5 million loss for the year ended December 31, 2022 to a $0.5 million gain for the year ended December 31, 2023. The increase was driven by favorable changes in foreign currency exchange rates between the British Pound and the U.S. Dollar in the current period. These changes affect the remeasurement of our British Pound denominated monetary assets and liabilities, primarily our recoverable research and development tax credits and cash.

Interest Income, net

Interest income, net increased from $1.4 million for the year ended December 31, 2022 to $4.6 million for the year ended December 31, 2023, which was driven by an increase in investment income. The increase was due to higher returns on our investments as a result of rising interest rates in the current period.

Liquidity and Capital Resources

Sources of Liquidity

We primarily generate cash and cash equivalents from the sale of our equity securities, including common stock and redeemable convertible preferred stock, and to a lesser extent from cash received pursuant to U.K. research and development tax credits and incentives. From our inception to December 31, 2023, we raised aggregate proceeds of $208.3 million from the issuance of shares of our redeemable convertible preferred stock and from our initial public offering of our common stock. We have not generated any revenue from product sales or otherwise. We have incurred net losses from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. As of December 31, 2023 and December 31, 2022, we had cash, cash equivalents and marketable securities of $106.8 million and $123.6 million and an accumulated deficit of $156.0 million and $120.9 million, respectively.

Funding Requirements

We believe our cash, cash equivalents and marketable securities of $106.8 million as of December 31, 2023 will be sufficient to meet our projected operating requirements for at least the next twelve months following the date of this filing. Continued cash generation is highly dependent on our ability to finance our operations through the sale of equity, debt financings or other capital sources, which could include income from collaborations, strategic partnerships or other strategic arrangements. However, our resource requirements could materially change depending on the outcome of our ongoing strategic alternative review process, including to the extent we identify and enter into any potential strategic transaction.

Cash Flows

The following table summarized our cash flows (in thousands):

	Year Ended December 31,	
	2023	2022
Net cash used in operating activities	$ (20,599)	$ (37,369)
Net cash provided by investing activities	68,981	34,440
Net cash provided by financing activities	841	—

Operating activities

In 2023, net cash used in operating activities was $20.6 million. This consisted primarily of net loss of $35.1 million, which was partially offset by (i) non-cash charges of $10.8 million that consisted of stock-based compensation expense of $12.8 million, right-of-use (ROU) asset impairment expense of $0.2 million, and non-cash lease expense of $0.4 million, partially offset by accretion of discounts on investments of $2.3 million and foreign currency gain on remeasurement of $0.3 million and (ii) changes in our operating assets and liabilities that resulted in a net increase in cash of $3.7 million, primarily related to receipt of research and development tax credits from the U.K.

In 2022, net cash used in operating activities was $37.4 million. This consisted primarily of net loss of $45.2 million, which was partially offset by non-cash charges of $7.6 million that primarily related to stock-based compensation of $7.0 million, and changes in our operating assets and liabilities that resulted in a net increase in cash of $0.2 million, primarily related to research and development activities.

Investing activities

In 2023, net cash provided by investing activities was $69.0 million. This consisted of $127.4 million of proceeds received from maturities of investments in marketable securities, partially offset by purchases of $58.4 million of investments in marketable securities.

In 2022, net cash provided by investing activities was $34.4 million. This consisted of $122.4 million of proceeds received from maturities of investments in marketable securities, partially offset by purchases of $88.0 million of investments in marketable securities.

Financing activities

In 2023, net cash provided by financing activities was $0.8 million, attributable to proceeds from the exercise of stock options.

Contractual Commitments and Obligations

In the normal course of business, we enter into contracts with contract research organizations (CROs), contract development and manufacturing organizations (CDMOs), and other third parties for preclinical studies and clinical trials, research and development supplies, and other testing and manufacturing services. These contracts do not contain material minimum purchase commitments and generally provide us the option to cancel, reschedule and adjust our requirements based on our business needs, prior to the delivery of goods or performance of services. However, it is not possible to predict the maximum potential amount of future payments under these agreements due to the conditional nature of our obligations and the unique facts and circumstances involved in each agreement.

We lease various operating spaces in the U.S. and the U.K. under non-cancelable operating lease arrangements that expire on various dates through January 31, 2025. As discussed further in Note 5 in our consolidated financial statements *Commitments and Contingencies*, we entered into a non-cancellable sublease agreement for the Bellevue office space in July 2023. As of December 31, 2023, our undiscounted future minimum lease payments under non-cancelable lease agreements (net of sublease income) was approximately $0.2 million.

We estimate we will incur additional cash payments up to approximately $1.2 million for restructuring costs, which is largely expected to be paid by the first quarter of 2024.

Off Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of December 31, 2023 and December 31, 2022.

Critical Accounting Policies and Estimates

A summary of the significant accounting policies is provided in Note 2 to our consolidated financial statements.

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of consolidated financial statements requires us 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 consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Management considers an accounting estimate to be critical if:

- it requires a significant level of estimation uncertainty; and
- changes in the estimate are reasonably likely to have a material effect on our financial condition or results of operations.

We believe the following critical accounting policies and estimates describe the more significant judgments and estimates used in the preparation of our consolidated financial statements.

Stock-Based Compensation

We measure our stock-based awards granted to employees, non-employee directors, consultants and independent advisors based on the estimated grant-date fair value of the awards. We use the Black-Scholes option pricing model to estimate the fair value of our stock option awards. The Black-Scholes option pricing model requires us to make assumptions and judgments about the variables used in the calculation, including the expected term, expected volatility of our common stock, risk-free interest rate and expected dividend yield. Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation is recognized. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation recognized in future periods could be materially different.

Refer to Notes 2 and 6 in our consolidated financial statements for further details regarding the development and evaluation of the assumptions used to estimate the fair value of our stock-based awards, and the related effect of stock-based compensation expense on the consolidated financial statements.

Internal Controls over Financial Reporting

In connection with the preparation of our consolidated financial statements for the year ended December 31, 2020, we identified material weaknesses in our internal control over financial reporting, two of which remain unremediated as of December 31, 2023. The material weaknesses, and our remediation plan, are disclosed in Item 9A of this Annual Report on Form 10-K.

Emerging Growth Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act (JOBS Act). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued after the enactment of the JOBS Act until those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for emerging growth companies include presentation of only two years audited consolidated financial statements in a registration statement for an initial public offering, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to the Sarbanes-Oxley Act, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements. We have elected to use the extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that (i) we are no longer an emerging growth company or (ii) we affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act.

As a result, our consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates. We will remain an emerging growth company under the JOBS Act until the earliest of (i) the last day of our first fiscal year in which we have total annual gross revenue of $1.24 billion or more, (ii) the date on which we have issued more than $1.0 billion of non-convertible debt instruments during the previous three fiscal years, (iii) the date on which we are deemed a "large accelerated filer" under the rules of the SEC with at least $700.0 million of outstanding equity securities held by non-affiliates, or (iv) December 31, 2026.

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

As a smaller reporting company, we are not required to provide the information requested by this item pursuant to Item 305(e) of Regulation S-K.

Item 8. Financial Statements and Supplementary Data.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Eliem Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Eliem Therapeutics, Inc. and its subsidiary (the "Company") as of December 31, 2023 and 2022, and the related consolidated statements of operations and comprehensive loss, of stockholders' equity and of cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP
Seattle, Washington
March 28, 2024

We have served as the Company's auditor since 2021.

Eliem Therapeutics, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	As of December 31,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 93,112	$ 43,585
Short-term marketable securities	13,686	79,981
Prepaid expenses and other current assets	3,457	10,827
Total current assets	$ 110,255	$ 134,393
Operating lease right-of-use assets	199	471
Other long-term assets	15	128
Total assets	$ 110,469	$ 134,992
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 66	$ 750
Accrued expenses and other current liabilities	2,433	5,047
Operating lease liabilities	334	300
Total current liabilities	$ 2,833	$ 6,097
Other long-term liabilities	22	—
Operating lease liabilities, net of current portion	15	180
Total liabilities	$ 2,870	$ 6,277
Commitments and contingencies (Note 5)		
Stockholders' equity		
Common stock, $0.0001 par value per share, 250,000,000 shares authorized; 27,699,446 and 26,567,681 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	3	3
Additional paid-in capital	263,577	249,930
Accumulated other comprehensive loss	(2)	(358)
Accumulated deficit	(155,979)	(120,860)
Total stockholders' equity	$ 107,599	$ 128,715
Total liabilities and stockholders' equity	$ 110,469	$ 134,992

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

Eliem Therapeutics, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2023	2022
Operating expenses:		
Research and development	$ 15,411	$ 26,214
General and administrative	24,864	18,921
Total operating expenses	40,275	45,135
Loss from operations	(40,275)	(45,135)
Other income (expense):		
Foreign currency gain (loss)	536	(1,484)
Interest income, net	4,620	1,375
Total other income (expense)	5,156	(109)
Net loss	$ (35,119)	$ (45,244)
Net loss per share, basic and diluted	$ (1.30)	$ (1.72)
Weighted-average number of shares used to compute net loss per share, basic and diluted	26,987,122	26,311,554
Comprehensive loss:		
Net loss	$ (35,119)	$ (45,244)
Other comprehensive income (loss):		
Unrealized gain (loss) on investments, net of tax of $0	356	(235)
Comprehensive loss	$ (34,763)	$ (45,479)

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

Eliem Therapeutics, Inc.
Consolidated Statements of Stockholders' Equity
(In thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2021	26,235,317	$ 3	$ 242,939	$ (123)	$ (75,616)	$ 167,203
Vesting of restricted stock awards	154,869	—	—	—	—	—
Stock-based compensation	—	—	6,991	—	—	6,991
Other comprehensive loss	—	—	—	(235)	—	(235)
Net loss	—	—	—	—	(45,244)	(45,244)
Balance as of December 31, 2022	26,390,186	$ 3	$ 249,930	$ (358)	$ (120,860)	$ 128,715
Vesting of restricted stock awards and units	124,737	—	—	—	—	—
Exercise of stock options	1,111,512	—	841	—	—	841
Stock-based compensation	—	—	12,806	—	—	12,806
Other comprehensive income	—	—	—	356	—	356
Net loss	—	—		—	(35,119)	(35,119)
Balance as of December 31, 2023	27,626,435	$ 3	$ 263,577	$ (2)	$ (155,979)	$ 107,599

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

Eliem Therapeutics, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	As of December 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (35,119)	$ (45,244)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	12,806	6,991
Right-of-use asset impairment	180	—
Non-cash operating lease expense	405	443
Accretion of discounts and amortization of premiums on investments, net	(2,331)	(177)
Foreign currency (gain) loss from remeasurement	(304)	408
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	7,370	945
Long-term assets	115	(60)
Accounts payable	(686)	(653)
Accrued expenses and other liabilities	(2,613)	425
Long-term liabilities	22	—
Operating lease liabilities	(444)	(447)
Net cash used in operating activities	$ (20,599)	$ (37,369)
Cash flows from investing activities:		
Purchase of marketable securities	(58,449)	(87,963)
Proceeds from maturities of marketable securities	127,430	122,403
Net cash provided by investing activities	$ 68,981	$ 34,440
Cash flows from financing activities:		
Proceeds from exercise of stock options	841	—
Net cash provided by financing activities	$ 841	$ —
Effect of exchange rate changes on cash	304	(408)
Net change in cash and cash equivalents	$ 49,527	$ (3,337)
Cash and cash equivalents at beginning of period	43,585	46,922
Cash and cash equivalents at end of period	$ 93,112	$ 43,585
Supplemental disclosure of cash flow information:		
Cash paid for leases included in operating cash outflows	$ 507	$ 462
Supplemental disclosure of non-cash investing and financing activities:		
Right-of-use assets obtained in exchange for lease liabilities	$ 313	$ 915

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

Note 1. Nature of Operations and Basis of Presentation

Organization

Eliem Therapeutics, Inc. (the Company) is a biotechnology company focused on developing novel therapies for neuronal excitability disorders to address unmet needs in psychiatry, epilepsy, chronic pain, and other disorders of the peripheral and central nervous systems. The Company was incorporated on October 18, 2018 as a Delaware corporation and is headquartered in Delaware.

On February 7, 2023, the Company's board of directors approved a restructuring plan (the Restructuring Plan) to conserve financial resources and better align the Company's workforce with current business needs, as a result of the decision to pause development of ETX-155 and focus on the Company's preclinical Kv7 program. As part of the Restructuring Plan, the Company's workforce was reduced by approximately 55%, with substantially all of the reduction in personnel completed in the first half of 2023.

On July 20, 2023, the Company announced that it made the determination to pause further development of its Kv7 program and to conduct a comprehensive exploration of strategic alternatives focused on maximizing stockholder value. As part of that effort, the Company is exploring a variety of options, including seeking a partner for further development of both Kv7 and ETX-155. The Company further reduced its workforce by 10 employees in October 2023.

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements of the Company and its wholly owned subsidiary have been prepared in conformity with accounting principles generally accepted in the United States (U.S. GAAP). All intercompany transactions and balances have been eliminated in consolidation.

Liquidity

Since inception, the Company has experienced recurring losses from operations and generated negative cash flows from operations. The Company has an accumulated deficit of $156.0 million and expects to incur additional losses from operations in the future. The Company estimates the available cash, cash equivalents and marketable securities of $106.8 million as of December 31, 2023 will be sufficient to meet its projected operating requirements for at least the next twelve months from the filing date of these consolidated financial statements and the Company anticipates that it will need to raise substantial financing in the future to fund its operations.

The Company may finance future cash needs through the sale of equity, debt financings, or other capital sources, which could include income from collaborations, strategic partnerships or other strategic arrangements. There are no assurances that the Company will be able to raise sufficient amounts of funding in the future on acceptable terms, or at all.

Note 2. Summary of Significant Accounting Policies

A summary of the significant accounting policies followed by the Company in the preparation of the accompanying consolidated financial statements follows:

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect reported amounts and disclosures. Accordingly, actual results could differ from those estimates. Estimates include those related to the accrual of research and development expenses, recoverable research and development tax credits, and the valuation of stock-based awards. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could differ from those estimates.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company's cash is held by two financial institutions in the U.S. and two financial institutions in the U.K. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. The Company's deposits held in the U.S. and U.K. may exceed the Federal Depository Insurance Corporation and Financial Services Compensation Scheme, respectively, insured limits. As of December 31, 2023, the Company has investments in money market funds, U.S. Treasury securities, and government agency debt securities, which are held in a segregated account at a third-party custodian. The Company has established guidelines relative to credit ratings and maturities intended to safeguard principal balances and maintain liquidity. Through December 31, 2023, and the date of this filing, the Company has not experienced any losses on such deposits.

