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

# Form 10-K

**(Mark One)**

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

**For the fiscal year ended December 31, 2025**

**OR**

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

**For the transition period from_____to**

**Commission file number**

**001-36620**

# ELEDON PHARMACEUTICALS, INC.

**(Exact name of registrant as specified in its charter)**

| | |
|---|---|
| **Delaware**<br>**(State or other jurisdiction of incorporation or organization)** | **20-1000967**<br>**(I.R.S. Employer Identification No.)** |
| **19800 MacArthur Boulevard, Suite 250**<br>**Irvine, California**<br>**(Address of principal executive offices)** | **92612**<br>**(Zip code)** |

**(949) 238-8090**

**(Registrant's telephone number, including area code)**

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

| Title of Class | Trading Symbol(s) | Name of Exchange on Which Registered |
|---|---|---|
| **Common Stock, $0.001 par value** | **ELDN** | **Nasdaq Capital Market** |

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

**None.**

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

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

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

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

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

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

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

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

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

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

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

As of June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates was $145,168,781, based on the last reported sale price of such stock on the Nasdaq Global Market as of such date.

As of March 13, 2026 the registrant had 75,851,722, shares of Common Stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2026 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, 2025, are incorporated by reference into Items 10, 11, 12, 13 and 14 of Part III of this Annual Report on Form 10-K.

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## EXPLANATORY NOTE

*In this Annual Report on Form 10-K, Annual Report, unless the context requires otherwise, "Eledon", the "Company", "we", "our", and "us" means Eledon Pharmaceuticals, Inc. (formerly Novus Therapeutics, Inc.) and all wholly owned subsidiaries.*

***Special Note Regarding Forward-Looking Statements***

This Annual Report on Form 10-K contains "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995, which statements involve substantial risks and uncertainties. Any statements other than statements of historical or current fact in this Annual Report on Form 10-K are forward looking statements. In some instances, you can identify forward-looking statements by the use of words such as "believes," "anticipates," "plans," "expects," "estimates," "intends," "predicts," "projects," "targets," "could," "may," "will," and similar expressions, although not all forward-looking statements include such identifying words. Forward-looking statements include, but are not limited to statements regarding:

- our product development plans, expectations for and the timing of commencement, enrollment, completion, data, and release of results of clinical trials for our product candidates;
- our estimates regarding our liquidity, expenses, capital requirements and needs for additional financing;
- our strategies with respect to our preclinical and clinical development programs, including our expectations regarding the production of clinical quantities of our product candidates;
- our plans, strategy and timing to obtain and maintain regulatory approvals of our product candidates;
- our expectations regarding competitive conditions for our product candidates; and
- our expectations about our future financial performance or condition.

Although we believe that we have a reasonable basis for each forward looking statement contained in this Annual Report on Form 10-K, actual results may differ materially from those indicated by such forward-looking statements as a result of various factors, including the factors listed under "Risk Factor Summary" below. These risks and uncertainties, as well as other risks and uncertainties that could cause the Company's actual results to differ significantly from the forward-looking statements contained herein, are described in greater detail in Part I, Item 1A. *Risk Factors* in this Annual Report on Form 10-K.

Forward-looking statements contained in this Annual Report on Form 10-K are based on our current beliefs, assumptions, expectations, estimates and projections, which may be impacted by known or unknown factors. Any forward-looking statements contained in this Annual Report on Form 10-K speak only as of the date hereof and not as of any future date, and the Company expressly disclaims any intent to update any forward-looking statements, whether as a result of new information, future events or otherwise. You are therefore cautioned not to place undue reliance on the forward-looking statements included in this Annual Report on Form 10-K.

The market data and certain other statistical information used in this Annual Report on Form 10-K are based on independent industry publications, governmental publications, reports by market research firms or other independent sources. Some data are also based on our good faith estimates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information.

## RISK FACTOR SUMMARY

The following summarizes the principal factors that make an investment in the Company speculative or risky, all of which are more fully described in Part I, Item 1A, *Risk Factors* in this Annual Report on Form 10-K. This summary should be read in conjunction with the Risk Factors section and should not be relied upon as an exhaustive summary of the material risks facing our business. The occurrence of any of these risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described in our public filings when evaluating our business.

- Our short operating history and shifts in our business strategy may make it difficult to evaluate the success of our business to date and to assess our future viability.
- We have incurred significant operating losses since our inception and expect that we will continue to incur losses over the next several years and may never achieve or maintain profitability.
- We will require additional funding to be able to complete the development of our lead drug candidate. If we are unable to raise such capital, or if we are unable to do so on acceptable terms, we will be forced to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether.
- Future issuances of our common stock, including common stock that may be issuable pursuant to outstanding warrants or other convertible securities, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.
- Our product candidates are in the early stages of clinical development and may not be successfully developed. If we are unable to successfully develop and commercialize these or any other product candidate, or if we experience significant delays in doing so, our business will be materially harmed.
- Public health crises, including pandemics or epidemics could adversely affect our business.
- Unfavorable global economic conditions could have a material adverse effect on our business.
- Adverse conditions in the financial markets, including bank failures, could adversely affect our liquidity and financial performance.
- Drug development involves a lengthy and expensive process with an uncertain outcome, including failure to demonstrate safety and efficacy to the satisfaction of the U.S. Food and Drug Administration ("FDA") or similar regulatory authorities outside the United States. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development, formulation and commercialization of our product candidates.
- The results of non-clinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials, and there is a risk that additional non-clinical and/or clinical safety studies will be required by the FDA or similar regulatory authorities outside the United States or that subsequent studies will not match results seen in prior studies.
- Delays or difficulties in the enrollment of patients in clinical trials could delay or prevent our receipt of necessary regulatory approvals and increase expenses for the development of our product candidates.
- Our ability to conduct clinical trials in some jurisdictions outside of the United States may be adversely affected'
- If serious adverse events or unacceptable side effects are identified during the development of our product candidates, we may need to abandon or limit our development of some of our product candidates.
- Our future success depends on our ability to retain executives and key employees and to attract, retain and motivate qualified personnel in the future.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, or the approvals may be for a narrow indication, we may not be able to commercialize our product candidates, and our ability to generate revenue may be materially impaired.
- Legislation regulating the pharmaceutical and healthcare industries may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.
- Our internal computer systems, or those of our third-party collaborators, service providers, contractors or consultants, may fail or suffer security breaches, disruptions, or incidents, which could result in a material disruption

of our development programs or loss of data and have a material adverse effect on our reputation, business, financial condition or results of operations.

- The compromise of privacy, security, integrity or confidentiality of sensitive information related to our business or failure to comply with confidentiality and data privacy obligations could have a material adverse effect on our business.
- Even if any of our product candidates receives marketing approval, we may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community necessary for commercial success.
- If our current product candidates, or a future product candidate receives marketing approval and we, or others, later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the product could be compromised.
- We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.
- The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.
- Our reliance on third parties for the manufacture of our product candidates for non-clinical and clinical trials, and for eventual commercialization, increases the risk that we will not have sufficient quantities of our product candidates or products at an acceptable cost and quality, which could delay, prevent or impair our development or commercialization efforts.
- We depend on contract research organizations ("CROs") and other contracted third parties to perform non-clinical and clinical testing and certain other research and development activities. As a result, the outcomes of the activities performed by these organizations will be, to a certain extent, beyond our control.
- If we are unable to obtain and maintain intellectual property protection for our technology and products or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.
- Public health crises, including pandemics or epidemics, could adversely affect our business.
- Our stock price could be volatile, and the market price of our common stock may drop unexpectedly.
- If we fail to maintain effective internal controls, we may conclude that our internal control over financial reporting is not effective, which could adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner.
- Provisions in our corporate charter and under Delaware law could make an acquisition of the Company more difficult and may prevent attempts by our stockholders to replace or remove our current management.

## WEBSITE REFERENCES

In this Annual Report on Form 10-K, we make references to our website at www.eledon.com. References to our website through this Form 10-K are provided for convenience only and the content on our website does not constitute a part of, and shall not be deemed incorporated by reference into, this Annual Report on Form 10-K.

## PART I

### Item 1. Business.

### Overview

Eledon is a clinical stage biotechnology company using our immunology expertise in targeting the CD40 Ligand ("CD40L") pathway to develop therapies to protect transplanted organs and prevent rejection, and to treat amyotrophic lateral sclerosis ("ALS"). Our lead compound in development is tegoprubart, an IgG1, anti-CD40L antibody with high affinity for the CD40L, a well-validated biological target that we believe has broad therapeutic potential. We believe the central role of CD40L signaling in both adaptive and innate immune cell activation and function positions it as an attractive target for non-lymphocyte depleting, immunomodulatory therapeutic intervention.

Tegoprubart is engineered to potentially both improve safety and provide pharmacokinetic, pharmacodynamic, and dosing advantages compared to other anti-CD40 approaches. The CD40L/CD40 pathway is recognized for its prominent role in immune regulation. CD40L is primarily expressed on activated CD4+ T cells, platelets and endothelial cells while the CD40 receptor is constitutively expressed on antigen presenting cells such as macrophages and dendritic cells, as well as B cells. By blocking CD40L and not the CD40 receptor, tegoprubart inhibits both the CD40 and CD11 costimulatory signaling pathways, providing the potential for improved efficacy compared to anti-CD40 receptor approaches. Blocking CD40L also increases polarization of CD4+ lymphocytes to Tregs, a specialized subpopulation of T cells that act to suppress an immune response, thus creating a more tolerogenic environment, which may play a therapeutic role in autoimmune diseases and in the prevention of allograft rejection after solid organ transplantation.

Tegoprubart is designed to negate the risk of thrombolytic events seen in the first generation of anti-CD40L antibodies by introducing structural modifications that have been shown in preclinical models to eliminate binding to the Fcγ receptors associated with platelet activation without altering the binding of tegoprubart to CD40L. In non-human primate studies, dosing of tegoprubart up to 200 mg/kg per week for 26 weeks, demonstrated no adverse events regarding coagulation, platelet activation or thromboembolism.

**Figure 1: Mechanism overview of CD40L inflammatory signaling and tegoprubart site of action**

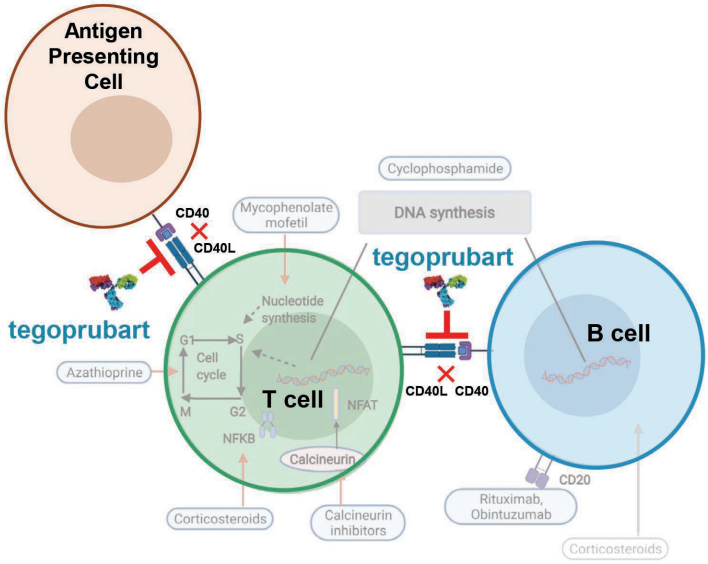
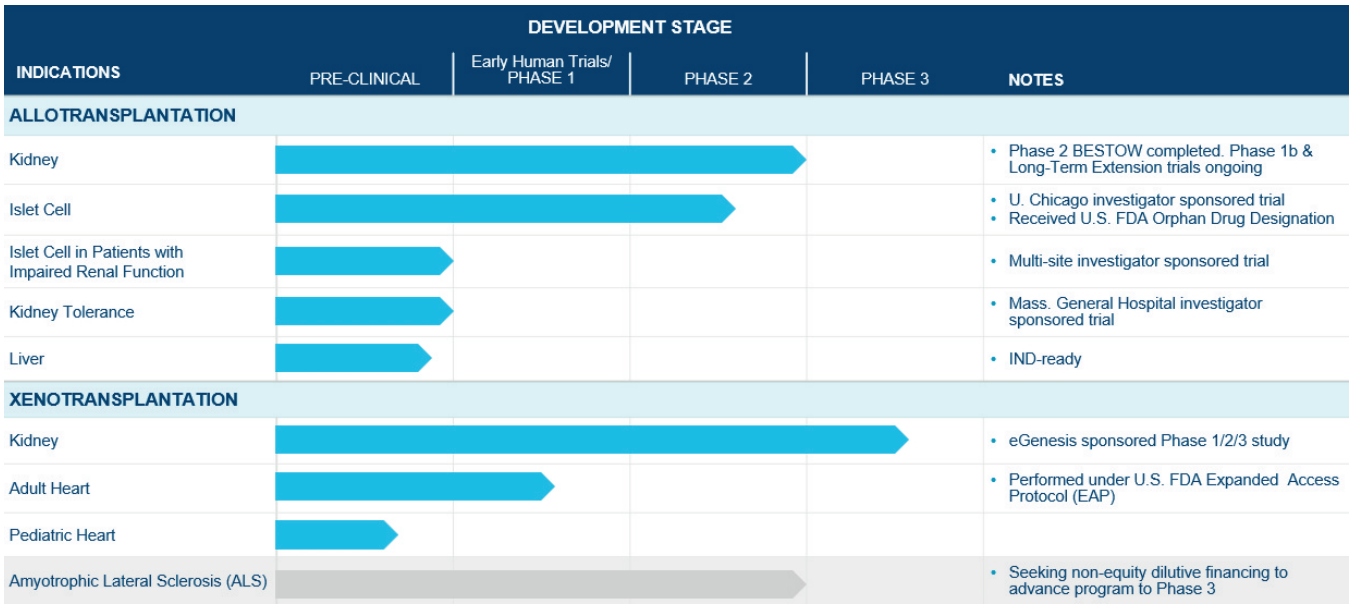



**Figure 1:** Interaction of CD40 with CD40L on immune cells mediates activation of the co-stimulatory immune pathway, controlling "cross talk" between the adaptive and innate immune systems. Blocking CD40L shifts polarization away from pro-inflammatory signaling to T cell anergy, apoptosis, and polarization to a "T-reg" environment. (Source: Adapted from Kant et al., Principles of Immunosuppression in the Management of Kidney Disease: Core Curriculum 2022, AJKD.)

**Strategy**

Our business strategy is to optimize the clinical and commercial value of tegoprubart and become a global biopharmaceutical company with a focused immunology franchise. Our strategy is to develop tegoprubart for the prevention of rejection of allograft (i.e., transplanting an organ from one human to another) and xenograft (i.e., transplanting an organ from an animal to a human) organs and cells, and for the treatment of ALS. We selected our indications based on preclinical and clinical data that was generated with either tegoprubart or historical anti-CD40L molecules. In January 2023, we announced plans to prioritize and focus resources on our kidney transplantation programs, discontinue the Company funded islet cell transplantation program and the IgAN program. We also remain committed to further progressing ALS clinical development and are working with key stakeholders on potential next steps to do so. However, we are unable to continue our clinical development of tegoprubart for people with ALS without additional financing.