Comprehensive Loss

Comprehensive loss consists of net loss and unrealized gains or losses on available-for-sale investments. The Company presents comprehensive loss and its components as part of the statements of operations and comprehensive loss.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, reliance on single-source vendors and collaborators, availability of raw materials, patentability of the Company's products and processes and clinical efficacy and safety of any product the Company may develop, compliance with government regulations and the need to obtain additional financing to fund operations. Any product candidates the Company may develop in the future will require significant additional research and development efforts, including extensive preclinical studies, clinical trials, and regulatory approval, prior to commercialization. These efforts will require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance and reporting.

There can be no assurance that any future research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained or maintained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if any future product development efforts are successful, it is uncertain when, if ever, the Company will generate revenue from product sales. The Company operates in an environment of rapid technological change and substantial competition from other pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees, consultants and other third parties.

Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker (the CODM). The Company's CODM is its executive chairman who reviews financial information together with certain operating metrics principally to make decisions about how to allocate resources and to measure the Company's performance. Management has determined that the Company operates as a single operating and reportable segment. The Company's CODM evaluates financial information on a consolidated basis. As the Company operates as one operating segment, all required segment financial information is found in the consolidated financial statements.

Fair Value Measurement

Assets and liabilities recorded at fair value on a recurring basis in the consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The Company measures fair value based on a three-tier hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value as follows:

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

Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the assets or liabilities. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

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.

In determining fair value, the Company utilizes quoted market prices, or valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

There were no transfers into or out of Level 3 for any of the periods presented.

The Company's fair value measurements as of December 31, 2023 and 2022 were as follows (in thousands):

	December 31, 2023		
	Level 1	Level 2	Balance
Assets:			
Cash equivalents:			
Money market funds	$ 89,197	$ —	$ 89,197
Marketable securities:			
U.S. Treasury securities	8,962	—	8,962
U.S. government agency debt securities	—	4,724	4,724
Total marketable securities	8,962	4,724	13,686
Total assets	$ 98,159	$ 4,724	$ 102,883

	December 31, 2022		
	Level 1	Level 2	Balance
Assets:			
Cash equivalents:			
Money market funds	$ 27,472	$ —	$ 27,472
Marketable securities:			
U.S. Treasury securities	30,451	—	30,451
Commercial paper	—	29,543	29,543
Corporate bonds	—	16,626	16,626
U.S. government agency debt securities	—	3,361	3,361
Total marketable securities	30,451	49,530	79,981
Total assets	$ 57,923	$ 49,530	$ 107,453

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. As of December 31, 2023 and 2022, the Company's cash equivalents consisted of money market funds.

Investments in Marketable Securities

Marketable securities are classified as available-for-sale, primarily consisting of U.S. Treasury and government agency debt securities, commercial paper, and corporate bonds, and are reported at fair value. Unrealized holding gains and losses are reflected as a separate component of stockholders' equity in accumulated other comprehensive loss until realized. The cost of debt securities is adjusted for amortization of purchase premiums and accretion of discounts to maturity. Such amortization and accretion is included in interest income, net in the statements of operations and comprehensive loss. Realized gains and losses on the sale of these securities are recognized in interest income, net in the consolidated statement of operations and comprehensive loss. The cost of marketable securities sold is based on the specific identification method.

The Company periodically reviews its available-for-sale securities to assess for credit losses. Some of the factors considered in assessing whether an allowance for credit losses is necessary include the extent to which the fair value is less than the amortized cost basis, adverse conditions related to the security, an industry or geographic area, changes to security rating or sector credit ratings, and other relevant market data.

Research and Development Expenses

Research and development expenses consist of research and development services and personnel-related expenses such as salaries, bonuses, benefits, stock-based compensation, termination benefits, professional service fees, and other related costs such as facility rent, partially offset by fully refundable U.K. research and development tax credits.

Research and development expenses include estimates of the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. Management estimates accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known at that time. Examples of estimated accrued research and development expenses include those related to fees paid to:

- vendors in connection with preclinical development activities;
- contract research organizations (CROs) in connection with preclinical studies and clinical trials; and
- contract development and manufacturing organizations (CDMOs) in connection with the production of preclinical and clinical trial materials.

All research and development costs are expensed in the period incurred, based on the estimates of the services received and efforts expended considering a number of factors, including, progress towards completion of the research, development and manufacturing activities, invoicing to date under the contracts, communication from the CROs, CDMOs and other companies of any actual costs incurred during the period that have not yet been invoiced and the costs included in the contracts and purchase orders. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which advance payments are made or payments made to vendors will exceed the level of services provided and result in a prepayment of the expense.

Research and Development Tax Credits

The Company receives tax credits from the U.K. government based on claims made under the Small Medium Enterprises (SME) research and development tax relief program. Qualifying expenditures largely relate to research and development activities performed by third parties on our behalf, as well as employment costs for research staff and consumables incurred. The research and development tax credits are recognized when the qualifying expenditure has been incurred and there is reasonable assurance that the reimbursement will be received.

Each reporting period, the Company evaluates its eligibility for the SME program based on criteria established by HM Revenue and Customs (HMRC) and records a reduction to research and development expense for the amount of the credit estimated to be claimed based on qualifying expenses and information available at that time. The Company qualified for tax credits under the SME program for the year ended December 31, 2022 and expects to qualify for the year ending December 31, 2023.

The following table outlines the changes to the research and development tax credit receivable, including amount recognized as an offset to research and development expense, during the years ended December 31, 2023 and 2022:

	Year Ended December 31,	
	2023	2022
Balance at beginning of period	$ 6,492	$ 6,523
Recognition of credit claims	1,971	6,683
Receipt of credit claims	(7,125)	(5,462)
Foreign currency gain (loss)	686	(1,252)
Balance at end of period	$ 2,024	$ 6,492

As of December 31, 2023 and 2022, the tax credit receivable was $2.0 million and $6.5 million respectively, all of which is classified within the prepaid expenses and other current assets line item in the consolidated balance sheets.

General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel-related expenses such as salaries, bonuses, benefits, stock-based compensation, and termination benefits, for our personnel in executive, finance and accounting, human resources, business development and other administrative functions. Other significant general and administrative expenses include legal fees relating to intellectual property and corporate matters, professional fees for accounting, audit, regulatory, tax and consulting services, insurance costs, as well as investor and public relations costs. General and administrative costs are expensed as incurred.

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist primarily of receivables from refundable research and development tax credits from the U.K. government and operating expenses paid in advance.

Leases

The Company determines if a contract is or contains a lease at the inception of the contract, and classifies that lease as a finance lease if it meets certain criteria or as an operating lease when it does not. The Company reassesses if a contract is or contains a lease upon modification of the contract.

The Company leases office space in the U.S. and the U.K. under non-cancelable operating leases. Operating lease right-of-use (ROU) assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized based on the present value of lease payments over the lease term at the commencement date of the lease. ROU assets also include any initial direct costs incurred and any lease payments made at or before the lease commencement date, less any lease incentive received. The Company uses the rate implicit in the lease in determining the present value of lease payments and, if that rate is not readily determinable, the Company uses its incremental borrowing rate commensurate with the lease term based on the information available at the date of lease commencement. The incremental borrowing rate reflects the rate of interest that a lessee would have to pay to borrow, on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Short-term leases with an initial term of 12 months or less are not recorded on the balance sheet. The Company does not have material short-term lease costs. Lease expense for lease payments is recognized on a straight-line basis over the lease term. For real estate leases, the Company does not separate lease and non-lease components. The Company's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

The Company's non-lease components are primarily related to property taxes, insurance, and common area maintenance, which vary based on future outcomes, and are recognized as rent expense when incurred.

As discussed further in Note 5 to the consolidated financial statements *Commitments and Contingencies,* the Company entered into a non-cancellable sublease agreement for the Bellevue office space in July 2023. Sublease income is presented as a reduction of rent expense in the consolidated statement of operations and comprehensive loss.

Stock-Based Compensation

The Company measures its stock-based awards granted to employees, non-employee directors, consultants and independent advisors based on the estimated grant-date fair value of the awards. For awards with only service conditions, including stock options, restricted stock awards, and restricted stock units, compensation expense is recognized over the requisite service period using the straight-line method. The Company uses the Black-Scholes option pricing model to estimate the fair value of its stock option awards. The Black-Scholes option pricing model requires the Company to make assumptions and judgments about the variables used in the calculations, including the expected term, expected volatility of the Company's common stock, risk-free interest rate and expected dividend yield. As the stock-based compensation is based on awards ultimately expected to vest, it is reduced by forfeitures, which the Company accounts for as they occur.

Income Taxes

Income taxes are accounted for using the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts or existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using the enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period of enactment. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company recognizes the tax benefit from an uncertain tax position if it is more likely than not that the tax position will be sustained upon examination by the tax authorities, based on the merits of the position. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

Foreign Currency

The Company's reporting currency is the U.S. dollar. The functional currency of the Company and its subsidiary is the U.S. dollar. Monetary assets and liabilities resulting from transactions denominated in currencies other than the functional currency are remeasured in the functional currency at exchange rates prevailing at the balance sheet date, and income items and expenses are translated into U.S. dollars at the average exchange rate in effect during the period. Exchange gains and losses resulting from remeasurement and foreign currency transactions are included in the determination of net loss.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period, adjusted for outstanding shares that are subject to repurchase.

Diluted net loss per share is computed by giving effect to all potentially dilutive securities outstanding for the period using the treasury stock method or the if-converted method based on the nature of such securities. For periods in which the Company reports net losses, diluted net loss per share is the same as basic net loss per share, because potentially dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Emerging Growth Company Status

The Company is an emerging growth company (EGC), as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued after the enactment of the JOBS Act until those standards apply to private companies. The Company has elected to avail itself of this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Recently Adopted Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The standard changes how entities measure credit losses for most financial assets, including accounts and notes receivables. The standard replaces today's "incurred loss" approach with an "expected loss" model, under which companies recognize allowances based on expected rather than incurred losses. Entities are required to apply the standard's provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective. Based on the Company's status as an EGC, the Company follows the adoption calendar for non-public companies and as such, the effective date of this update is for fiscal years beginning after December 15, 2022 and interim periods therein. The Company adopted ASU 2016-13 on January 1, 2023, which did not have a material impact on its consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging —Contracts in Entity's Own Equity (Subtopic 815-40)—Accounting For Convertible Instruments and Contracts in an Entity's Own Equity*. The standard simplifies accounting for convertible instruments by removing major separation models required under current GAAP. Consequently, more convertible debt instruments will be reported as a single liability instrument with no separate accounting for embedded conversion features. ASU 2020-06 removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, which will permit more equity contracts to qualify for it. The standard also simplifies the diluted net income per share calculation in certain areas. The effective date of this update for non-public companies is for fiscal years beginning after December 15, 2023, including interim periods therein. Early adoption is permitted for fiscal years beginning after December 15, 2020 and interim periods therein. The Company estimates that adoption will not have a material impact on its consolidated financial statements.

In November 2023, the FASB issued ASU No. 2023-07 (ASU 2023-07), *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* which requires, among other things, the following: (i) enhanced disclosures about significant segment expenses that are regularly provided to the CODM and included in a segment's reported measure of profit or loss; (ii) disclosure of the amount and description of the composition of other segment items, as defined in ASU 2023-07, by reportable segment; and (iii) reporting the disclosures about each reportable segment's profit or loss and assets on an annual and interim basis. The provisions of ASU 2023-07 are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024; early adoption is permitted. The Company expects ASU 2023-07 to require additional disclosures in the notes to its consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09 (ASU 2023-09), *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires, among other things, the following for public business entities: (i) enhanced disclosures of specific categories of reconciling items included in the rate reconciliation, as well as additional information for any of these items meeting certain qualitative and quantitative thresholds; (ii) disclosure of the nature, effect and underlying causes of each individual reconciling item disclosed in the rate reconciliation and the judgment used in categorizing them if not otherwise evident; and (iii) enhanced disclosures for income taxes paid, which includes federal, state, and foreign taxes, as well as for individual jurisdictions over a certain quantitative threshold. The amendments in ASU 2023-09 eliminate the requirement to disclose the nature and estimate of the range of the reasonably possible change in unrecognized tax benefits for the 12 months after the balance sheet date. The effective date of this update for non-public companies is for fiscal years beginning after December 15, 2025; early adoption is permitted. The Company expects ASU 2023-09 to require additional disclosures in the notes to its consolidated financial statements.

There were no other significant updates to the recently issued accounting standards other than as disclosed herewith for the year ended December 31, 2023. Although there are several other new accounting pronouncements issued or proposed by the FASB, the Company does not believe any of those accounting pronouncements have had or will have a material impact on its financial position or operating results.

Note 3. Investments

Investments consists of available-for-sale securities as follows (in thousands):

	December 31, 2023			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Short-term marketable securities:				
U.S. Treasury securities	$ 8,962	$ —	$ —	$ 8,962
U.S. government agency debt securities	4,726	—	(2)	4,724
Total short-term marketable securities	$ 13,688	$ —	$ (2)	$ 13,686

	December 31, 2022			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Short-term marketable securities:				
U.S. Treasury securities	$ 30,628	$ —	$ (177)	$ 30,451
Commercial paper	29,543	—	—	29,543
Corporate bonds	16,815	—	(189)	16,626
U.S. government agency debt securities	3,353	8	—	3,361
Total short-term marketable securities	$ 80,339	$ 8	$ (366)	$ 79,981

All the commercial paper, U.S. Treasury and government agency debt securities, and corporate bonds designated as short-term marketable securities have a contractual maturity date that is equal to or less than one year from the respective balance sheet date.

Prior to 2023, the Company followed the guidance in Accounting Standards Codification (ASC) 320, *Investments—Debt and Equity Securities* in determining whether unrealized losses were other than temporary. The Company adopted ASC 326 on January 1, 2023, and now considers whether unrealized losses have resulted from a credit loss or other factors. The unrealized losses on the Company's available-for-sale securities as of December 31, 2023 and December 31, 2022 were caused by fluctuations in market value and interest rates as a result of the economic environment. The Company concluded that an allowance for credit losses was unnecessary as of December 31, 2023 and that there were no impairments as of December 31, 2022 considered as other-than-temporary because the decline in the market value was attributable to changes in market conditions and not credit quality, and that it is neither management's intention to sell nor is it more likely than not that the Company will be required to sell these investments prior to recovery of their cost basis or recovery of fair value. There was no material realized gain or loss on available-for-sale securities in the periods presented.

The Company elected the practical expedient to exclude accrued interest from both the fair value and the amortized cost basis of the available-for-sale debt securities for the purposes of identifying and measuring an impairment and to not measure an allowance for expected credit losses for accrued interest receivables. Accrued interest receivable is written off through net realized investment gains (losses) at the time the issuer of the bond defaults or is expected to default on payment. The Company made an accounting policy election to present the accrued interest receivable balance as part of prepaid expenses and other current assets in the condensed consolidated balance sheets. Accrued interest receivable related to marketable securities was $0.4 million and $0.1 million as of December 31, 2023 and December 31, 2022, respectively.