The following chart summarizes the status of our current clinical development programs. Details for each program are outlined below.




**Acquisition**

In September 2020, we acquired Anelixis Therapeutics, Inc. ("Anelixis"), the company that owned and controlled the intellectual property related to tegoprubart. See *Note 7. Commitments and Contingencies* of the Notes to Financial Statements included in this Annual Report on Form 10-K, for further details of grants and licenses related to this acquisition.

Prior to our acquisition of Anelixis, we focused on developing medicines for patients with disorders of the ear, nose, and throat ("ENT"). In June 2020, we announced that our lead program did not achieve statistical significance for the primary efficacy endpoints in the treatment of acute otitis media. As a result of this failure to achieve the primary study endpoint, we suspended the clinical development of our legacy ENT assets while we assessed potential development strategies. Following the June 2020 announcement, we significantly curtailed development expenses as we sought to identify strategic alternatives that would maximize stockholder value. As a result of these activities, we acquired Anelixis and raised additional capital in September 2020, as described above. After acquiring Anelixis, we terminated our ENT activities and returned our product rights to the original license holders in July 2021.

**Clinical Development of Tegoprubart for the Prevention of Allograft Rejection in Kidney Transplantation**

In January 2023, we announced plans to prioritize and focus resources on our kidney transplantation programs. We are first focusing on kidney transplantation as this is the most common type of solid organ transplantation in the U.S. with an estimated 270,000 Americans living with a transplanted kidney. There are an estimated 27,000 kidneys transplanted annually in the U.S. Approximately 90,000 people in the U.S. are on a waiting list where they typically wait an average 3-5 years for a kidney transplant while about 5,000 people in the U.S. in need of a kidney transplant die each year waiting for a suitable kidney. Approximately 11% of U.S. people on the waiting list are waiting for a repeat transplant. There remains a critical shortage of kidneys and other organs available for transplantation.

There has been little innovation in immunosuppression therapy for organ transplant patients over the past 30 years. The standard of care immunosuppressive drugs used post-transplant have been shown to reduce the risk of organ rejection, but they are also associated with potentially toxic side effects. Organ transplant recipients require immunosuppression on a lifelong basis, and any disruption in the immunosuppression therapy can trigger transplant rejection. Calcineurin inhibitors ("CNI"s) are a critical component of most immunosuppressive regimens to prevent acute and long-term kidney transplant rejection. However, chronic exposure to CNIs (tacrolimus is the drug most commonly used) is associated with nephrotoxicity, hypertension, new onset diabetes due to pancreatic beta cell toxicity, as well as central nervous system ("CNS") side effects, like tremor. Over time, these CNI side effects may significantly damage the transplanted kidneys or result in a requirement for reduced exposures to CNIs which can lead to an increased risk of rejection. Moreover, CNS side effects like tremors may result in patients decreasing their adherence to their medicines. Today, an implanted kidney is expected to fail within 10-15 years on average using currently available immunosuppression options. The fact that American transplant patients are on average in their 50s means that many of them will ultimately need a second or even third transplant procedure during their lifetime or a return to dialysis.

The central role of CD40L signaling in generating pro-inflammatory responses makes it a highly attractive candidate for therapeutic intervention in the protection of transplanted organs and prevention of transplant rejection. Results from prior studies demonstrate that targeting and blocking CD40L has the potential for better efficacy and improved safety, including reduced risk of nephrotoxicity, diabetes, hypertension, and other side effects associated with standard-of-care CNIs such as tacrolimus.

Tegoprubart seeks to address challenges associated with current immunosuppressive transplantation regimens using CNI-based therapies. The ability to prevent acute and chronic transplant rejection without the need for CNIs has the potential to transform the clinical management of preventing graft rejection by mitigating the adverse events associated with CNIs and improving long-term graft survival, thus potentially decreasing the need for repeat kidney transplants and increasing organ availability for other patients on the wait list. By identifying and advancing novel strategies in immunosuppression including targeting the CD40L pathway, we may be able to help organs remain functional for longer and potentially throughout the natural lifespan of each recipient.

In aggregated data from the published studies referenced in Figure 1 below, non-human primates undergoing allograft renal transplantation receiving anti-CD40L monotherapy (e.g., 5c8, AI794, IDEC-131) had longer average survival than both those receiving anti-CD40 monotherapy (e.g., 4D11, cH5D12, Chi220, ASKP1240), tacrolimus monotherapy or untreated controls (Figure 2).

**Figure 2: Inhibition of CD40L improved survival vs. CD40 inhibition in non-human primate kidney transplantation monotherapy studies**

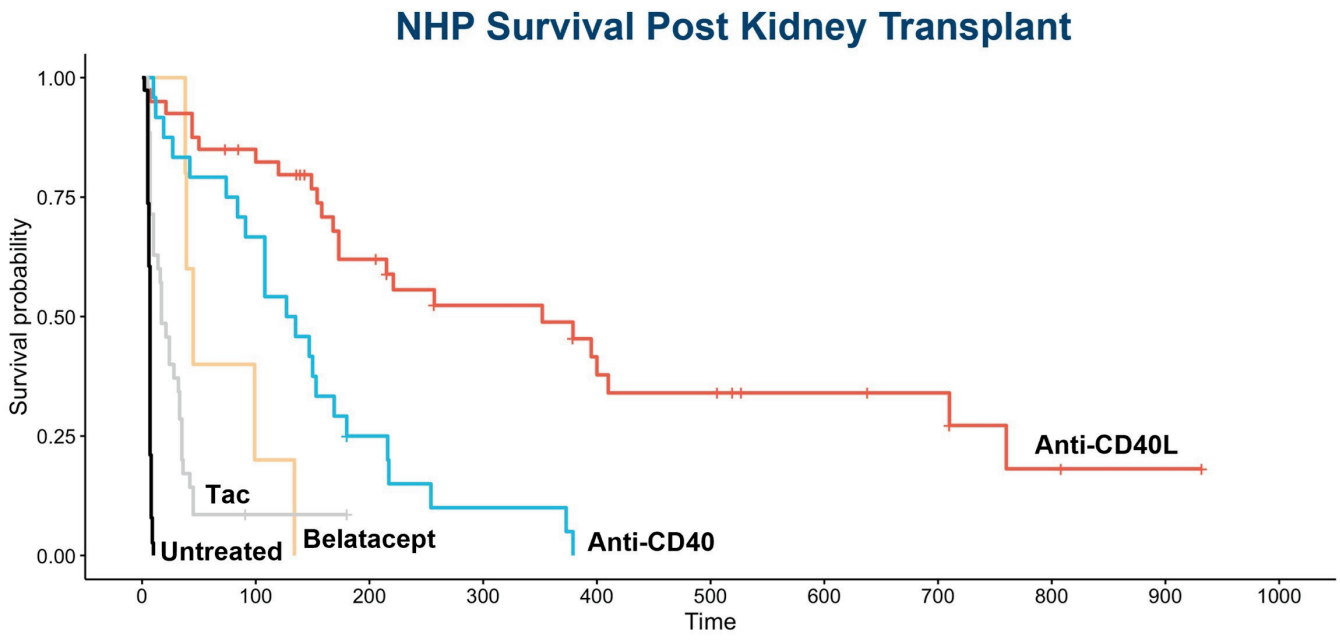


**Figure 2:** Kaplan-Meir estimates of the probability of rejection free survival by treatment group from eleven published studies of allograft kidney transplant in non-human primates. Sources: Perrin, 2022; Song, 2014; Song, 2016; Duan, 2017. Note: In aggregated data from published studies, NHPs receiving anti-CD40L (e.g., 5c8, AI794, IDEC-131) immunomodulation monotherapy post kidney transplantation had longer average survival than those receiving anti-CD40 monotherapy (e.g., 4D11, cH5D12, Chi220, ASKP1240), tacrolimus monotherapy or untreated controls. Tac = tacrolimus. Meta-analysis is not based on head-to-head studies. Differences between any individual programs may vary.