Investments in a continual unrealized loss position for less than 12 months consist of the following (in thousands):

	December 31, 2023	December 31, 2022
	Fair Value	Fair Value
U.S. Treasury securities	$ 5,967	$ 26,506
U.S. government agency debt securities	2,234	—
Corporate bonds	—	1,977
Total available-for-sale securities	$ 8,201	$ 28,483

Investments in a continual unrealized loss position for greater than 12 months consist of the following (in thousands):

	December 31, 2022
	Fair Value
Corporate bonds	$ 14,649
U.S. Treasury securities	3,945
Total available-for-sale securities	$ 18,594

The Company did not have any investments in a continual unrealized loss position for greater than 12 months as of December 31, 2023.

Note 4. Certain Balance Sheet Accounts

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31, 2023	December 31, 2022
Recoverable research and development tax credits	$ 2,024	$ 6,492
Prepaid expenses	847	1,330
Other assets	552	456
Research and development expenses	34	2,549
Total prepaid expenses and other current assets	$ 3,457	$ 10,827

Accrued Expenses and Other Current Liabilities

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

	December 31 2023	December 31, 2022
Accrued payroll expenses	$ 1,111	$ 2,900
Accrued restructuring expenses	1,066	—
Other current liabilities	138	—
Other accrued expenses	90	245
Accrued research and development expense	28	1,902
Total accrued expenses and other current liabilities	$ 2,433	$ 5,047

Note 5. Commitments and Contingencies

Operating Leases

The Company leases office space in the U.S. and U.K. under non-cancelable operating leases.

In May 2021, the Company entered into an agreement for office space in Cambridge, U.K. The term of this lease is for a period of 24 months, which commenced on July 1, 2021. In March 2023, the Company agreed to extend this lease until June 30, 2024. This extension was accounted for as a lease modification under ASC 842, *Leases* and the ROU asset and lease liability were remeasured at the modification date. The remeasurement of the lease resulted in an increase in both the operating right-of-use asset and the operating lease liability of approximately $0.3 million.

In November 2021, the Company agreed to lease approximately 5,000 square feet of office space in Bellevue, Washington. The term of this lease is 39 months, which commenced on November 1, 2021. The lease contains rent escalation clauses and an option to extend the term of the lease for an additional 3-year period at a market rate determined according to the lease. At the lease's inception and as of December 31, 2023, the Company does not expect that it will exercise its option to extend the lease, and therefore the period covered by this option is not included in the lease term.

In July 2023, the Company entered into a non-cancellable sublease agreement for the Bellevue office space, under the terms of which the Company is entitled to receive $0.2 million in lease payments over the term of the sublease, which commenced in July 2023 and ends concurrently with the original lease in January 2025.

In advance of the sublease, the Company ceased use of and vacated the Bellevue office space in June 2023. The Company considered these circumstances to be an indicator of impairment and recorded an ROU asset impairment loss during the second quarter of 2023 of $0.2 million, which was the amount by which the carrying value of the lease ROU asset exceeded the fair value. The fair value is based on the discounted cash flows of anticipated net rental income for the office space subleased. The ROU asset impairment loss is included in general and administrative expense in the consolidated statements of operations and comprehensive loss.

As of December 31, 2023, the remaining weighted-average lease term was 0.8 years. The weighted-average incremental borrowing rate used to determine the operating lease liability was 7.5%.

The Company incurred $0.4 million and $0.5 million in rent expense for the years ended December 31, 2023 and 2022, respectively. Sublease income was $48,000 for the year ended December 31, 2023, which was classified as a reduction in rent expense.

As of December 31, 2023, the annual future minimum lease payments due under the Company's non-cancelable operating leases are as follows (in thousands):

Year Ending December 31,	Operating Lease Payments	Sublease Income	Net Operating Lease Payments
2024	$ 343	(132)	211
2025	15	(11)	4
Total undiscounted lease payments	$ 358	$ (143)	$ 215
Present value adjustment	(9)		
Total operating lease liabilities	$ 349		

Legal Proceedings

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount. As of the date of these consolidated financial statements, the Company is not party to any material legal matters or claims.

Indemnification

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless, and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company intends to enter into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. The Company currently has directors' and officers' insurance coverage that reduces its exposure and enables the Company to recover a portion of any future amounts paid. The Company believes the estimated fair value of these indemnification agreements in excess of applicable insurance coverage is immaterial.

Note 6. Stock-Based Compensation

2019 Plan

In 2019, the Company adopted the 2019 Equity Incentive Plan (the 2019 Plan). The 2019 Plan provides for the Company to grant qualified stock options, non-qualified stock options, and restricted stock awards to employees, non-employee directors and consultants of the Company under terms and provisions established by the Company's board of directors. Under the terms of the 2019 Plan, options are granted at an exercise price no less than fair value of the Company's common stock on the grant date, except in certain cases related to employees outside of the U.S. Option awards granted typically have 10-year terms measured from the option grant date. While no shares are available for future issuance under the 2019 Plan, it continues to govern outstanding equity awards granted thereunder.

2021 Plan and ESPP

The compensation committee of the Company's board of directors adopted and the Company's stockholders approved the 2021 Equity Incentive Plan (the 2021 Plan) and the 2021 Employee Stock Purchase Plan (the ESPP), which became effective immediately prior to the effectiveness of the Company's initial public offering (IPO). The 2021 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units, stock appreciation rights and other stock-based awards. The Company's employees, officers, directors and consultants are eligible to receive awards under the 2021 Plan. Under the terms of the 2021 Plan, options are granted at an exercise price no less than fair value of the Company's common stock on the grant date, except in certain cases related to significant corporate transactions. Option awards granted typically have 10-year terms measured from the option grant date. As of December 31, 2023, the total number of shares authorized for issuance under the 2021 Plan was 5,368,077. Any shares that are returned under the 2019 Plan as a result of cancellation or forfeiture become available under the 2021 Plan. Further, the number of shares of common stock reserved for issuance under the 2021 Plan automatically increases on January 1 of each year, beginning on January 1, 2022, and continuing through and including January 1, 2031, by 5% of the total number of shares of common stock outstanding on December 31 of the immediately preceding calendar year, or a lesser number of shares determined by the Company's board of directors prior to the applicable January 1st.

The ESPP allows employees, including executive officers, to contribute up to 15% of their earnings, subject to certain limitations, for the purchase of the Company's common stock at a price per share equal to the lower of (a) 85% of the fair market value of a share of common stock on the first day of the offering period, or (b) 85% of the fair market value of a share of common stock on the last day of the offering period. As of December 31, 2023, there were 787,231 shares of common stock reserved for future issuance under the ESPP. The number of shares of common stock reserved for issuance under the ESPP automatically increases on January 1 of each calendar year, beginning on January 1, 2022 and continuing through and including January 1, 2031, by the lesser of (1) 1% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year or (2) a number of shares determined by the Company's board of directors. Shares subject to purchase rights granted under the ESPP that terminate without having been exercised in full will not reduce the number of shares available for issuance under the ESPP.

As of December 31, 2023, no shares have been granted or purchased under the ESPP.

Stock Options

Awards with vesting conditions under both plans typically include either: (i) vesting 25% on the first anniversary of the grant date with the remainder vesting monthly over the following three years or (ii) monthly vesting over four years.

The activity for stock options is as follows:

	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contract Terms (in years)	Aggregate Intrinsic Values (in thousands)
Balance as of December 31, 2022	5,988,271	$ 4.70	8.83	$ 5,699
Options granted	50,000	3.00		
Options cancelled and forfeited	(340,283)	7.93		
Options exercised	(1,111,512)	0.76		2,282
Balance as of December 31, 2023	4,586,476	$ 5.40	2.28	$ 1,060
Vested and expected to vest, December 31, 2023	4,586,476	$ 5.40	2.28	$ 1,060
Options exercisable as of December 31, 2023	4,036,926	$ 5.46	1.45	$ 885

The aggregate intrinsic value disclosed in the above table is based on the difference between the exercise price of the stock option and the fair value of the Company's common stock as of the respective period-end dates. The weighted-average grant-date fair value of stock options granted during the years ended December 31, 2023 and 2022 was $2.25 per share and $4.00 per share, respectively.

The Black-Scholes option pricing model for employee and nonemployee stock options incorporates the following assumptions:

- *Fair Value of Common Stock* — The fair value of each share of common stock is based on the closing price of the Company's common stock on the date of grant as reported on the Nasdaq Global Market.
- *Volatility* — The expected stock price volatilities are estimated based on the historical and implied volatilities of comparable publicly traded companies as the Company does not have sufficient history of trading its common stock.
- *Risk-free Interest Rate* — The risk-free interest rates are based on US Treasury yields in effect at the grant date for notes with comparable terms as the awards.
- *Expected Term* — The expected term represents the period that the Company's stock options are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term).
- *Dividend Yield* — The expected dividend yield assumption is based on the Company's current expectations about its anticipated dividend policy.

The fair value of the Company's stock option awards was estimated at the date of grant using a Black-Scholes option pricing model with the following assumptions for the years ended December 31, 2023 and 2022:

	Year Ended December 31,	
	2023	2022
Expected term (in years)	5.50	5.50-6.50
Expected volatility	92.90%	77.33% - 91.74%
Risk-free interest rate	3.69%	1.69% - 4.22%
Expected dividend yield	0.00%	0.00%

Restricted Stock

The Company has: (i) restricted stock awards with service conditions that vest 25% on the first anniversary of the grant date and the remainder vesting monthly over the following three years and (ii) restricted stock units that vest quarterly over a two and a half year period. The restricted stock awards are subject to repurchase by the Company at the original purchase price in the event that the award recipient's employment or relationship is terminated prior to the shares vesting.

The activity for restricted stock awards and units is as follows:

	Number of Shares	Weighted-Average Grant-Date Fair Value
Unvested at December 31, 2022	177,495	$ 8.32
Granted	113,333	3.64
Vested	(124,737)	6.85
Forfeited	(16,116)	8.11
Unvested at December 31, 2023	149,975	$ 6.03

The fair value of restricted stock awards and units vested during the years ended December 31, 2023 and 2022 was approximately $0.4 million and $0.6 million, respectively.

Modifications & Accelerations

Certain equity awards are subject to provisions in which the vesting of these awards is automatically accelerated upon the occurrence of events such as an involuntary termination in connection with a reduction in force. Further, in connection with the Restructuring Plan and workforce reduction in October 2023, the Company modified the terms of certain equity awards for impacted employees including partial or full acceleration of vesting of stock options and restricted stock awards upon separation and extension of exercise periods for stock options post-separation.

As a result of: (i) the contractual acceleration and (ii) the discretionary modification of equity awards in connection with the Restructuring Plan and workforce reduction in October 2023, the Company recorded incremental stock-based compensation expense of $9.6 million for the year ended December 31 2023, of which $0.9 million and $8.7 million is included in research and development expense and general and administrative expense in the consolidated statement of operations and comprehensive loss, respectively.

Stock-Based Compensation

The following table shows stock-based compensation for stock options, restricted stock awards, and restricted stock units included in the Company's consolidated statements of operations and comprehensive loss (in thousands):

	Year Ended December 31, 2023	2022
Research and development expense	$ 2,778	$ 2,538
General and administrative expense	10,028	4,453
Total stock-based compensation expense	$ 12,806	$ 6,991

As of December 31, 2023, there was $1.8 million of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted average period of 1.91 years. Further, there was $0.9 million of unrecognized compensation cost related to unvested restricted stock awards and units, which is expected to be recognized over a weighted average period of 1.4 years.

Note 7. Net Loss Per Share

The following table shows the computation of basic and diluted net loss per share (in thousands, except share and per share data):

	Year Ended December 31, 2023	2022
Net loss	$ (35,119)	$ (45,244)
Weighted-average number of shares used to compute net loss per share, basic and diluted	26,987,122	26,311,554
Net loss per share, basic and diluted	$ (1.30)	$ (1.72)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share for the periods presented because their effect would have been anti-dilutive:

	Year Ended December 31,	
	2023	2022
Common stock options	4,586,476	5,988,271
Unvested restricted stock awards and units	149,975	177,495
Total potentially dilutive shares	4,736,451	6,165,766

Note 8. Income Taxes

The components of net loss before tax provision from income taxes are as follows (in thousands):

	Year Ended December 31,	
	2023	2022
United States	$ (17,768)	$ (6,272)
United Kingdom	(17,351)	(38,972)
Total	$ (35,119)	$ (45,244)

The following table presents a reconciliation of the Company's expected tax computed at the U.S. statutory federal income tax rate to the total provision for income taxes (in thousands):

	Year Ended December 31,	
	2023	2022
U.S. federal taxes at statutory rate	$ (7,375)	$ (9,497)
State taxes, net of federal benefit	1	1
Foreign rate differential	(232)	471
Non-deductible officer compensation	713	—
Other non-deductible expenses	1	1
Research credit addback	1,729	4,220
Refundable tax credit	(414)	(1,407)
Return to provision and other adjustments	1,049	(2)
Stock-based compensation	510	742
Tax credits	(69)	(110)
U.K. tax rate change impact on deferred income taxes	—	(1,390)
Change in valuation allowance	4,087	6,971
Total	$ —	$ —

The significant components of the Company's deferred tax assets and liabilities are presented below (in thousands):

	Year Ended December 31,	
	2023	2022
Deferred tax assets:		
Stock-based compensation, including 162m limitations	$ 1,147	$ 1,105
Intangible asset	1,843	2,374
Accrued compensation and benefits	84	334
Operating lease liabilities	38	70
Net operating losses	17,137	12,413
Research credits	612	531
Total gross deferred tax assets	20,861	16,827
Deferred tax liabilities:		
Unrealized gain or loss	3	20
Operating lease right-of-use assets	(8)	(65)
Other	—	(23)
Total gross deferred tax liabilities	(5)	(68)
Valuation allowance	(20,856)	(16,759)
Net deferred tax liabilities	$ —	$ —

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Due to the uncertainty of the business in which the Company operates, projections of future profitability are difficult and past profitability is not necessarily indicative of future profitability. The Company does not believe it is more likely than not that the deferred tax assets will be realized, and accordingly, the Company recorded a valuation allowance of $20.9 million and $16.8 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, the Company had net operating loss carryforward of approximately $13.1 million for federal income tax purposes, $55.5 million for foreign income tax purposes and $8.3 million for state income tax purposes. These may be used to offset future taxable income. The federal net operating loss carryforward can be carried forward indefinitely while the state net operating loss carryforward will begin to expire in varying amounts in 2038. The Company also has research and development credits of approximately $0.5 million and $0.1 million for federal and state income taxes purposes, respectively. The federal credits may be used to offset future taxable income and will begin to expire in varying amounts in 2039. The state credits may be used to offset future taxable income and will begin to expire in varying amounts in 2035.

The Company is subject to taxation in the U.S. (federal and various states) and the U.K. Currently, no historical years are under examination. The Company’s tax years starting in December 31, 2018 are open and subject to examination by the U.S. (federal and various states) and the U.K. taxing authorities due to the carryforward of utilized net operating losses and research and development credits.

Uncertain tax positions are recorded when it is more likely than not that a given tax position would not be sustained upon examination by taxing authorities. The Company’s policy for recording interest and penalties related to income taxes, including uncertain tax positions, is to record such items as a component of the provision for income taxes. As of December 31, 2023 and 2022, the Company does not have any uncertain tax positions.

The Company has not completed a Section 382 study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since the Company’s formation. Pursuant to Internal Revenue Code Sections 382 and 383, annual use of the Company’s net operating loss and research and development tax credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, will not impact the Company’s effective tax rate.

Note 9. Defined Contribution Plan

The Company has a 401(k) defined contribution plan. Participation in the plan is available to substantially all US-based employees. Company contributions to the plan are discretionary. The Company made matching contributions of up to 4% of each participating employee’s eligible compensation. For each of the years ended December 31, 2023 and 2022, total expense recognized from the 401(k) matching contributions was approximately $0.1 million.

The Company also has a workplace pension contribution scheme for U.K.-based employees. For the years ended December 31, 2023 and 2022, the Company made contributions to the pension scheme of approximately $0.3 million and $0.2 million, respectively.

Note 10. Restructuring Costs

On February 7, 2023, the Company's board of directors approved a restructuring plan to conserve financial resources and better align the Company's workforce with current business needs. As part of the Restructuring Plan, the Company's workforce was reduced by approximately 55%, with substantially all of the reduction in personnel completed in the first half of 2023.

The Company further reduced its workforce by 10 employees in October 2023. The Company incurred additional restructuring costs of $2.0 million in the fourth quarter of 2023 associated with this reduction.

During the year ended December 31, 2023, the Company recorded restructuring costs of $18.8 million. These costs are primarily related to severance payments, healthcare benefits and stock-based compensation.

A summary of the restructuring costs recorded in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2023 is as follows (in thousands):

	Year Ended December 31, 2023			
	ROU Asset Impairment	Severance and Benefits Costs	Stock-based Compensation	Total Restructuring Cost Recorded
General and administrative expense	$ 180	$ 6,089	8,707	$ 14,976
Research and development expense	—	2,894	939	3,833
Total restructuring costs	$ 180	$ 8,983	$ 9,646	$ 18,809

Employees affected by the reduction in workforce under the Restructuring Plan obtained involuntary termination benefits that are provided pursuant to a one-time benefit arrangement. For employees who were notified of their termination in February 2023 and had no requirement to provide future service beyond a minimum retention period, the Company recognized the liability for the full termination benefits at fair value in the first quarter of 2023. For employees who are required to provide services beyond a minimum retention period to receive their termination benefits, the Company recognizes the termination benefits ratably over their future service periods. The service periods began in February 2023 and the majority ended at various dates during the third quarter of 2023. The remaining termination benefits are expected to be recognized through March 2024.

Employees who were notified of their termination in October had no requirement to provide future service beyond a minimum retention period, and therefore the Company recognized the liability for the full termination benefits at fair value in the fourth quarter of 2023.

The activity in the restructuring liability during the year ended December 31, 2023 is as follows (in thousands):

	Restructuring Liability 2023
Restructuring liability as of December 31, 2022	$ —
Severance costs incurred during the period	8,983
Severance costs paid during the period	(7,906)
Restructuring liability as of December 31, 2023	$ 1,077

The Company expects to incur aggregate restructuring costs of approximately $18.9 million. The remaining accrued restructuring liability is subject to assumptions, and actual amounts may differ. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the Restructuring Plan.

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

Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our executive chair (who is our principal executive officer and principal financial officer) or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Based on our evaluation, the executive chair has concluded that the Company's disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) were not effective as of December 31, 2023 because of the material weaknesses in our internal control over financial reporting described below.

Notwithstanding the material weaknesses, management believes the consolidated financial statements as included in Item 8 of this Annual Report on Form 10-K present fairly, in all material respects, the Company's financial condition, results of operations and cash flows as of and for the periods presented in accordance with generally accepted accounting principles in the United States.

Management's Report on Internal Control Over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is a process designed under the supervision of our executive chair and our chief accounting officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the Company's financial statements for external reporting purposes in accordance with generally accepted accounting principles.

As of December 31, 2023, management conducted an assessment of the effectiveness of the Company's internal control over financial reporting based on the framework established in "Internal Control—Integrated Framework" (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management has determined that the Company's internal control over financial reporting was not effective as of December 31, 2023, because of the unremediated material weaknesses in our internal control over financial reporting described below.

A material weakness is a deficiency, or 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 consolidated financial statements will not be prevented or detected on a timely basis. The material weaknesses are as follows:

- We did not design or maintain an effective control environment. Specifically, we lacked a sufficient number of professionals with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters commensurate with accounting and reporting requirements. The lack of personnel contributed to the following material weakness.
- We did not design and maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, including segregation of duties and controls over the preparation and review of journal entries, account reconciliations and consolidation.

These material weaknesses did not result in a misstatement to the consolidated financial statements. However, these material weaknesses could result in a misstatement of our account balances or disclosures that would result in a material misstatement of our annual or interim consolidated financial statements that would not be prevented or detected.

Management's report on internal control over financial reporting was not subject to attestation by the Company's independent registered public accounting firm pursuant to the rules of the SEC that permit the Company to provide only management's report.

Remediation Efforts to Address Material Weaknesses

Management has concluded that the material weaknesses in internal control over financial reporting were due to the fact that we were a private company with limited resources when the material weaknesses were identified and did not have the necessary business processes and related internal controls formally designed and implemented, coupled with the appropriate resources with the appropriate level of experience and technical expertise, to oversee our business processes and controls.

We have implemented measures designed to improve internal control over financial reporting to remediate the control deficiencies that led to our material weaknesses. The remediation measures we have taken include:

- Hired qualified personnel with appropriate expertise to perform specific functions and ensure adequate segregation of key duties and responsibilities;
- Designed and implemented improved policies, processes, and internal controls, including senior management review and audit committee oversight, to achieve complete, accurate and timely financial accounting, reporting and disclosures;
- Implemented and formalized policies, processes, and internal controls to identify and assess complex accounting transactions and other technical accounting and financial reporting matters; and
- Implemented financial systems to improve segregation of duties and controls and reliability of system generated data.

We believe we have made substantial progress toward achieving the effectiveness of our internal control over financial reporting and disclosure controls and procedures. The actions that have been taken are subject to continued review and testing by management as well as oversight by the audit committee of our board of directors. We will not be able to conclude whether the steps we have taken will fully remediate these material weaknesses in our internal control over financial reporting until we have completed our remediation efforts and subsequent evaluation of their effectiveness.

Changes in Internal Control over Financial Reporting

There have not been any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

Item 9B. Other Information.

Not applicable.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this item and not set forth below will be set forth in the sections headed *Election of Directors* and *Executive Officers* contained in our definitive Proxy Statement to be filed with the Commission within 120 days after the conclusion of our year ended December 31, 2023 (the Proxy Statement) pursuant to General Instructions G(3) of Form 10-K and is incorporated herein by reference.

We have adopted a code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of our code of business conduct and ethics is available under the Corporate Governance section of our website at www.eliemtx.com. If we make any substantive amendments to the code of business conduct and ethics or grants any waiver from a provision of the code of business conduct and ethics to any executive officer or director that are required to be disclosed pursuant to SEC rules, we will promptly disclose the nature of the amendment or waiver on our website or in a current report on Form 8-K.

Item 11. Executive Compensation.

The information required by this item will be set forth in our Proxy Statement in the sections headed *Executive and Director Compensation* and *Director Compensation* contained in our Proxy Statement and is incorporated herein by reference.

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

Information required by this item will be set forth in the sections headed *Security Ownership of Certain Beneficial Owners and Management* and *Executive and Director Compensation* contained in our Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information required by this item will be set forth in the sections headed *Certain Related-Person Transactions* and *Information Regarding the Board of Directors and Corporate Governance* contained in our Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

Information required by this item will be set forth in the sections headed *Ratification of Selection of Independent Registered Public Accounting Firm* contained in our Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Documents filed as part of this report

(1) Financial Statements. The following consolidated financial statements of Eliem Therapeutics, Inc., together with the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, required to be filed pursuant to Part II, Item 8 of this Annual Report on Form 10-K are included on the following pages:

(2) Financial Statement Schedules. None.

(3) List of exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b) Exhibits.

Exhibit Index

Exhibit Number	Description of Exhibit	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-40708	3.1	August 12, 2021
3.2	Amended and Restated Bylaws of the Registrant.	S-1	333-257980	3.4	August 2, 2021
4.1	Form of common stock certificate of the Registrant.	S-1	333-257980	4.1	August 2, 2021
4.3	Description of Securities	10-K	001-40708	4.3	March 7, 2022
10.1	Amended and Restated Investor Rights Agreement, dated May 21, 2021, by and among the Registrant and the investors listed on Schedule A thereto.	S-1	333-257980	10.1	July 16, 2021
10.2+	2021 Equity Incentive Plan.	S-1	333-257980	10.4	August 2, 2021
10.3+	Forms of Option Agreement, Stock Option Grant Notice and Notice of Exercise under the 2021 Equity Incentive Plan.	S-1	333-257980	10.5	August 2, 2021
10.4+	Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the 2021 Equity Incentive Plan.	S-1	333-257980	10.6	August 2, 2021
10.5+	2021 Employee Stock Purchase Plan.	S-1	333-257980	10.7	August 2, 2021
10.6+	Form of Indemnification Agreement, by and between the Registrant and each of its directors and executive officers.	S-1	333-257980	10.8	August 2, 2021
10.7+	Executive Employment Agreement by and between the Registrant and Robert Azelby, effective October 1, 2020, as amended.	S-1	333-257980	10.9	August 2, 2021
10.8+	Executive Employment Agreement by and between the Registrant and Erin M. Lavelle, effective October 1, 2020, as amended.	S-1	333-257980	10.10	August 2, 2021
10.9+	Executive Employment Agreement by and between Eliem Therapeutics (UK) Ltd. and Valerie Morisset, Ph.D., effective January 1, 2021.	S-1	333-257980	10.11	July 16, 2021
10.10+	Separation and Consulting Agreement, dated February 13, 2023, by and between Eliem Therapeutics, Inc. and Robert Azelby.	8-K	001-40708	10.1	February 13, 2023
10.11+	Separation and Consulting Agreement, dated February 13, 2023, by and between Eliem Therapeutics, Inc. and Erin Lavelle.	8-K	001-40708	10.2	February 13, 2023
10.12+	Retention Agreement, dated February 14, 2023, by and between Eliem Therapeutics, Inc. and Valerie Morisset.	10-K	001-40708	10.12	March 6, 2023
21.1	List of subsidiaries.	S-1	333-257980	21.1	August 2, 2021

10.13+*	Executive Employment Agreement by and between the Eliem Therapeutics, Inc. and James B. Bucher, effective October 1, 2020.
10.14+*	Separation and Consulting Agreement, dated February 13, 2023, by and between Eliem Therapeutics, Inc. and James B. Bucher.
23.1*	Consent of Independent Registered Public Accounting Firm.
31.1*	Certification of Principal Executive Officer and 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 and 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*	Eliem Therapeutics, Inc. Clawback Policy.
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (embedded within inline XBRL document)

* Filed herewith.
+ Indicates management contract or compensatory Plan.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Eliem Therapeutics, Inc.

Date: March 28, 2024

By: /s/ Andrew Levin

Andrew Levin, M.D., Ph.D.
Executive Chairman of the Board of Directors

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

Name	Title	Date
/s/ Andrew Levin **Andrew Levin, M.D., Ph.D.**	Executive Chairman of the Board of Directors *(Principal Executive Officer and Principal Financial Officer)*	March 28, 2024
/s/ Emily Pimblett **Emily Pimblett**	Chief Accounting Officer *(Principal Accounting Officer)*	March 28, 2024
/s/ Judith Dunn **Judith Dunn, Ph.D.**	Director	March 28, 2024
/s/ Liam Ratcliffe **Liam Ratcliffe, M.D., Ph.D.**	Director	March 28, 2024
/s/ Adam Rosenberg **Adam Rosenberg**	Director	March 28, 2024
/s/ Simon Tate **Simon Tate**	Director	March 28, 2024

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K/A

Amendment No. 1

(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, 2023

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: 001-40708

Eliem Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**83-2273741**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

PMB #117
2801 Centerville Road 1st Floor
Wilmington, DE 19808-1609
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: 1-877-ELIEMTX (354-3689)

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

Title of class	**Name of each exchange on which registered**
Common Stock, par value $0.0001	**The Nasdaq Stock Market LLC (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 Section 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

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

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

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

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

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

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

As of June 30, 2023, the market value of voting stock held by non-affiliates of the Registrant was $13.2 million. The calculation of the aggregate market value of voting and non-voting stock excludes certain shares of the Registrant's common stock held by current executive officers, directors and stockholders that the Registrant has concluded are affiliates of the Registrant. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the Registrant or that such person is controlled by or under common control with the Registrant.

There were 27,723,824 shares of the registrant's Common Stock issued and outstanding as of March 31, 2024.

ELIEM THERAPEUTICS, INC.

AMENDMENT NO. 1 TO ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2023

TABLE OF CONTENTS

EXPLANATORY NOTE

Eliem Therapeutics, Inc. (the "Company" or "Eliem". References throughout to "we," "us" or "our" refer to the Company) is filing this Amendment No. 1 to its Annual Report on Form 10-K ("Amendment"), originally filed with the Securities and Exchange Commission (the SEC) on March 28, 2024 (the "Initial Filing"), solely for the purposes of amending and supplementing Part III of the Initial Filing. This Amendment changes the Company's Initial Filing by including information required by Part III (Items 10, 11, 12, 13 and 14) because the Company's definitive proxy statement will not be filed within 120 days after December 31, 2023, the end of the fiscal year covered by the Initial Filing.

In addition, in connection with the filing of this Amendment, the Company is including new certification of our principal executive officer and principal financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Accordingly, Item 15 of Part IV of the Initial Filing has also been amended to reflect the filing of the new certifications. Because no financial statements are contained within this Amendment, the Company is not including certifications pursuant to Section 906 of The Sarbanes-Oxley Act of 2002.

Except as contained herein, this Amendment does not modify or update disclosures contained in the Initial Filing. This Amendment should be read in conjunction with the Company's other filings made with the SEC subsequent to the date of the Initial Filing.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Background of Directors and Executive Officers

Directors

Set forth below are the name and age of each of our current directors, as of March 31, 2024, and the positions held by each director with us, each director's principal occupation and business experience during the last five years, and the year of the commencement of each director's term as a director. Additionally, for each director, included below is information regarding the specific experience, qualifications, attributes and skills that contributed to the decision of the Board of Directors of the Company to nominate such director for election as a director and the names of other publicly held companies of which such director serves or has served as a director in the previous five years. There is no family relationship between any of our directors, director nominees or executive officers. Except as otherwise disclosed below, no director was selected as a director or nominee pursuant to any arrangement or understanding.