We have received regulatory approvals in the United States, Canada, the United Kingdom and Australia, for a Phase 1b clinical trial of tegoprubart in up to 36 subjects, replacing tacrolimus as an immunosuppressive regimen component in patients undergoing de novo kidney transplantation. Each participant will receive rabbit antithymocyte globulin induction and a maintenance regimen consisting of tegoprubart, mycophenolate mofetil, and corticosteroids. The primary endpoint of the study is safety. Other endpoints include glomerular filtration rate ("eGFR"), characterizing the pharmacokinetic profile of tegoprubart, and the incidence of biopsy proven rejection. The first subject in the Phase 1b study was dosed in July 2022.

Better graft function as assessed by eGFR has been associated with improved long-term patient and graft survival and is an early predictor of future graft failure. Historical studies have reported average eGFRs generally in the low 50 mL/min/1.73m2 range during the first year after kidney transplant using current standard of care immunosuppression. An eGFR of 50 mL/min/1.73m2 or below indicates chronic kidney disease.

We reported interim safety and efficacy results from the Phase 1b clinical trial in March 2023, and provided updated data in November 2023, June 2024 and August 2025.

At the time of the August 2025 update, which reported data as of July 2025, 32 patients undergoing kidney transplantation have been enrolled in the Phase 1b study. Updated data showed that kidney function, as assessed by eGFR, stabilized after the first month post-transplant and remained in the range of approximately 68 mL/min/1.73 m2 through 12 months for patients (n = 12) who remained on tegoprubart. Kidney function in the intention-to-treat population (n=15) was approximately 63 mL/min/1.73 m2 at 12 months. Data from historical studies using the standard of care, calcineurin inhibitor-based immunosuppression therapy, typically report aggregate mean eGFR of approximately 53 mL/min/1.73 m2 during the first year after kidney transplant. In addition, preliminary abbreviated iBox data was presented suggesting that tegoprubart may improve 5-year graft survival. Abbreviated iBox, a composite biomarker panel developed by the Paris Transplant Group, incorporates kidney function (eGFR, proteinuria) and immunologic response (donor-specific antibodies) parameters into a single prognostic score. Based on data collected as of July 2025, abbreviated iBox scores were -3.75 in the intention-to-treat population and -4.11 in the on-treatment population, which compare favorably to a -2.98 historical mean for calcineurin inhibitors. A difference in abbreviated iBox score of -0.40 at 12 months is considered predictive of a 4-5% difference in 5-year graft survival suggesting that tegoprubart may have a predicted 5-year allograft survival rate of over 96%. As of July 2025, there were six (18.8%) rejection episodes, and 75% of patients who experienced a rejection had received low-dose rabbit antithymocyte globulin induction. All rejection episodes were successfully treated. Of the patients who experienced a rejection episode and completed a year in the study, three who remained on tegoprubart had a mean eGFR of approximately 73 mL/min/1.73 m2 at 12 months, indicating full recovery of kidney function, while the two patients who switched to standard of care tacrolimus had a mean eGFR of approximately 34 mL/min/1.73 $m^2$ at 12 months.

In July 2022, we received Investigational New Drug ("IND") application clearance from the FDA for our controlled, Phase 2 BESTOW trial of tegoprubart for the prevention of transplant rejection in persons receiving a kidney transplant. The BESTOW study is a multi-center, two-arm, active comparator, head-to-head superiority clinical study, with approximately 120 participants undergoing kidney transplantation in the U.S. and other countries to evaluate the safety, pharmacokinetics, and efficacy of tegoprubart compared to the calcineurin inhibitor tacrolimus. The study's primary objective is to assess graft function as measured by estimated eGFR at 12 months post-transplant in participants treated with tegoprubart compared to tacrolimus. Secondary objectives are the assessment of graft survival, biopsy-proven acute rejection, and the incidence of new onset diabetes mellitus after transplant. The BESTOW study is running in parallel to the ongoing Phase 1b clinical trial of tegoprubart in kidney transplantation. The first subject in the BESTOW study was dosed in August 2023 and the last patient was dosed on September 4, 2025.

On November 6, 2025, we announced topline efficacy and safety data from the Phase 2 BESTOW trial evaluating tegoprubart for the prevention of kidney transplant rejection. Safety and efficacy results supported the potential for tegoprubart to provide effective immunosuppression with a favorable safety and tolerability profile compared to tacrolimus. Safety findings underscore tegoprubart's potential to maintain effective immunosuppression while minimizing the metabolic, neurologic, and cardiovascular toxicities characteristic of tacrolimus-based therapy. Notably, new-onset diabetes developed in approximately 17% of patients receiving tacrolimus versus 2% receiving tegoprubart. Tremor was markedly higher in the

tacrolimus group (25.0% vs. 1.6%) and cardiovascular effects, including hypertension (25.0% vs. 15.9%), hypertensive crisis (7.8% vs. 1.6%), and heart failure (4.7% vs. 0%) all favored tegoprubart. Delayed graft function occurred less often with tegoprubart and required shorter dialysis (14.3% vs. 25%; 4.6 days vs. 6.1 days) suggesting potential reductions of 115 days on dialysis post-transplant per 100 deceased donor kidney recipients on tegoprubart versus tacrolimus. Sepsis or bacteremia occurred more frequently in the tacrolimus arm (17.2% vs. 4.8%) and viral infection rates (CMV, BK, EBV, fungal) were similar across groups, with no cases of Post-Transplant Lymphoproliferative Disorder or Progressive Multifocal Leukoencephalopathy. Additionally, overall rates of serious adverse events were comparable between treatment arms. From an efficacy standpoint, tegoprubart achieved an eGFR of approximately 69 mL/min/1.73 m² (n=51) at 12 months compared to 66 mL/min/1.73 m² for tacrolimus (n=56). Although the primary endpoint did not reach statistical significance, tegoprubart maintained strong renal function, delivering what the Company believes is one of the highest mean eGFR level reported to date in kidney transplant clinical trials evaluating rejection prevention. Subgroup analyses showed higher eGFRs in nearly all tegoprubart subgroups compared to tacrolimus, particularly among living-related donor recipients (72 mL/min/1.73 m² vs. 62 mL/min/1.73 m²) and high Kidney Donor Profile Index (KDPI > 35) transplants (62 mL/min/1.73 m² vs. 53 mL/min/1.73 m²). In the deceased donor subgroup, tegoprubart achieved a mean eGFR of approximately 68 mL/min/1.73 m² at 12 months compared to 68 mL/min/1.73 m² for tacrolimus. The efficacy failure composite endpoint, comprising death, graft loss and biopsy proven acute rejection, is the approval endpoint historically recognized by the FDA. Efficacy failure composite endpoint was 22% in the tegoprubart group versus 17% in the tacrolimus group, demonstrating non-inferiority for tegoprubart versus tacrolimus, using a 20% non-inferiority margin. We believe these results, if replicated in a Phase 3 study, would be sufficient to support tegoprubart's approvability. The rate of acute rejection in all biopsies was 20.6% for tegoprubart group compared with 14.1% in the tacrolimus group. Among patients in the tegoprubart group who experienced acute rejection and remained on treatment through month 12, mean eGFR was 73 mL/min/1.73 m² compared to 50 mL/min/1.73 m² in those who switched to tacrolimus. Additionally, there was one case of donor-specific antibodies in the tegoprubart arm versus two in the tacrolimus arm.

In October 2023, we enrolled the first participant in a Phase 2 open-label extension study which is designed to evaluate the long-term safety, pharmacokinetics, and efficacy of tegoprubart in participants who have completed one year of treatment in either the ongoing Phase 1b study or the Phase 2 BESTOW study.

In January 2026, we presented 24-month follow-up data from eight patients enrolled in the Phase 1b trial long-term extension evaluating tegoprubart in kidney transplantation at the American Society of Transplant Surgeons Winter Symposium held in Scottsdale, Arizona. During the reported follow-up period, no episodes of biopsy-proven acute rejection, graft loss, death, new-onset diabetes mellitus, or de novo donor-specific antibody formation were observed among participating patients. Mean eGFR increased over the measurement period from 67.0 mL/min/1.73 m² at 12 months to 74.2 mL/min/1.73 m² at 24 months.

In 2026, we plan to seek guidance from the FDA regarding the design of a potential Phase 3 clinical trial evaluating tegoprubart in kidney transplantation and, subject to regulatory feedback and alignment, may initiate a Phase 3 trial.

**Clinical Development of Tegoprubart for the Prevention of Allograft Rejection in Xenotransplantation**

While inhibition of CD40L has shown it may play an important role in immunosuppression in allograft kidney transplantation, this mechanism of action has also demonstrated that it may be a promising option in xenotransplantation (i.e., transplanting an organ from an animal to a human).

In January 2023, we entered into a non-exclusive collaborative research agreement with eGenesis, Inc., ("eGenesis"), under which eGenesis gained access to tegoprubart for preclinical and clinical xenotransplantation studies in support of eGenesis' kidney, heart and islet cell xenotransplantation programs.

To date, tegoprubart has been used as a key component of the immunosuppression regimen in four xenotransplantation procedures: three involving genetically modified pig kidneys and one involving a genetically modified pig heart. Two of the kidney transplant recipients remain alive. One continues to maintain kidney function with the transplanted pig kidney, while the other had the graft removed on day 271 and has since received an allograft kidney from a donor.

**Clinical Development of Tegoprubart for the Prevention of Allograft Rejection in Islet Cell Transplantation ("ICT")**

Type 1 diabetes ("T1D") is a T cell mediated autoimmune disease with progressive loss of insulin producing pancreatic beta cells and affects approximately 2 million persons in the United States. Approximately 33% of people with

T1D report impaired awareness of hypoglycemia regardless of continuous glucose monitoring or automated insulin usage. Approximately 12% of people with T1D experience recurrent severe hypoglycemic events annually, putting them at higher risk for adverse outcomes. Approximately 5% to 8% of adults with T1D experience diabetic ketoacidosis annually, often as a result of poor glycemic control. ICT is gaining attention as a therapeutic option for T1D because it can restore physiological insulin secretion, minimize the risk of hypoglycemic unawareness, and reduce the risk of death due to severe hypoglycemia. The advances made in this field over the past decade have improved patient outcomes, and the procedure has been evolving from an experimental treatment to a clinical treatment option.

A number of issues are believed to continue to hamper the overall success of ICT and to need to be addressed in order for there to be widespread clinical acceptance. These include the acute loss of transplanted islets with current immunosuppressive treatments, particularly those with CNI-based therapies, due to islet cell toxicity and alloreactive immunologic responses to transplanted islets. Over time, the progressive loss of islet cells and decline in islet cell function can lead to the need for multiple transplants in order for T1D patients to have optimal response to blood glucose levels and possibly achieve insulin independence. Tegoprubart seeks to address the challenges associated with current ICT immunosuppressive regimens using CNI-based therapies, by replacing the CNIs with tegoprubart to prevent rejection and protect the transplanted cells. We believe that tegoprubart may unlock the ICT market by potentially improving islet cell graft survival and reduce the side effects associated with standard of care regimens.

Historical studies in nonhuman primate models of ICT have demonstrated that treatment with anti-CD40L antibodies induces long term islet cell function and graft survival, even as a monotherapy. Tegoprubart has shown pre-clinical, proof-of-concept efficacy in a non-human primate model of T1D, where animals undergoing ICT maintained glucose control and sustained levels of C-peptide with chronic tegoprubart treatment for up to a year. Compared to combination immunosuppressive therapy including CNIs, tegoprubart monotherapy was more effective in preventing long term islet cell rejection, associated with better graft function, and showed an improved safety profile.

In 2022, the FDA granted orphan designation to tegoprubart for the prevention of allograft rejection in pancreatic islet cell transplantation.

In January 2024, we announced that tegoprubart would be evaluated in an investigator-initiated clinical trial conducted at the University of Chicago Medicine's Transplant Institute. The study is designed to assess the safety of a calcineurin inhibitor-free immunosuppression regimen utilizing tegoprubart in individuals with type 1 diabetes mellitus undergoing islet cell transplantation. We are not funding the trial and our involvement is limited to supplying tegoprubart for use in the study.

As of November 2025, preliminary data from the first six subjects enrolled in the study demonstrated improvements in glycemic control following islet transplantation, with all six subjects achieving insulin independence after one or two transplant procedures. The first three participants have remained insulin-free for more than one year following transplantation, while additional subjects achieved insulin independence within several weeks following transplantation and have maintained hemoglobin A1c levels below 6% during follow-up. All treated subjects have remained free of severe hypoglycemic events since transplantation.

Tegoprubart has been generally well tolerated to date, with no reported serious infections, thromboembolic events, or biopsy-confirmed rejection events observed during the reported follow-up period, and without evidence of kidney or neurological toxicities commonly associated with calcineurin inhibitor-based immunosuppression. As of November 2025, a total of eight patients had undergone islet transplantation using tegoprubart as the core immunosuppressive agent, and one additional patient with calcineurin inhibitor-associated nephrotoxicity had been transitioned from tacrolimus to tegoprubart.

**Clinical Development of Tegoprubart for ALS**

ALS is a progressive, paralytic disorder characterized by degeneration of motor neurons in the brain and spinal cord. In the U.S., the incidence is estimated at approximately 5,000 cases per year with a prevalence of approximately 30,000 cases overall. Despite 3 approved drugs, in most cases, death from respiratory failure occurs between 3 to 5 years from diagnosis, with 50% of patients living at least 3 years from diagnosis and only 20% of patients living at least 5 years from diagnosis.

While the exact pathogenic mechanism of ALS is still not fully understood, there is strong evidence indicating that neuroinflammation plays an important role in the disease's pathogenesis. Neuroinflammation in ALS is characterized by the infiltration of lymphocytes and macrophages into the central nervous system, and the activation of microglia and reactive astrocytes. Reactive astrocytes and microglia as well as infiltrating lymphocytes, dendritic cells, monocytes, macrophages

and immune complexes have been identified in cerebrospinal fluid and neural tissues in both animal models of ALS and at autopsy in ALS patients.

Tegoprubart is designed to block CD40L binding to CD40, thereby potentially inhibiting neuroinflammatory pathways leading to disease progression in ALS. In vitro proof-of-concept studies have shown that tegoprubart binds to CD40L in human cells and blocks CD40L binding on antigen presenting cells and activated T cells. The potential for therapeutic benefit of CD40L blockage in treating ALS has been demonstrated in a SOD1 mouse model of ALS, where a murine anti-CD40L antibody, MR1 (as defined below), prolonged survival and delayed the onset of neurological disease progression. These pathophysiological manifestations are believed to be due to reduced immune cell infiltration of macrophages into skeletal muscle and their destroying denervated nerves. The plasticity of the nervous system to repair itself in the absence of this immune cell attack is believed to result in improved neuromuscular junction occupancy and improved muscle function. Blocking CD40L signaling also prevents pro-inflammatory polarization of lymphocytes, reduced neuroinflammation and improved motor neuron survival in rodent ALS models (Figure 3).