Name	Age	Principal Occupation/ Position Held With the Company
Andrew Levin, M.D., Ph.D.	47	Executive Chair of the Board of Directors of the Company; Managing Director at RA Capital Management, L.P.
Judith Dunn, Ph.D.	61	Entrepreneur in Residence at Atlas Ventures
Liam Ratcliffe, M.D., Ph.D.	60	Lead Independent Director of the Company; Head of Biotechnology at Access Industries, Inc.
Adam Rosenberg	53	Chair of Ambagon Therapeutics, Inc. and Chair of Seamless Therapeutics, Inc.
Simon Tate	58	Managing Director at Intermediate Capital Group PLC

Andrew Levin, M.D., Ph.D. is a Co-Founder of Eliem, served as our Chief Executive Officer from October 2018 to October 2020, and has served as the Chairman of our Board of Directors since February 2019 and as Executive Chairman of our Board of Directors since February 2023. Since 2015, Dr. Levin has served as a Managing Director on the Investment Team at RA Capital Management, L.P. Previously, Dr. Levin was a Vice President at H.I.G. BioVentures, and prior to that he served as the Director of Pharmaceutical Sciences for the Clinton Health Access Initiative. Dr. Levin holds a B.S. in mechanical engineering from Princeton University, a Ph.D. in biomedical engineering from the Massachusetts Institute of Technology and an M.D. from Harvard Medical School.

The Nominating and Corporate Governance Committee believes that Dr. Levin is qualified to serve on our Board of Directors due to his substantial experience as an investor in early stage biopharmaceutical and life sciences companies, as well as his experience of serving on the boards of directors for several biopharmaceutical companies.

Judith Dunn, Ph.D. has been a member of our Board of Directors since February 2021. Dr. Dunn currently serves as Entrepreneur in Residence at Atlas Ventures. Since October 2023, Dr. Dunn serves as Head of R&D for Vima Tx, an Atlas portfolio company. From April 2021 to January 2023, Dr. Dunn served as President of R&D of Fulcrum Therapeutics, Inc. From March 2018 to April 2021, Dr. Dunn served as Entrepreneur in Residence at Atlas Ventures. From 2010 to 2018, Dr. Dunn served as Vice President of Clinical Development for F. Hoffmann-La Roche. Dr. Dunn led Psychiatry Clinical Development at Sepracor from 2005 to 2010 and held research and commercial positions at Pfizer from 1997 to 2005. Dr. Dunn holds a B.S. in neurobiology from University of Rochester. and a Ph.D. in Neurobiology from Wesleyan University.

The Nominating and Corporate Governance Committee believes that Dr. Dunn is qualified to serve on our Board of Directors due to her experience in the biotechnology and biopharmaceutical industries and her substantial professional experience.

Liam Ratcliffe, M.D., Ph.D. has served as a member of our Board of Directors since October 2019 and as our Lead Independent Director since March 2023. Dr. Ratcliffe has also served as the Head of Biotechnology at Access Industries, Inc. since April 2019. From September 2008 to April 2019, Dr. Ratcliffe served as Managing Director at New Leaf Venture Partners, where he focused on investing in therapeutics and therapeutic platform companies. Prior to joining New Leaf, Dr. Ratcliffe held various positions of increasing responsibility at Pfizer Inc., a multinational pharmaceutical corporation, including Senior Vice President and Development Head for Neuroscience, and Worldwide Head of Clinical Research and Development. Dr. Ratcliffe currently serves on the board of directors of Disc Medicines, a biopharmaceutical company, and several privately held biotechnology companies. Dr. Ratcliffe previously served on the boards of directors of several biotechnology and biopharmaceutical companies, including Deciphera Pharmaceuticals, Inc. and Arvinas, Inc, Unum Therapeutics, Inc., from March 2018 to April 2019, Edge Therapeutics, Inc., from October 2015 to November 2018, and Array Biopharmaceuticals, Inc., from April 2012 to April 2014. Dr. Ratcliffe holds an M.B.A. from the University of Michigan and an M.D. and Ph.D. in Immunology from the University of Cape Town, and he completed his internal medicine training and fellowship in Immunology at Groote Schuur Hospital and associated teaching hospitals in Cape Town, South Africa.

The Nominating and Corporate Governance Committee believes that Dr. Ratcliffe is qualified to serve on our Board of Directors due to his extensive experience in the venture capital industry, medical and scientific background and training, and leadership at various biopharmaceutical and biotechnology companies.

Adam Rosenberg was President, Chief Executive Officer and a member of the board of directors of Athenen Therapeutics, Inc. from July 2020 through its merger with Eliem in October 2020, and has been a member of our board of directors since October 2020. Mr. Rosenberg is currently Chair of Ambagon Therapeutics, Inc. and Seamless Therapeutics, Inc., and on the boards of directors of other private, venture-backed companies. He was Chief Executive Officer and a member of the board of directors of Aliada Therapeutics from July 2021 through February 2024. From January 2020 through June 2021, Mr. Rosenberg served as a Venture Partner at Carnot Pharma, LLC dba RA Ventures. From September 2015 until its acquisition by Alkermes plc in November 2019, Mr. Rosenberg served as President, Chief Executive Officer and member of the board of directors of Rodin Therapeutics, Inc. Previously, Mr. Rosenberg served as Chief Executive Officer, and as a member of the boards of directors, for other venture-backed biotechnology companies. Mr. Rosenberg holds a J.D. from the University of Virginia School of Law, and a B.A. from Whittier College.

The Nominating and Corporate Governance Committee believes that Mr. Rosenberg is qualified to serve on our Board of Directors due to his experience in the biotechnology industry.

Simon Tate has been a member of our board of directors since February 2019. Since January 2021, Mr. Tate has served as a Managing Director at Intermediate Capital Group, plc. From December 2017 to January 2021, Mr. Tate served as a partner at Bridge Valley Ventures. Mr. Tate has spent most of his career working in the fields of pain and neuroscience. He was one of the founders of Convergence Pharmaceuticals, founded in 2010, and served as Chief Scientific Officer and head of R&D until its acquisition in 2015. Following this acquisition, Mr. Tate joined Biogen where he assumed the role of Vice President and Head of the Pain Therapeutic Area. Prior to Convergence, Mr. Tate was Vice President and Head of Pain, Epilepsy, and Migraine Drug Discovery and Early Development at GSK. Mr. Tate holds a master's degree from the University of Dundee.

The Nominating and Corporate Governance Committee believes that Mr. Tate is qualified to serve on our Board of Directors due to his experience and standing in the neuroscience, pharmaceutical and biotechnology sectors.

Executive Officers

The following table sets forth certain information with respect to our executive officers as of March 31, 2024. Biographical information with regard to Dr. Levin is presented under ***Directors*** above.

Name	Age	Position(s)
Andrew Levin	47	Executive Chairman of the Board of Directors
Valerie Morisset, Ph.D.	54	Executive Vice President, Research and Development and Chief Scientific Officer

Valerie Morisset, Ph.D. has served as our Executive Vice President, Research and Development and Chief Scientific Officer since October 2020, and previously as our President and Chief Scientific Officer since April 2019. Prior to joining Eliem, Dr. Morisset was a founding venture partner at Bridge Valley Ventures, where she served from January 2018 until March 2019. In October 2010, she co-founded Convergence Pharmaceuticals, where she established and led the Biology and Translational Medicine team until Biogen's acquisition of Convergence in 2015. Dr. Morisset subsequently joined Biogen in a senior leadership role. She has worked extensively in the field of drug development for pain and across a number of other therapeutic areas including neurology, psychiatry, gastrointestinal disorders and sensory biology, including during her time at GlaxoSmithKline (GSK) from January 2001 to October 2010. Dr. Morisset holds a degree, a masters and a Ph.D. from the University of Bordeaux.

Code of Ethics

The Company has adopted a Code of Business Conduct and Ethics that applies to all officers, directors and employees. The Code of Business Conduct and Ethics is available on the Company's website at www.eliemtx.com. If the Company makes any substantive amendments to the Code of Business Conduct and Ethics or grants any waiver from a provision of the Code to any executive officer or director, the Company will promptly disclose the nature of the amendment or waiver on its website.

Hedging Policy

Our Insider Trading Policy, adopted in 2021 and amended and restated in 2023, prohibits officers, directors, employees and designated consultants of the Company and its subsidiaries from purchasing our securities on margin or holding our securities in margin accounts, hedging or monetization transactions, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars, and exchange funds, trading in derivative securities related to our common stock or engaging in short selling of our common stock.

Corporate Governance Guidelines

In July 2021, the Board of Directors documented the governance practices followed by the Company by adopting Corporate Governance Guidelines to assure that the Board of Directors will have the necessary authority and practices in place to review and evaluate the Company's business operations as needed and to make decisions that are independent of the Company's management. The guidelines are also intended to align the interests of directors and management with those of the Company's stockholders. The Corporate Governance Guidelines set forth the practices the Board of Directors intends to follow with respect to board composition and selection, board meetings and involvement of senior management, Chief Executive Officer performance evaluation and succession planning, and board committees and compensation. The Corporate Governance Guidelines, as well as the charters for each committee of the Board of Directors, may be viewed at www.eliemtx.com.

Information Regarding Committees of the Board of Directors

The Board of Directors has three permanent committees: an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. The following table provides membership and meeting information for 2023 for each of these committees:

Name	Audit	Compensation	Nominating and Corporate Governance
Andrew Levin, M.D., Ph.D.			
Judith Dunn, Ph.D.	X	X	
Liam Ratcliffe, M.D., Ph.D.		X*	X*
Adam Rosenberg	X*	X	
Simon Tate	X		X
Total meetings in 2023	4	0	0

* Committee Chairperson

Board Diversity

2023 Board Diversity Matrix

Total Number of Directors	5	
	Female	Male
Part I: Gender Identity		
Directors	1	4
Part II: Demographic Background		
White	1	4

2024 Board Diversity Matrix

Total Number of Directors	5	
	Female	Male
Part I: Gender Identity		
Directors	1	4
Part II: Demographic Background		
White	1	4

Audit Committee

The Audit Committee of the Board of Directors was established by the Board of Directors in accordance with Section 3(a)(58)(A) of the Exchange Act, to oversee the Company's corporate accounting and financial reporting processes and audits of its financial statements. Our Audit Committee consists of Adam Rosenberg, Judith Dunn and Simon Tate. Our Audit Committee met four times during 2023.

Our Board of Directors has determined that each of Dr. Dunn, Mr. Rosenberg, and Mr. Tate satisfy the independence requirements under the Nasdaq listing standards and Rule 10A-3(b)(1) of the Exchange Act. Mr. Rosenberg is the chairperson of our Audit Committee. Our Board of Directors has determined that Mr. Rosenberg is an "audit committee financial expert" within the meaning of SEC regulations. Each member of our Audit Committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, our Board of Directors has examined each Audit Committee member's scope of experience and the nature of their employment.

The primary purpose of the Audit Committee is to discharge the responsibilities of our Board of Directors with respect to our corporate accounting and financial reporting processes, systems of internal control and financial statement audits, and to oversee our independent registered public accounting firm. For this purpose, the Audit Committee performs several functions. Specific functions of the Audit Committee include:

- helping our Board of Directors oversee our corporate accounting and financial reporting processes;
- reviewing and discussing with our management the adequacy and effectiveness of our disclosure controls and procedures;
- assisting with design and implementation of our risk assessment functions, including the Company's policies and other matters relating to the Company's investments, cash management and foreign exchange management, major financial risk exposures, the adequacy and effectiveness of the Company's information security policies and practices and the internal controls regarding information security, and the steps taken by management to monitor and mitigate or otherwise control these exposures and to identify future risks;
- managing the selection, engagement, qualifications, independence and performance of a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;

- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing related person transactions;
- obtaining and reviewing a report by the independent registered public accounting firm at least annually that describes our internal quality control procedures, any material issues with such procedures and any steps taken to deal with such issues when required by applicable law; and
- approving or, as permitted, pre-approving, audit and permissible non-audit services to be performed by the independent registered public accounting firm.

Our Audit Committee operates under a written charter, adopted by our Board of Directors on June 29, 2021, as amended, that satisfies the applicable Nasdaq listing standards and which is available on our website at eliemtx.com.

Nominating and Corporate Governance Committee

Our Nominating and Corporate Governance Committee consists of Liam Ratcliffe and Simon Tate. The Nominating and Corporate Governance Committee did not meet in 2023 but instead elected to act by written consent. The chairperson of our Nominating and Corporate Governance Committee is Liam Ratcliffe. Our Board of Directors has determined that each member of the Nominating and Corporate Governance Committee is independent under the Nasdaq listing standards. Specific responsibilities of our Nominating and Corporate Governance Committee include:

- identifying and evaluating candidates, including the nomination of incumbent directors for reelection and nominees recommended by stockholders, to serve on our Board of Directors;
- considering and making recommendations to our Board of Directors regarding the composition and chairmanship of the committees of our Board of Directors;
- reviewing with our Chief Executive Officer, when one is serving, the plans for succession to the offices of our executive officers and make recommendations to our Board of Directors with respect to the selection of appropriate individuals to succeed to these positions;
- developing and making recommendations to our Board of Directors regarding corporate governance guidelines and matters;
- reviewing and evaluating with the Chief Executive Officer the succession plans for our executive officers;
- reviewing and making recommendations to our Board of Directors regarding the Company's process for stockholder communications with the Board of Directors, and make such recommendations to the Board of Directors with respect to such communications as the Committee deems appropriate;
- monitoring the Company's overall approach to corporate social responsibility and ensuring it is in line with the overall business strategy and the Company's corporate and social obligations as a responsible citizen; and periodically receiving and reviewing reports on the Company's sustainability and environmental, social and related governance strategies, initiatives, policies and practices and making such recommendations to our Board of Directors about them as the Committee deems appropriate; and
- overseeing periodic evaluations of the Board of Directors' performance, including committees of the Board of Directors.

Our Nominating and Corporate Governance Committee operates under a written charter, adopted by our Board of Directors in June 2021, that satisfies the applicable Nasdaq listing standards and which is available on our website at eliemtx.com.

Item 11. Executive Compensation.

Our named executive officers (the "NEOs") for the year ended December 31, 2023, which consist of our principal executive officer, our other executive officer, our former principal executive officer, and two other former executive officers, are:

- Andrew Levin, our Executive Chairman of the Board of Directors;
- Valerie Morisset, Ph.D., our Executive Vice President, Research and Development and Chief Scientific Officer;
- Robert Azelby, our former President and Chief Executive Officer;
- Erin M. Lavelle, our former Executive Vice President, Chief Operating Officer and Chief Financial Officer; and
- James Bucher, our former Executive Vice President and General Counsel.

The following table sets forth all of the compensation awarded to, earned by or paid to our NEOs during the years ended December 31, 2022 and December 31, 2023.