**Figure 3: Blocking CD40L Improves Survival and Pathophysiology Associated with ALS**

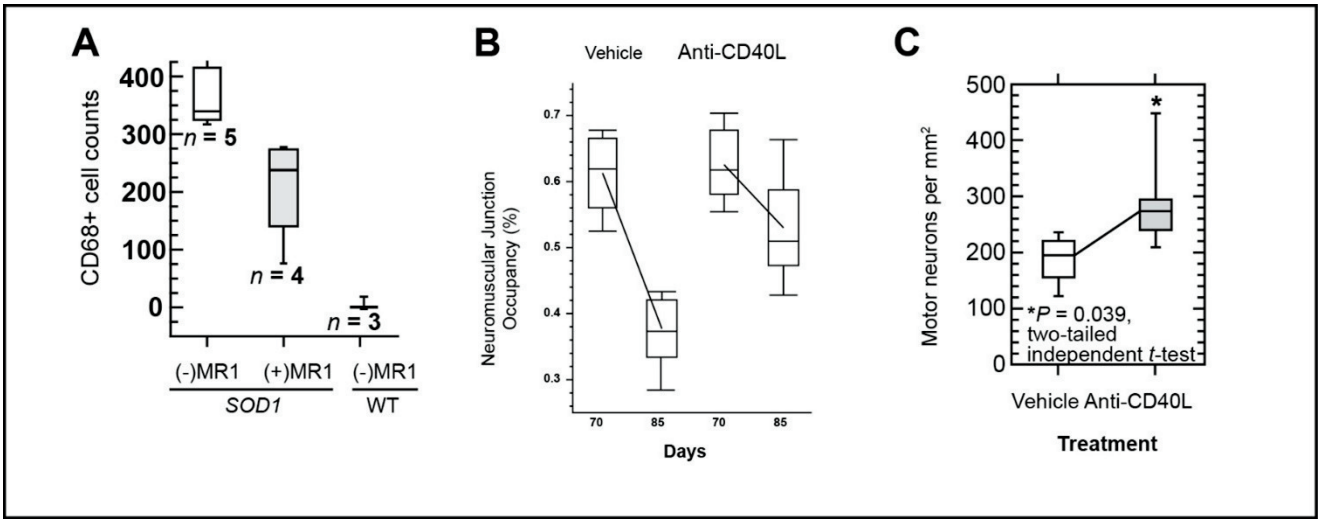



**Figure 3: Anti-CD40L ("MR1") treatment decreases CD68+ macrophages, improves neuromuscular junction occupancy and improves motor neuron survival.** (A) Quantification of reduction of CD68+ macrophages by anti-CD40L treatment at day 100. (White bar, control IgG); gray bar (anti-CD40L–treatment); black bar (untreated age-matched non-transgenic mice) (B) Quantification of neuromuscular occupancy in SOD1 mice prior to overt symptoms (day 70) versus after symptom onset (day 85) treated with an IgG control antibody (vehicle) or anti-CD40L antibody. (C) Quantitative comparison of lumbar spinal cord motor neuron counts per mm2 in IgG vehicle control (White bar) versus anti-CD40L treated mice (grey bar) at day 100 (Lincecum, 2010).

In 2018, the FDA granted orphan drug designation to tegoprubart for ALS. In 2019, we completed a single ascending dose Phase 1 study of tegoprubart in healthy volunteers and people with ALS. In this study, the doses of tegoprubart studied were well tolerated in healthy adult subjects and adults with ALS. Tegoprubart demonstrated low anti-drug antibody responses that were not dose related, linear dose proportionality across the dose ranges, and a half-life of up to 26 days.

In October 2020, we initiated a Phase 2a, open-label, multi-center study to evaluate the safety and tolerability of multiple doses of tegoprubart in adult subjects with ALS. Fifty-four subjects with ALS were enrolled into the study in the United States and Canada at 13 ALS treatment sites. Ascending doses of tegoprubart were administered as IV infusions to four sequentially enrolling cohorts. The first two cohorts consisted of nine participants, and the last two cohorts of 18 participants each. All enrolled subjects received six infusions of tegoprubart over a 12-week period. Blood samples for target engagement, and exploratory biomarkers for inflammation and neurodegeneration were taken and analyzed. Participant-focused clinical outcomes were also assessed. In May 2022, we completed the Phase 2a study and released positive topline results. Tegoprubart successfully met the primary endpoints of safety and tolerability. Fifty of the fifty-four subjects completed all six study infusions, and adverse events were typical of an ALS patient population. Tegoprubart was well-tolerated, and no drug-related serious adverse events were observed. No new safety signals emerged. Anti-drug antibodies ("ADAs") were present in less than 5 percent of samples. All ADAs were of low titer and did not impact tegoprubart drug

levels. Tegoprubart target engagement was demonstrated in all dose cohorts with increasing target engagement in a dose-dependent manner, plateauing at the 4 and 8 mg / kg dosing levels using CD40L and CXCL13 biomarkers related to T cell and B cell function, respectively. Tegoprubart exposure decreased inflammatory biomarker levels, in a dose dependent manner, in 20 of 32 pro-inflammatory proteins. Pro-inflammatory biomarkers reduced included biomarkers also associated with IgA nephropathy and kidney transplant rejection, such as IgA, IgE, IgM, C3, CXCL9, and CXCL10.

We are seeking to further progress ALS clinical development and plan to work with key stakeholders on potential next steps to do so. However, we will be unable to continue our clinical development of tegoprubart for people with ALS without additional financing specific for our ALS program, and we can provide no assurances that we will be able to obtain financing on acceptable terms or at all.

**Clinical Development of Tegoprubart for IgA Nephropathy**

In January 2023, the Company announced the deprioritization of its IgAN program and all IgAN clinical development activities were discontinued in 2023. IgAN is the leading cause of chronic glomerulonephritis, a state of inflammation producing damage to the filtering part of the kidney. Disease manifestation and clinical presentation involves renal dysfunction characterized by proteinuria with a slow relentless course. Approximately 30%-40% of persons living with IgAN ultimately reach end stage renal disease ("ESRD"). The standard of care for ESRD is dialysis or kidney transplant, which represents a significant economic burden as well as a major impact on a patient's quality of life. With an estimated prevalence of approximately 150,000 persons in the United States, IgAN is one of the most common autoimmune glomerulonephropathies. In the United States, oral budesonide Tarpeyo was approved for use in IgAN by the FDA in December 2021 and Kinpeygo received conditional approval by the European Medicines Agency ("EMA") in July 2022.

In August 2022, we received IND clearance from the FDA to evaluate tegoprubart for the treatment of IgAN. The Phase 2 global study was a 96-week open-label, dose ranging trial, and included both a high dose and a low dose cohort. The primary endpoint was change in urinary protein:creatinine ratio at week twenty-four. Secondary endpoints included change in estimated eGFR at week 96 as well as safety and tolerability. The first subject was dosed in May 2022. We reported interim safety data from the Phase 2 high dose cohort in March 2023.

**Intellectual Property**

Eledon's success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, novel discoveries, product technologies and other know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. We seek to protect our product candidates by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trademarks, trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain proprietary protection for our product candidates.

Our intellectual property portfolio includes issued patents and pending patent applications directed toward (i) isolated antibodies and (ii) methods of treatment using the isolated antibodies that block the interaction of CD40L and CD40 to treat CD40L-related diseases or disorders. We own and have exclusive rights to ten active patent families, of which three families are exclusively licensed and the rest are wholly-owned by Eledon. The first exclusively-licensed family is directed to methods for treating ALS with antibodies and includes two issued United States patents and 14 issued foreign patents (Japan, Hong Kong, Belgium, Germany, Denmark, Spain, Finland, France, Great Britain, Ireland, Italy, the Netherlands, Sweden, and Switzerland). Absent any patent term adjustments or extensions, patents in this family expire in December 2029. The second exclusively-licensed family is directed to tegoprubart, with 11 pending applications, and issued patents including five issued United States patents and 23 issued foreign patents (Australia, Belgium, Switzerland, China, Germany, Denmark, France, Great Britain, Hong Kong, Ireland, Israel, India, Italy, Japan, South Korea, Mexico, the Netherlands, New Zealand, Russia, Sweden, Singapore). Absent any term adjustments or extensions, patents in this family expire in February 2036. The third exclusively-licensed family is directed to therapeutic anti-CD40L antibodies, with 14 pending applications, including one pending United States patent application, and issued patents, including one issued United States patent and nine issued foreign patents (China, Hong Kong, Israel, Japan, South Korea, Mexico, Russia). Absent any term adjustments or extensions, patents in this family expire in May 2038. Our Eledon-owned patent families are directed to methods for treating neurodegenerative disorders, kidney disorders, and transplant rejection. Two of our Eledon-owned patent families are pending in the United States, Europe, Australia, Canada, China, Japan, South Korea, Mexico, and Singapore, three of our Eledon-owned patent families are at the Patent Cooperation Treaty stage, and three of our Eledon-owned patent families are

at the provisional stage. Absent any term adjustments or extensions, any patents to issue from the pending applications in these patent families would expire between May 2043 and November 2046, respectively.

Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country.

Eledon also protects its proprietary information by requiring its employees, consultants, contractors, and other advisors to execute nondisclosure and assignment of invention agreements upon commencement of their respective employment or engagement. In addition, Eledon also requires confidentiality or service agreements from third parties that receive confidential information or materials.

See *Note 7. Commitments and Contingencies* of the Notes to Financial Statements included in this Annual Report on Form 10-K under the caption "Grants and Licenses" for further information about the Company's intellectual property.

**Competition**

The biotechnology and pharmaceutical industries are characterized by continuing technological advancement and significant competition. While we believe that our product candidates, technology, knowledge, experience and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products. The availability of reimbursement from the government and other third-party payors will also significantly affect the pricing and competitiveness of our products. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of the companies against which we may compete have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical studies, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs.

The competitive conditions faced by the Company are also described in greater detail in Part I, Item 1A. *Risk Factors* in this Annual Report on Form 10-K under the caption "We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do."

**Manufacturing**

We do not own or operate manufacturing facilities for the production of tegoprubart or any future product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on third parties for raw materials and the manufacturing of drug substance and drug product for non-clinical and clinical activities. As of the date of this Annual Report, we have not experienced any difficulty in obtaining raw materials required with respect to the manufacturing of tegoprubart. We believe we have enough drug substance and drug product on hand and manufacturing capacity with our third-party manufacturing providers to meet forecasted clinical trial demand.

We also rely on third parties to label, store and distribute drug product for our non-clinical and clinical trials.

**Government Regulation**

Government authorities in the United States, including federal, state, and local authorities, and in other countries, extensively regulate, among other things, the manufacturing, research and clinical development, marketing, labeling, and packaging, storage, distribution, post-approval monitoring and reporting, advertising and promotion, and export and import of pharmaceutical and biological products, such as those we are developing. Pricing of such products is also subject to

regulation in many countries. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

*U.S. Government Regulation*

The FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations, and biologics under the FDCA and the Public Health Service Act ("PHSA") and its implementing regulations. FDA approval is required before any new unapproved drug or biologic or dosage form, including a new use of a previously approved drug, can be marketed in the U.S. Drugs and biologics are also subject to other federal, state, and local statutes and regulations. If we fail to comply with applicable FDA or other requirements at any time during the product development process, clinical testing, approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, untitled or warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any FDA enforcement action could have a material adverse effect on us.

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

- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the Good Laboratory Practices ("GLP") regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin and must be updated annually;
- approval by an independent institutional review board ("IRB") or ethics committee representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- completion of manufacturing scale up and stability studies, all performed in accordance with the Good Manufacturing Practices ("GMP") regulations;
- preparation of and submission to the FDA of a biologics license application ("BLA") or a new drug application, or NDA, after completion of all pivotal clinical trials;
- potential review of the product application by an FDA advisory committee, where appropriate and if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA or NDA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities where the proposed product is produced to assess compliance with current Good Manufacturing Practices ("cGMP") regulations;
- potential FDA audit of the clinical trial sites that generated the data in support of the BLA or NDA; and
- FDA review and approval of a BLA or NDA prior to any commercial marketing or sale of the product.

The preclinical and clinical testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

An IND is a request for authorization from the FDA to administer an investigational new drug product to humans in clinical trials. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. 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 new drug. An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical trials. 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 clinical trials can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence. The FDA may impose a clinical hold at any time during clinical trials and may impose a partial clinical hold that would limit trials, for example, to certain doses or for a certain length of time.

*Clinical Trials*

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with Good Clinical Practices ("GCPs") which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety, and the efficacy 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. Additionally, approval must also be obtained from each clinical trial site's IRB before the trials may be initiated, and the IRB must monitor the trial until completed. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

The clinical investigation of a drug is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined.

- Phase 1. The drug is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational new drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness.
- Phase 2. The drug is administered to a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse side effects and safety risks, and preliminarily evaluate efficacy.
- Phase 3. The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites to generate enough data to evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational new drug product, and to provide an adequate basis for physician labeling.

In some cases, the FDA may condition approval of a BLA or NDA for a product candidate on the sponsor's agreement to conduct additional clinical trials after approval. In other cases, a sponsor may voluntarily conduct additional clinical trials after approval to gain more information about the drug. Such post-approval studies are typically referred to as Phase 4 clinical trials.

Sponsors must also report to the FDA, within certain timeframes, serious and unexpected adverse reactions, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator's brochure, or any findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the product candidate. The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. We may also suspend or terminate a clinical trial based on evolving business objectives or competitive climate.

The clinical trial process can take three to ten years or more to complete, and there can be no assurance that the data collected will support FDA approval or licensure of the product. Results from one trial are not necessarily predictive of results from later trials.

A drug being studied in clinical trials may be made available to individual patients in certain circumstances. Pursuant to the 21st Century Cures Act ("Cures Act") which was signed into law in December 2016, the manufacturer of an investigational drug for a serious disease or condition is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational drug (compassionate use). This requirement applies on the later of 60 calendar days after the date of enactment of the Cures Act or the first initiation of a Phase 2 or Phase 3 trial of the investigational drug. At this time, Eledon does not have a program for the compassionate use of an investigational product outside of a clinical trial as it is not applicable to our investigational products.

*Submission of a BLA or NDA to the FDA*

Assuming successful completion of all required testing (e.g., completion of pivotal clinical trials) in accordance with all applicable regulatory requirements, detailed investigational new drug product information is submitted to the FDA in the form of a BLA or NDA requesting approval to market the product for one or more indications. Under federal law, the submission of most BLAs and NDAs is subject to an application user fee and these fees are typically increased on an annual basis. Applications for orphan drug products are exempted from the BLA and NDA user fees and may be exempted from product and establishment user fees, unless the application includes an indication for other than a rare disease or condition. No application user fees were paid for tegoprubart in calendar 2025.

A BLA or NDA for a new molecular entity must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from several alternative sources, including investigator-initiated trials that are not sponsored by Eledon. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational new drug product to the satisfaction of the FDA.