Name and Principal Position	Year	Salary($)	Bonus($)	Option Award(s)($)[1]	All Other Compensation($)	Total($)
Andrew Levin, Executive Chairman of the Board of Directors	2023	—	—	22,522[2]	65,387[2]	87,909
Valerie Morisset, Ph.D., Executive Vice President, Research and Development and Chief Scientific Officer[3]	2023	510,853	255,723	—	311,044[4]	1,077,620
	2022	399,916	179,962	1,371,917	37,987[5]	1,989,782
Robert W. Azelby, former Chief Executive Officer	2023	82,799	—	—	2,377,388[6]	2,460,187
	2022	675,000	438,750	4,035,050	12,200	5,161,000
Erin M. Lavelle, former Executive Vice President, Chief Operating Officer and Chief Financial Officer	2023	99,359	—	—	1,081,467[7]	1,180,826
	2022	465,750	209,588	1,371,917	12,200	2,059,455
James Bucher, former Executive Vice President and General Counsel	2023	104,948	—	—	1,090,388[8]	1,195,336

(1) The amounts reported in this column do not reflect dollar amounts actually received by the named executive officer. Instead, the amounts reflect the aggregate grant date fair value.
(2) Represents option awards and fees earned by Andrew Levin as the chairman of our board of directors.
(3) Dr. Morisset is employed and compensated by our wholly owned subsidiary, Eliem Therapeutics (UK) Ltd. The dollar amounts shown in this table, except the amounts in the column titled "Option Awards," reflect the US$ equivalent of the amounts paid to Dr. Morisset in British Pounds. The amounts were converted to U.S. dollars from British Pound using the yearly average exchange rate. Applying this formula, £1.00 was equal to US$1.24 for both fiscal years 2022 and 2023.
(4) Represents a retention bonus of $261,323 paid in 2023 as well as the amount of company contributions to a defined contribution pension plan maintained for our employees in the United Kingdom.
(5) Represents the amount of company contributions to a defined contribution pension plan maintained for our employees in the United Kingdom.
(6) Represents a severance payment of $2,316,600 made in 2023 as well as the amount of safe-harbor matching contributions under our 401(k) plan and unused vacation days paid out upon Mr. Azelby's departure.
(7) Represents a severance payment of $1,053,527 made in 2023 as well as the amount of safe-harbor matching contributions under our 401(k) plan and unused vacation days paid out upon Ms. Lavelle's departure.
(8) Represents a severance payment of $1,053,527 made in 2023 as well as the amount of safe-harbor matching contributions under our 401(k) plan and unused vacation days paid out upon Mr. Bucher's departure.

Employment Arrangements

We have entered into offer of employment letters with each of the NEOs in connection with their employment with us other than Dr. Levin, who serves as the executive chairman of our Board of Directors. With the oversight and approval of our Board of Directors, each of these employment agreements was negotiated on our behalf by our former Chief Executive Officer, with the exception of his own employment agreement, which was negotiated by the executive chairman of our Board of Directors. These agreements provided for "at will" employment and set forth the terms and conditions of employment of each NEO, including base salary, standard employee benefit plan participation, and the acceleration of the vesting of restricted stock and stock options held by such NEOs upon the occurrence of certain conditions. These employment agreements were each subject to execution of our standard confidential information and invention assignment agreement.

If we terminate Dr. Morisset's employment without cause (as defined in her employment) and other than as a result of her death or disability or if she resigns for good reason (as defined in her employment agreement), in each case, following our initial public offering and not in connection with a change in control, then she will be eligible to receive the following severance benefits: (1) 18 months of her base salary, paid in accordance with our customary payroll practices over the 18 months following her separation from service; (2) an amount equal to her pro rata annual performance bonus, based on the target amount, for the calendar year in which termination occurs, payable on the first regularly scheduled payroll date following the effectiveness of the release of claims; and (3) the vesting of the unvested portion of any time or service-based equity awards held by Dr. Morisset that are scheduled to vest and become exercisable in the 12-month period following the termination date will be accelerated and immediately vested as of the termination date.

If we terminate Dr. Morisset's employment without cause (as defined in her employment) and other than as a result of her death or disability or if she resigns for good reason (as defined in her employment agreement), in each case, in the period commencing three months prior to and ending 12 months following a change in control, then she will be eligible to receive the following severance benefits: (1) 18 months of her base salary and annual bonus, based on the target amount, paid in a lump sum following the effectiveness of the release of claims; and (2) the vesting of the unvested portion of any time-based, performance-based or service-based equity awards held by Dr. Morisset will be accelerated and immediately vested as of the termination date.

On February 14, 2023, we entered into a retention agreement with Dr. Morisset which provided for (i) an increase in Dr. Morisset's base salary from £336,190 to £420,238, (ii) an increase in Dr. Morisset's target bonus percentage from 45% to 50% and (iii) up to two retention payments of £210,119 each if Dr. Morisset remains employed by the Company or its subsidiaries on April 1, 2023 and June 1, 2024, respectively. Dr. Morisset received the first such retention payment on April 1, 2023.

For purposes of Dr. Morisset's offer of employment letter, the term "cause" means any of the following: (i) any indictment of an NEO for a felony under applicable law; (ii) the NEO's commission of or participation in (A) a fraud or embezzlement against the Company or its affiliates or (B) act of dishonesty against the Company or its affiliates that results in (or would reasonably be expected to result in) material harm to the business of the Company; (iii) the NEO's material violation of any contract or agreement between the NEO and the Company, any statutory or fiduciary duty the NEO owes to the Company under applicable law, or any material Company policy; or (iv) the NEO's willful conduct that constitutes gross misconduct, insubordination, incompetence or habitual neglect of duties and that results in (or would reasonably be expected to result in) material harm to the business of the Company; provided, however, that the conduct described under clause (iii) or (iv) above, if deemed curable by the Board of Directors in its reasonable discretion, will only constitute Cause if such conduct is not cured within thirty (30) days after Dr. Morisset's receipt of written notice from the Company or the Board of Directors specifying the particulars of the conduct that may constitute Cause.

For purposes of Dr. Morisset's offer of employment letter, the term "good reason" means any of the following: (i) a material reduction in Dr. Morisset's Base Salary or Target Amount, which the parties agree is a reduction of at least ten percent (10%) of Dr. Morisset's Base Salary or Target Amount as in effect immediately prior to the time such reduction occurs (unless pursuant to a salary reduction or target bonus reduction program applicable generally to the Company's similarly situated executive officers); (ii) a change in Dr. Morisset's position, responsibilities, authority or offices that, results in a material diminution of position, responsibilities, authority or offices, provided, however, that the Company's hiring of personnel to handle duties that the NEO was responsible for but which are not regularly associated with Dr. Morisset's position will not be a "material diminution" of position, responsibilities, authority or offices; (iii) a material breach by the Company or any successor entity of any employment-related contract between the Company and the NEO; or (iv) the relocation of Dr. Morisset's principal place of employment, without Dr. Morisset's consent, in a manner that lengthens his one-way commute distance by fifty (50) or more miles from his then-current principal place of employment immediately prior to such relocation; provided, however, that, any such termination by the NEO shall only be deemed for Good Reason pursuant to this definition if: (1) the NEO gives the Company written notice of his intent to terminate for Good Reason within sixty (60) days following the first occurrence of the condition(s) that he believes constitute(s) Good Reason, which notice shall describe such condition(s); (2) the Company fails to remedy such condition(s) within sixty (60) days following receipt of the written notice (the "Cure Period"); (3) the Company has not, prior to receiving such notice from the NEO, already informed the NEO that his employment with the Company is being terminated; and (4) the NEO voluntarily terminates his employment within sixty (60) days following the end of the Cure Period. For purposes of clarity, a material reduction in Dr. Morisset's position, responsibilities, authority or offices that occurs as a result of the Company being acquired and made part of a larger entity (as, for example, when the NEO retains his position following a Change in Control, but not of the acquiring or successor corporation itself but of a subsidiary of the acquiring or successor company) shall constitute a Good Reason event under (ii), above.

Mr. Azelby resigned as an officer and director of the Company effective February 13, 2023. In connection with his resignation, we entered into a separation and consulting agreement with Mr. Azelby pursuant to which, and subject to a general release and waiver of claims against the Company, Mr. Azelby received the following severance benefits: (i) a lump sum payment of $1,404,000 on the first regularly-scheduled payroll date following his resignation, which was equal to twenty four months of Mr. Azelby's base salary at the time of his resignation, (ii) a payment of $912,600, which was equal to two times Mr. Azelby's annual bonus for the calendar year 2023, (iii) COBRA health insurance premiums for twenty four months following the date of Mr. Azelby's resignation, and (iv) accelerated vesting of Mr. Azelby's outstanding and unvested stock options as of the date of his resignation.

Ms. Lavelle resigned as an officer of the Company effective March 14, 2023. In connection with her resignation, we entered into a separation and consulting agreement with Ms. Lavelle pursuant to which, and subject to a general release and waiver of claims against the Company, Ms. Lavelle received the following severance benefits: (i) a lump sum payment of $726,570 on the first regularly scheduled payroll date following her resignation, which was equal to eighteen months of Ms. Lavelle's base salary at the time of her resignation, (ii) a payment of $326,957, which was equal to 1.5 times Ms. Lavelle's annual bonus for the calendar year 2023, (iii) COBRA health insurance premiums for eighteen months following the date of Ms. Lavelle's resignation, and (iv) accelerated vesting of Ms. Lavelle's outstanding and unvested stock options as of the date of her resignation.

Mr. Bucher resigned as an officer of the Company effective March 17, 2023. In connection with his resignation, we entered into a separation and consulting agreement with Mr. Bucher pursuant to which, and subject to a general release and waiver of claims against the Company, Mr. Bucher received the following severance benefits: (i) a lump sum payment of $726,570 on the first regularly scheduled payroll date following his resignation, which was equal to eighteen months of Mr. Bucher's base salary at the time of his resignation, (ii) a payment of $326,957, which was equal to 1.5 times Mr. Bucher's annual bonus for the calendar year 2023, (iii) COBRA health insurance premiums for eighteen months following the date of Mr. Bucher's resignation, and (iv) accelerated vesting of Mr. Bucher's outstanding and unvested stock options as of the date of his resignation.

Emerging Growth Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act). As an emerging growth company, we will be exempt from certain requirements related to executive compensation, including, but not limited to, the requirements to hold a nonbinding advisory vote on executive compensation and to provide information relating to the ratio of total compensation of our Chief Executive Officer to the median of the annual total compensation of all of our employees, each as required by the Investor Protection and Securities Reform Act of 2010, which is part of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

Nonqualified Deferred Compensations

Our named executive officers did not participate in, or earn any benefits under, any nonqualified deferred compensation plan sponsored by us during the year ended December 31, 2023. Our Board of Directors may elect to provide our officers and other employees with nonqualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

Pension and Defined Benefit Plan Retirement Benefits

Our named executive officers did not participate in, or otherwise receive any benefits under, any defined benefit retirement plan sponsored by us during 2023.

Health and Welfare Benefits

All of our current named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, life, disability and accidental death and dismemberment insurance plans, in each case on the same basis as all of our other employees. We generally do not provide perquisites or personal benefits to our named executive officers.

401(k) Plan

We currently maintain a 401(k) retirement savings plan for our U.S.-based employees, including our U.S.-based named executive officers, who satisfy certain eligibility requirements. The 401(k) plan is intended to qualify as a tax-qualified plan under the Internal Revenue Code. Our U.S.-based named executive officers are eligible to participate in the 401(k) plan on the same basis as our other employees. The Internal Revenue Code allows eligible employees to defer a portion of their compensation, within prescribed limits, on a pre-tax basis through contributions to the 401(k) plan.

Pension Plan

We currently maintain a pension plan for our U.K.-based employees. We have historically contributed 8% of each employee's annual basic salary as an employer contribution, and in April 2021, we increased this amount to 9%. Employees may choose to also make additional contributions, which, if elected, are deducted from their salaries. We also give back the 13.8% employer National Insurance savings into each employee's pension plan as an additional contribution. The pension plan is subject to an annual management charge of 0.36% and, in addition to our contributions and any employee contributions, accepts transfers from other schemes.

OUTSTANDING EQUITY AWARDS AT DECEMBER 31, 2023

The following table provides information regarding outstanding equity awards held by each of our NEOs as of December 31, 2023.

		Option Awards					Stock Awards			
Name (a)	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable (b)	Number of Securities Underlying Unexercised Options (#) Unexercisable (c)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#) (d)	Option Exercise Price ($) (e)	Option Expiration Date (f)	Number of Shares or Units of Stock That Have Not Vested (#) (g)	Market Value of Shares or Units of Stock That Have Not Vested ($) (h)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#) (i)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($) (j)
Dr. Levin	8/9/2021	15,555(1)	4,445(1)	—	12.50	8/8/2031	—	—	—	—
	5/19/2022	10,000(2)	—	—	3.46	5/18/2032	—	—	—	—
	5/18/2023	—	10,000(2)	—	3.00	5/17/2033	—	—	—	—
Dr. Morisset	2/26/2021	10,198(3)	35,695(3)	—	0.0002	2/25/2031	—	—	—	—
	4/27/2021	—	—	—	—	—	50,108(4)	135,292(4)	—	—
	1/27/2022	81,458(5)	88,542(5)	—	8.21	1/26/2032	—	—	—	—
	10/31/2022	49,583(6)	120,417(6)	—	3.27	10/30/2032	—	—	—	—
Mr. Azelby	2/26/2021	470,940(7)	— (7)	—	1.32	8/13/2024	—	—	—	—
	4/27/2021	406,494(7)	— (7)	—	6.10	8/13/2024	—	—	—	—
	1/27/2022	500,000(7)	— (7)	—	8.21	8/13/2024	—	—	—	—
	10/31/2022	500,000(7)	— (7)	—	3.27	8/13/2024	—	—	—	—
Ms. Lavelle	4/27/2021	121,948(8)	— (8)	—	6.10	9/14/2024	—	—	—	—
	1/27/2022	170,000(8)	— (8)	—	8.21	9/14/2024	—	—	—	—
	10/31/2022	170,000(8)	— (8)	—	3.27	9/14/2024	—	—	—	—
Mr. Bucher	2/26/2021	80,260(9)	— (9)	—	1.32	9/17/2024	—	—	—	—
	4/27/2021	67,749(9)	— (9)	—	6.10	9/17/2024	—	—	—	—
	1/27/2022	95,000(9)	— (9)	—	8.21	9/17/2024	—	—	—	—
	10/31/2022	95,000(9)	— (9)	—	3.27	9/17/2024	—	—	—	—

(1) The shares subject to this option vest in equal monthly installments at a rate of 1/36th of the total number of shares on each monthly anniversary of August 9, 2021.

(2) The shares subject to this option vest on the earlier to occur of (i) the one-year anniversary of the grant date or (ii) immediately prior to the subsequent annual meeting of the Company's stockholders.

(3) Twenty-five percent of the shares subject to Dr. Morisset's option vested on February 26, 2022, with 75% of the shares subject to the option vesting in equal monthly installments over the subsequent 36 months, subject to Dr. Morisset's continued service with us through each applicable vesting date.
(4) Twenty-five percent of the shares subject to Dr. Morisset's grant vested on April 27, 2022, with 75% of the shares subject to the grant vesting in equal monthly installments over the subsequent 36 months, subject to Dr. Morisset's continued service with us through each applicable vesting date. The market value of the shares that have not vested was determined based on the closing price of our common stock as reported by the Nasdaq Global Market on December 31, 2023, which was $2.70 per share.
(5) The shares subject to Dr. Morisset's grant vest in equal monthly installments over 48 months from January 27, 2022, subject to Dr. Morisset's continued service with us through each applicable vesting date.
(6) The shares subject to Dr. Morisset's grant vest in equal monthly installments over 48 months from October 31, 2022, subject to Dr. Morisset's continued service with us through each applicable vesting date.
(7) Pursuant to Mr. Azelby's separation agreement, the vesting of 100% of Mr. Azelby's outstanding equity awards at the time of his separation was accelerated.
(8) Pursuant to Ms. Lavelle's separation agreement, the vesting of 100% of Ms. Lavelle's outstanding equity awards at the time of her separation was accelerated.
(9) Pursuant to Mr. Bucher's separation agreement, the vesting of 100% of Mr. Bucher's outstanding equity awards at the time of his separation was accelerated.

DIRECTOR COMPENSATION

The following tables show certain information with respect to the compensation of all non-employee directors of the Company for the fiscal year ended December 31, 2023:

DIRECTOR COMPENSATION FOR FISCAL YEAR 2023

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	Total ($)
Liam Ratcliffe, M.D.	$ 48,806	$22,522	$71,328
Simon Tate(2)	—	$22,522	$22,522
Andrew Levin, M.D., Ph.D.	$ 65,387	$22,522	$87,909
Adam Rosenberg	$ 54,637	$22,522	$77,159
Judith Dunn, Ph.D.	$ 47,137	$22,522	$69,659
Leone Patterson(3)	$ 2,758	—	$ 2,758

(1) The amounts reported in this column do not reflect dollar amounts actually received our non-employee directors. Instead, the amounts reflect the aggregate grant date fair value computed in accordance with ASC 718. Assumptions used in the calculation of these amounts are included in our Annual Report on Form 10-K for the year ended December 31, 2023.
(2) Mr. Tate waived Director fees for fiscal year 2023.
(3) Ms. Patterson resigned from our Board of Directors in January 2023.

The following table shows certain information with respect to the outstanding options of the non-employee directors of the Company for the fiscal year ended December 31, 2023

Name	Number of Shares Subject to Outstanding Options as of December 31, 2023
Liam Ratcliffe, M.D.	40,000
Simon Tate	40,000
Andrew Levin, M.D., Ph.D.	40,000
Adam Rosenberg	40,000
Judith Dunn, Ph.D.	74,581
Leone Patterson	—

In July 2021, we adopted a non-employee director compensation policy pursuant to which our non-employee directors are eligible to receive cash and equity compensation for service on our Board of Directors and committees of our Board of Directors.

Under the non-employee director compensation policy, each non-employee director receives an annual cash retainer of $35,000 for serving on our Board of Directors. The chairperson of our Board of Directors is also be entitled to an annual cash retainer of $30,000 in addition to the annual retainer received by non-employee directors for serving as our lead director.

The chairperson and members of the following three committees of our Board of Directors are entitled to the following additional annual cash retainers:

Board Committee	Chairperson Fee	Member Fee
Audit Committee	$ 15,000	$ 7,500
Compensation Committee	10,000	5,000
Nominating and Corporate Governance Committee	8,000	4,000

All annual cash retainers are payable in equal quarterly installments in arrears, on the last day of each fiscal quarter for which the service occurred, pro-rated based on the number of days served in the applicable fiscal quarter.

Each new non-employee director who joins our Board of Directors will receive an option to purchase 20,000 shares of our common stock under our 2021 Equity Incentive Plan. The shares subject to this option will vest on a monthly basis over 36 months commencing on the grant date, subject to the non-employee director's continuous service with us on each applicable vesting date. Such newly joining director will also receive a prorated initial annual option grant consisting of an option to purchase a number of shares of our common stock determined by multiplying 20,000 by the percentage obtained by dividing the number of calendar days from the date such new director joins us to the date of the next scheduled annual stockholder meeting by the total number of calendar days scheduled to follow the date of the last annual stockholder meeting through the date of the next annual stockholder meeting. Such prorated initial annual option will vest in full on the date immediately preceding the date of next annual stockholder meeting, subject to the non-employee director's continuous service through such vesting date.

On the date of each annual meeting of our stockholders, each continuing non-employee director will receive an option to purchase 10,000 shares of our common stock under the 2021 Equity Incentive Plan, vesting on the earlier of the one-year anniversary of the grant date or the date immediately prior to the next annual stockholder meeting date, subject to the non-employee director's continuous service with us on the applicable vesting date. The number of shares comprising the initial and annual stock option awards granted under the non-employee director compensation policy is subject to adjustment from time to time as may be determined by the Board of Directors or the Compensation Committee acting on its behalf.

The exercise price per share of each stock option granted under the non-employee director compensation policy will be the closing price of our common stock as reported by the Nasdaq Global Market on the date of grant. Each stock option will have a term of ten years from the date of grant, subject to earlier termination in connection with a termination of the non-employee director's continuous service with us. Each stock option and other equity award granted to our non-employee directors is also entitled to immediate vesting acceleration upon a change in control if the non-employee director remains in our continued services through the date of such change in control.

Each non-employee director is subject to an annual director compensation limit. In any one-year period measured as commencing on the date of each annual meeting of stockholders that is held following the closing of our initial public offering and ending on the day immediately prior to the date of the subsequent annual meeting of stockholders, the aggregate value of all compensation granted or paid to each non-employee director may not exceed (i) $750,000 in total value or (ii) in the event such non-employee director is first appointed or elected during such annual period, $1,000,000 in total value, in each case calculating the value of any equity awards based on the grant date fair market value for financial reporting purposes.

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

Certain Beneficial Owners and Management

The following table sets forth information with respect to the beneficial ownership of our common stock as of March 31, 2024, for:

- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our directors and executive officers as a group.

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially own, subject to applicable community property laws.

Applicable ownership percentages are based on 27,723,824 shares of common stock outstanding as of March 31, 2024. In computing the number of shares beneficially owned by a person and the percentage ownership of such person, we deemed to be outstanding all shares subject to options held by the person that are currently exercisable, or exercisable within 60 days of March 31, 2024. However, except as described above, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person. The information contained in the following table is not necessarily indicative of beneficial ownership for any other purpose, and the inclusion of any shares in the table does not constitute an admission of beneficial ownership of those shares.

Unless otherwise indicated, the address of each beneficial owner listed below is c/o Eliem Therapeutics, PMB #117, 2801 Centerville Road 1st Floor, Wilmington, DE 19808. We believe, based on information provided to us, that each of the stockholders listed below has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

	Beneficial Ownership	
Beneficial Owner	**Number of Shares**	**Percent of Total**
Directors and Executive Officers		
Andrew Levin, M.D., Ph.D.(1)	38,333	*
Judith Dunn, Ph.D.(2)	62,888	*
Liam Ratcliffe, M.D., Ph.D.(1)	38,333	*
Adam Rosenberg(3)	216,433	*
Simon Tate(1)	38,333	*
Valerie Morisset, Ph.D.(4)	673,322	2.4%
All directors and executive officers as a group (6 persons)(5)	1,067,642	3.8%
Former Executive Officers		
Robert Azelby(6)	1,582,844	5.4%
Erin Lavelle(7)	461,948	1.6%
James Bucher(8)	327,010	1.2%
5% Stockholders		
Entities affiliated with RA Capital(9)	13,150,849	47.4%
LifeArc(10)	1,461,538	5.3%
AI ETI LLC(11)	5,009,400	18.1%
Intermediate Capital Investments Ltd.(12)	2,002,563	7.2%
BML Investment Partners, L.P.(13)	2,180,000	7.9%

* Less than one percent.

(1) Consists of 38,333 shares issuable pursuant to stock options exercisable within 60 days of March 31, 2024.

(2) Consists of 62,888 shares issuable pursuant to stock options exercisable within 60 days of March 31, 2024.

(3) Consists of 178,100 shares of common stock held directly and 38,333 shares issuable pursuant to stock options exercisable within 60 days of March 31, 2024.

(4) Consists of 487,460 shares of common stock held directly and 185,862 shares issuable pursuant to stock options exercisable within 60 days of March 31, 2024.

(5) Consists of (i) 665,560 shares of common stock held directly or indirectly by all current executive officers and directors as a group and (ii) 402,082 shares issuable pursuant to stock options exercisable within 60 days of March 31, 2024.

(6) Consists of 1,582,844 shares issuable pursuant to stock options exercisable within 60 days of March 31, 2024.

(7) Consists of 461,948 shares issuable pursuant to stock options exercisable within 60 days of March 31, 2024.

(8) Consists of 327,010 shares issuable pursuant to stock options exercisable within 60 days of March 31, 2024

(9) Consists of: (i) 10,599,586 shares of common stock held by RA Capital Healthcare Fund, L.P. (RA Healthcare); (ii) 1,266,497 shares of common stock held by RA Capital Nexus Fund, L.P. (Nexus Fund); (iii) 841,087 shares of common stock held directly by a separately managed account (the Account) and (iv) 483,679 shares of common stock held by RA Capital Nexus Fund II, L.P. (Nexus Fund II). RA Capital Management, L.P. (RACM) is the investment manager for RA Healthcare, Nexus Fund, the Account, and Nexus Fund II. The general partner of RACM is RA Capital Management GP, LLC. The general partner of RA Healthcare is RA Capital Healthcare Fund GP, LLC. The general partner of Nexus Fund is RA Capital Nexus Fund GP, LLC. The general partner of Nexus Fund II is RA Capital Nexus Fund II GP, LLC. Peter Kolchinsky and Rajeev Shah are the managing members of RA Capital Management GP, LLC, RA Capital Healthcare Fund GP, LLC, RA Capital Nexus Fund GP, LLC, and RA Capital Nexus Fund II GP, LLC and have the power to vote or dispose of the shares held by RA Healthcare, Nexus Fund, the Account and Nexus Fund II. The address of the persons and entities listed above is 200 Berkeley Street, 18th Floor, Boston, Massachusetts 02116.

(10) Consists of 1,461,538 shares of common stock held by LifeArc. The board of trustees are responsible for the general control and management of the administration of LifeArc, including the exercise of any voting or other rights attaching to its shares in Eliem Therapeutics, Inc. The board of trustees of LifeArc are John Stageman, Daniel Morgan, David Zahn, Paul Mussenden, Aisling Burnand, Mike Romanos, Melanie Lee, Les Hughes, Lynne Robb, Andrew Mercieca and Jo Pisani. The address of LifeArc is Lynton House, 7-12 Tavistock Square, London, WC1H 9LT United Kingdom.

(11) Consists of 5,009,400 shares of common stock owned directly by AI ETI LLC and that may be deemed to be beneficially owned by Access Industries Holdings LLC ("AIH"), Access Industries Management, LLC ("AIM") and Len Blavatnik because (i) AIH indirectly controls all of the outstanding voting interests in AI ETI LLC, (ii) AIM controls AIH and (iii) Mr. Blavatnik controls AIM and holds a majority of the outstanding voting interests in AIH. Liam Ratcliffe, a member of our Board of Directors, is Head of Biotechnology at Access Industries, Inc., which is an affiliate of AI ETI LLC. Each of AIM, AIH, Mr. Blavatnik and Dr. Ratcliffe, and each of their affiliated entities and the officers, partners, members and managers thereof, disclaims beneficial ownership of the shares held by AI ETI LLC. The address of AI ETI LLC is c/o Access Industries, Inc., 40 West 57th Street, 28th Floor, New York, NY 10019.

(12) Consists of 2,002,563 shares of common stock held by Intermediate Capital Investments, Ltd. (ICG). ICG is indirectly, wholly owned by Intermediate Capital Group PLC which is deemed to have voting and investment power over the shares held of record of ICG. The address of the entities listed above is Procession House, 55 Ludgate Hill, London EC4M 7JW.

(13) Consists of 2,180,000 shares of common stock held by BML Investment Partners, L.P. (BML). BML is a Delaware limited partnership whose sole general partner is BML Capital Management, LLC. The managing member of BML Capital Management, LLC is Braden M. Leonard. As a result, Braden M. Leonard is deemed to be the indirect owner of the shares held directly by BML Investment Partners, L.P. Despite such shared beneficial ownership, the reporting persons disclaim that they constitute a statutory group within the meaning of Rule 13d-5(b)(1) of the Exchange Act. The address of BML Investment Partners, L.P. is 65 E Cedar—Suite 2, Zionsville, IN 46077.

Equity Compensation Plan Information

The following table summarizes information about our equity compensation plans as of December 31, 2023. All outstanding awards relate to our common stock.

Plan Category	(a) Number of securities to be issued upon exercise of outstanding options and rights	(b) Weighted-average exercise price of outstanding options	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders:			
2019 Equity Incentive Plan	1,389,620	$ 3.70	—
2021 Equity Incentive Plan[1]	3,276,190	$ 6.14	2,057,888
2021 Employee Stock Purchase Plan[1]	—	N/A	787,231
Equity compensation plans not approved by security holders:	—	N/A	—
Total	4,665,810	N/A	2,845,119

(1) Our 2021 Equity Incentive Plan includes provisions providing for an annual increase in the number of securities available for future issuance on the first day of each fiscal year equal 5% of the total number of shares of common stock outstanding on December 31 of the immediately preceding calendar year or a lesser number of shares determined by our Board of Directors prior to the applicable January 1st. Our 2021 Employee Stock Purchase Plan includes provisions providing for an annual increase in the number of securities available for future issuance on the first day of each fiscal year by the lesser of (1) 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year or (2) a number of shares determined by our Board of Directors.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Related-Person Transactions Policy and Procedures

Other than compensation arrangements for our directors and NEOs, which are described elsewhere in this Amendment, below we describe transactions since January 1, 2022 to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed $120,000; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of, or person sharing the household with, the foregoing persons, had or will have a direct or indirect material interest.

Private Placement in Support of the Acquisition

On April 10, 2024, we entered into an Agreement and Plan of Merger and Reorganization (the Acquisition Agreement) by and among the Company, Tango Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of the Company (Transitory Subsidiary), Tenet Medicines, Inc., a Delaware corporation (Tenet), and, solely in his capacity as company equityholder representative, Stephen Thomas. The Acquisition Agreement provides for the acquisition of Tenet by the Company through the merger of Transitory Subsidiary into Tenet, with Tenet surviving as a wholly owned subsidiary of the Company (the Acquisition).

Also on April 10, 2024, in connection with the Acquisition, we entered into a Securities Purchase Agreement with several accredited institutional investors (the PIPE Investors) pursuant to which we agreed to issue and sell to the PIPE Investors in a private placement an aggregate of 31,238,282 shares of our common stock (the PIPE Shares), at a price of $3.84 per PIPE Share (the Private Placement). We expect to receive aggregate gross proceeds from the Private Placement of approximately $120.0 million, before deducting estimated offering expenses payable by us. The Private Placement is expected to close immediately following the closing of the Acquisition. The closing of the Private Placement contemplated by the Securities Purchase Agreement is conditioned upon the satisfaction or waiver of the conditions to the closing of the Acquisition as well as certain other conditions as set forth in the Securities Purchase Agreement. The following table summarizes the shares of our common stock that holders of more than 5% of our voting securities agreed to purchase in the Private Placement.

Name	Number of Shares of Common Stock to be Purchased	Purchase Price to be Paid
RA Capital Healthcare Fund, L.P.	11,949,171	$45,902,023.45
RA Capital Nexus Fund III, L.P.	1,059,375	$ 4,069,525.50

In connection with the Private Placement, we also entered into a Registration Rights Agreement with the PIPE Investors on April 10, 2024, pursuant to which we agreed to register for resale the PIPE Shares. Under the Registration Rights Agreement, we have agreed to file a registration statement covering the resale of the PIPE Shares and the shares issued pursuant to the Acquisition Agreement within 45 days following the closing of the Private Placement. We have agreed to use commercially reasonable efforts to cause such registration statement to become effective as promptly as practicable and to keep such registration statement effective until the date the PIPE Shares and any other shares covered by such registration statement have been sold or cease to be registrable securities under such Registration Rights Agreement.

INVESTOR RIGHTS AGREEMENT

We are party to an investor rights agreement, or IRA, as amended in March 2021, with certain holders of our redeemable convertible preferred stock and common stock, including entities affiliated with our directors. The IRA provides the holders of our redeemable convertible preferred stock with certain registration rights, including the right to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. Simon Tate, Andrew Levin and Liam Ratcliffe are affiliated with Intermediate Capital Group plc, RA Capital Management, L.P. and AI ETI LLC, respectively. The holders of 15,679,479 shares of common stock issuable on conversion of outstanding redeemable convertible preferred stock are entitled to rights with respect to the registration of their shares of common stock under the Securities Act under this agreement. The registration of shares of our common stock pursuant to the exercise of certain registration rights would enable the holders to sell these shares without restriction under the Securities Act, when the applicable registration statement is declared effective. We will pay the registration expenses, other than underwriting discounts and commissions, of the shares registered pursuant to certain demand, piggyback and Form S-3 registrations.

Relationship with Carnot LLC

We were party to a services agreement with Carnot, LLC (along with its successor agreements, the Carnot Agreement). Under the terms of the Carnot Agreement, Carnot Pharma, LLC provided research and services related to our drug discovery, research and development programs and we compensate Carnot Pharma, LLC for the time its personnel devote to such efforts. The Carnot Agreement is terminable by either party without cause on thirty days' written notice. Subsequent to our entering into the Carnot Agreement, Carnot, LLC was dissolved and the services agreement transitioned to its successor Carnot Pharma, LLC. RACM is the manager of the members of Carnot Pharma, LLC and Andrew Levin, our former CEO and a member of our Board of Directors, is the President of Carnot Pharma, LLC. Adam Rosenberg, a member of our Board of Directors, was a Venture Partner at Carnot Pharma, LLC, dba RA Ventures until 2021. The Carnot Agreement was terminated in the fourth quarter of 2022.

Indemnification Agreements

Our amended and restated certificate of incorporation provides that we may indemnify our directors, officers, employees and other agents to the maximum extent permitted by the Delaware General Corporation Law, and our amended and restated bylaws provide that we will indemnify our directors and officers and may indemnify our other employees and other agents to the maximum extent permitted by the Delaware General Corporation Law. In addition, we have entered and expect to continue to enter into agreements to indemnify our directors and executive officers.

Policy on Related Party Transactions

In 2021, the Company adopted a written Related-Person Transactions Policy that sets forth the Company's policies and procedures regarding the identification, review, consideration and approval or ratification of "related-persons transactions." For purposes of the Company's policy only, a "related-person transaction" is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which the Company and any "related person" are participants involving an amount that exceeds $120,000. Transactions involving compensation for services provided to the Company as an employee, director, consultant or similar capacity by a related person are not covered by this policy. A related person is any executive officer, director, or more than 5% stockholder of the Company, including any of their immediate family members, and any entity owned or controlled by such persons.

Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to the Audit Committee (or, where Audit Committee approval would be inappropriate, to another independent body of the Board of Directors) for consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to the Company of the transaction and whether any alternative transactions were available. To identify related-person transactions in advance, the Company relies on information supplied by its executive officers, directors and certain significant stockholders. In considering related-person transactions, the Committee takes into account the relevant available facts and circumstances including, but not limited to (a) the risks, costs and benefits to the Company, (b) the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated, (c) the terms of the transaction, (d) the availability of other sources for comparable services or products and (e) the terms available to or from, as the case may be, unrelated third parties or to or from employees generally. In the event a director has an interest in the proposed transaction, the director must recuse himself or herself form the deliberations and approval. The policy requires that, in determining whether to approve, ratify or reject a related-person transaction, the Committee consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, the best interests of the Company and its stockholders, as the Committee determines in the good faith exercise of its discretion.

Independence of The Board of Directors

As required under the Nasdaq Stock Market (Nasdaq) listing standards, a majority of the members of a listed company's Board of Directors must qualify as "independent," as affirmatively determined by the Board of Directors. The Board of Directors consults with the Company's counsel to ensure that the Board's determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of Nasdaq, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his or her family members, and the Company, its senior management and its independent auditors, the Board of Directors has affirmatively determined that none of our current or former directors, except for Dr. Levin, who is our executive chairman, have any relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the applicable rules and regulations of the SEC and the listing requirements and rules of Nasdaq.

Board of Directors Leadership Structure

Our Board of Directors does not have a policy as to whether the positions of chair (the "Board Chair") and Chief Executive Officer should be separate, and believes that it should select the Board Chair and the Chief Executive Officer in the manner it considers to be in the best interests of the Company and our stockholders. Our Board of Directors believes that it should have the flexibility to make this determination as circumstances require and in a manner that it believes is best to provide appropriate leadership for the Company. The Board of Directors believes that its current leadership structure, with Dr. Levin serving as independent Executive Chairman of the Board of Directors, and with no currently-serving Chief Executive Officer, is appropriate because it enables the Board of Directors, as a whole, to engage in oversight of management, promote communication and collaboration between management and the Board of Directors, and to oversee governance matters as well as the operational leadership and strategic direction of the Company. Our Corporate Governance Guidelines, which are available on our website at eliemtx.com, provide that if the individual appointed as Board Chair is not independent or whenever the independent directors on the Board of Directors determine that it is in the best interests of the Company and our stockholders, the independent directors, by vote of a majority of such independent directors, shall annually select an independent director to serve as lead independent director. Our Corporate Governance Guidelines further provide that the lead independent director shall: (i) in consultation with the Chair, establish the agenda for regular meetings of the Board of Directors, (ii) preside at all meetings of the Board of Directors at which the Chair is not present, including executive sessions of the independent directors; (iii) establish the agenda for meetings of the independent directors; (iv) coordinate with the committee chairs regarding meeting agendas and information requirements; (v) preside over any portions of meetings of the Board of Directors at which the performance of the Board of Directors is presented or discussed; (vi) act as liaison between the independent directors, the Chief Executive Officer and the Chair; and (vii) perform such other functions as the Board of Directors may delegate. The Board of Directors has selected Dr. Ratcliffe as the lead independent director in 2024. The Board of Directors believes that this flexible approach provides it with the ability to establish a leadership structure, based upon its judgment, that is in the best interests of the Company and those of our stockholders at any given time.

Role of the Board of Directors in Risk Oversight

One of the Board of Directors' key functions is informed oversight of the Company's risk management process. The Board of Directors does not have a standing risk management committee, but rather administers this oversight function directly through the Board of Directors as a whole, as well as through various Board of Directors standing committees that address risks inherent in their respective areas of oversight. In particular, our Board of Directors is responsible for monitoring and assessing strategic risk exposure, including a determination of the nature and level of risk appropriate for the Company. Our Audit Committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The Audit Committee also monitors compliance with legal and regulatory requirements, in addition to oversight of the performance of our internal audit function. Our Nominating and Corporate Governance Committee monitors the effectiveness of our corporate governance guidelines, including whether they are successful in preventing illegal or improper liability-creating conduct. Our Compensation Committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

Item 14. Principal Accounting Fees and Services.

The following table represents aggregate fees billed to the Company for the years ended December 31, 2022 and December 31, 2023 by PricewaterhouseCoopers LLP, Seattle, WA (PCAOB ID 238) the Company's principal accountant.

	Year Ended	
	2022	2023
Audit Fees (1)	$929,500	$680,000
Audit-related Fees	—	—
Tax Fees	—	—
All Other Fees (2)	$ 6,650	$ 1,944
Total Fees	$936,150	$681,944

(1) This category includes fees for professional services provided in conjunction with the audit and quarterly review of our financial statements and review of our registration statements and related issuances of consents, and related services that are normally provided in connection with statutory and regulatory filings or engagements.

(2) All other fees relate to subscriptions for accounting-related research software.

All fees described above were pre-approved by the Audit Committee.

PRE-APPROVAL POLICIES AND PROCEDURES

The Charter of the Audit Committee provides for the pre-approval of audit and non-audit services rendered by the Company's independent registered public accounting firm, PricewaterhouseCoopers LLP. The Audit Committee generally pre-approves specified services in the defined categories of audit services, audit-related services and tax services up to specified amounts. Pre-approval may also be given as part of the Audit Committee's approval of the scope of the engagement of the independent auditor or on an individual, explicit, case-by-case basis before the independent auditor is engaged to provide each service. The pre-approval of services may be delegated to one or more of the Audit Committee's members, but the decision must be reported to the full Audit Committee at its next scheduled meeting.

The Audit Committee has determined that the rendering of services other than audit services by PricewaterhouseCoopers LLP is compatible with maintaining the principal accountant's independence.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

***(a)* Documents to be filed as part of this report.**

(1) Financial Statements. The Report of Independent Registered Public Accounting Firm (Seattle, WA; PCAOB ID 238) and our Consolidated Financial Statements as set out in Item 8 of the Initial Filing.

(2) Financial Statement Schedules. No financial statement schedules have been filed as part of this Amendment because they are not applicable, not required or because the information is otherwise included in our financial statements or notes thereto.

***(b)* Exhibits.**

The exhibits listed below on the Exhibit Index are filed or furnished as a part of this Amendment.

Exhibit Index

Exhibit Number	Description of Exhibit	Incorporated by Reference				
		Form	File No.	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-40708	3.1	August 12, 2021	
3.2	Amended and Restated Bylaws of the Registrant.	S-1	333-257980	3.4	August 2, 2021	
4.1	Form of common stock certificate of the Registrant.	S-1	333-257980	4.1	August 2, 2021	
4.3	Description of Securities	10-K	001-40708	4.3	March 7, 2022	
10.1	Amended and Restated Investor Rights Agreement, dated May 21, 2021, by and among the Registrant and the investors listed on Schedule A thereto.	S-1	333-257980	10.1	July 16, 2021	
10.2+	2021 Equity Incentive Plan.	S-1	333-257980	10.4	August 2, 2021	
10.3+	Forms of Option Agreement, Stock Option Grant Notice and Notice of Exercise under the 2021 Equity Incentive Plan.	S-1	333-257980	10.5	August 2, 2021	
10.4+	Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the 2021 Equity Incentive Plan.	S-1	333-257980	10.6	August 2, 2021	
10.5+	2021 Employee Stock Purchase Plan.	S-1	333-257980	10.7	August 2, 2021	
10.6+	Form of Indemnification Agreement, by and between the Registrant and each of its directors and executive officers.	S-1	333-257980	10.8	August 2, 2021	
10.7+	Executive Employment Agreement by and between the Registrant and Robert Azelby, effective October 1, 2020, as amended.	S-1	333-257980	10.9	August 2, 2021	
10.8+	Executive Employment Agreement by and between the Registrant and Erin M. Lavelle, effective October 1, 2020, as amended.	S-1	333-257980	10.10	August 2, 2021	
10.9+	Executive Employment Agreement by and between Eliem Therapeutics (UK) Ltd. and Valerie Morisset, Ph.D., effective January 1, 2021.	S-1	333-257980	10.11	July 16, 2021	
10.10+	Separation and Consulting Agreement, dated February 13, 2023, by and between Eliem Therapeutics, Inc. and Robert Azelby.	8-K	001-40708	10.1	February 13, 2023	
10.11+	Separation and Consulting Agreement, dated February 13, 2023, by and between Eliem Therapeutics, Inc. and Erin Lavelle.	8-K	001-40708	10.2	February 13, 2023	
10.12+	Retention Agreement, dated February 14, 2023, by and between Eliem Therapeutics, Inc. and Valerie Morisset.	10-K	001-40708	10.12	March 6, 2023	
21.1	List of subsidiaries.	S-1	333-257980	21.1	August 2, 2021	
23.1	Consent of Independent Registered Public Accounting Firm.	10-K	001-40708	23.1	March 28, 2024	23.1

10.13+	Executive Employment Agreement by and between the Eliem Therapeutics, Inc. and James B. Bucher, effective October 1, 2020.	10-K	001-40708	10.13	March 28, 2024
10.14+	Separation and Consulting Agreement, dated February 13, 2023, by and between Eliem Therapeutics, Inc. and James B. Bucher.	10-K	001-40708	10.14	March 28, 2024
31.1*	Certification of Principal Executive Officer and 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.				
31.2	Certification of Principal Executive Officer and 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.	10-K	001-40708	31.1	March 28, 2024
32.1	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	10-K	001-40708	32.1	March 28, 2024
97.1	Eliem Therapeutics, Inc. Clawback Policy	10-K	001-40708	97.1	March 28, 2024
101.INS*	Inline XBRL Instance Document				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	Inline XBRL Extension Definition Linkbase Document				
101.LAB*	Inline XBRL Taxonomy Label Linkbase Document				
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104*	Cover Page Interactive Data File (embedded within inline XBRL document)				

* Filed herewith.
\+ Indicates management contract or compensatory Plan

SIGNATURES

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 Levin Andrew Levin	Executive Chairman of the Board of Directors (Principal Executive Officer and Principal Financial Officer)	April 29, 2024
/s/ Emily Pimblett Emily Pimblett	Chief Accounting Officer (Principal Accounting Officer)	April 29, 2024

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