Once a BLA or NDA for a new molecular entity has been submitted, the FDA's goal is to review the application within ten months after it accepts the application for filing, or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months after the FDA accepts the application for filing. The review process is often significantly extended by the FDA's requests for additional information or clarification.

Before approving a BLA or 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 a BLA or NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

*The FDA's Decision on a BLA or NDA*

The FDA evaluates a BLA to determine whether the data demonstrate that the biologic is safe, pure, and potent, or effective, and an NDA to determine whether the drug is safe and effective. After the FDA evaluates the BLA or NDA and conducts inspections of manufacturing facilities where the product will be produced, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application is not ready for approval. A Complete Response Letter may require additional clinical data or an additional pivotal Phase 3 clinical trial(s), or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the BLA or NDA does not satisfy the criteria for approval and issue a denial. The FDA could also approve the BLA or NDA with a Risk Evaluation and Mitigation Strategy ("REMS") plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to

proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

*Pediatric Trials and Exclusivity*

Under the Pediatric Research Equity Act of 2003 ("PREA") as amended, BLAs and NDAs must contain data to assess the safety and effectiveness of an investigational new drug product for the claimed indications in all relevant pediatric populations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. A sponsor who is planning to submit a marketing application for a drug product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan ("PSP") within sixty days of an end-of-phase 2 meeting or as may be agreed between the sponsor and the FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. 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 if certain criteria are met. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials, and/or other clinical development programs. The requirements for pediatric data do not apply to any drug for an indication for which orphan designation has been granted. In the future we may seek pediatric approval for tegoprubart applications in connection with renal and islet cell transplantations, which may require the submission of a PSP.

Pediatric exclusivity is another type of non-patent exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the five-year and three-year non-patent and orphan exclusivity. This six-month exclusivity may be granted if a BLA or NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of FDA-requested pediatric trials are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection covering the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot accept or approve another application relying on the BLA or NDA sponsor's data.

*Post-Approval Requirements*

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

Drug manufacturers are subject to periodic unannounced inspections by the FDA and state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We rely, and expect to continue to rely, on third parties for the production of clinical quantities of our product candidates and expect to rely in the future on third parties for the production of commercial quantities. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production, distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or

holder of an approved BLA or NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions 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, untitled or warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending BLAs or NDAs or supplements to approved BLAs or NDAs, or suspension or revocation of licenses or withdrawal of approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

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

*Orphan Designation and Exclusivity*

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales in the United States.

Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product is the first to receive FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. The Company received orphan drug designations for tegoprubart for the treatment of ALS and prevention of allograft rejection in pancreatic islet cell transplantation.

*Patent Term Restoration*

Depending upon the timing, duration, and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA or NDA, plus the time between the submission date and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent and within 60 days of the product's approval. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of the patent term for one of our currently owned or

licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA or NDA.

*Abbreviated New Drug Applications for Generic Drugs*

In 1984, with passage of the Hatch-Waxman Amendments, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application ("ANDA") to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug ("RLD").

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to an RLD if "the rate and extent of absorption of the generic drug do not show a significant difference from the rate and extent of absorption of the listed drug."

Upon approval of an ANDA, the FDA indicates that the generic product is "therapeutically equivalent" to the RLD and it assigns a therapeutic equivalence rating to the approved generic drug in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider an "AB" therapeutic equivalence rating to mean that a generic drug is fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of an "AB" rating often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

The FDCA provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity. In cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval. The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication.

*Hatch-Waxman Patent Certification and the 30-Month Stay*

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or a method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval.

Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification

automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA applicant.

***European Union/Rest of World Government Regulation***

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. The cost of establishing a regulatory compliance system for numerous varying jurisdictions can be very significant. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union ("EU") and in other jurisdictions, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the EU, for example, a clinical trial authorization application ("CTA") must be submitted for each clinical protocol to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is accepted in accordance with a country's requirements, the clinical trial may proceed.

The requirements and process governing the conduct of clinical trials vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP the applicable regulatory requirements, and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational medicinal product under EU regulatory systems, we must submit a marketing authorization application. The content of the BLA or NDA filed in the United States is like that required in the EU, except, among other things, country-specific document requirements.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing product licensing, pricing, and reimbursement vary from country to country.

Countries that are part of the EU, as well as countries outside of the European Union, have their own governing bodies, requirements, and processes with respect to the approval of pharmaceutical and biologic products. 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.

*Authorization Procedures in the EU*

Medicines can be authorized in the EU by using either the centralized authorization procedure or national authorization procedures.

- Centralized procedure. The EMA implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid throughout the European Economic Area ("EEA"). This procedure results in a single marketing authorization issued by the EMA that is valid across the EEA. The centralized procedure is compulsory for human medicines that are: derived from biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and officially designated orphan medicines.
- For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the European Commission following a favorable opinion by the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

- National authorization procedures. There are also two other possible routes to authorize medicinal products in several EU countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure:
- Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure.
- Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

In some cases, a Pediatric Investigation Plan ("PIP") or a request for waiver or deferral, is required for submission prior to submitting a marketing authorization application. A PIP describes, among other things, proposed pediatric trials and their timing relative to clinical trials in adults. A PIP will be submitted to EMA and other EU countries, as required. The PIP will need to be submitted early during product development before marketing authorization applications are submitted. The timing of PIP submission cannot be after initiation of pivotal trials or confirmatory (phase 3) trials. In the future we may seek pediatric approval for tegoprubart applications in connection with renal and islet cell transplantations, which may require the submission of a PIP.

*Exclusivity of New Chemical Entities and New Fixed Dose Combinations*

In the EU, new chemical entities, sometimes referred to as new active substances as well as new fixed dose combinations, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic (abbreviated) application for eight years, after which a generic application can be submitted, and the innovator's data may be referenced, but not approved for two years. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

*Exceptional Circumstances/Conditional Approval*

Orphan drugs or drugs with unmet medical needs may be eligible for EU approval under exceptional circumstances or with conditional approval. Approval under exceptional circumstances may be applicable to orphan products and is used when an applicant is unable to provide comprehensive data on the efficacy and safety under normal conditions of use because the indication for which the product is intended is encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence, when the present state of scientific knowledge does not allow comprehensive information to be provided, or when it is medically unethical to collect such information. Conditional marketing authorization may be applicable to orphan medicinal products, medicinal products for seriously debilitating or life-threatening diseases, or medicinal products to be used in emergency situations in response to recognized public threats. Conditional marketing authorization can be granted on the basis of less complete data than is normally required in order to meet unmet medical needs and in the interest of public health, provided the risk-benefit balance is positive, it is likely that the applicant will be able to provide the comprehensive clinical data, and unmet medical needs will be fulfilled. Conditional marketing authorization is subject to certain specific obligations to be reviewed annually.

*Accelerated Review*

Under the centralized procedure in the EU, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the EMA's Committee for Medicinal Products for Human Use ("CHMP")). Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. In this circumstance, EMA ensures that the opinion of the CHMP is given within 150 days, excluding clock stops.

***Pharmaceutical Coverage, Pricing and Reimbursement***

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we obtain regulatory approval. In the United States and in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations. 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. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain 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 regulatory approvals. Our product candidates may 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.

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. By way of example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively (the "Affordable Care Act"), contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs. Since its enactment, there have been several judicial, administrative, executive and congressional challenges to certain aspects of the Affordable Care Act. In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. For example, the American Rescue Plan Act of 2021 eliminates the statutory Medicaid drug rebate cap, for single source and innovator multiple source drugs, beginning in January 2024.

Additionally, The Inflation Reduction Act of 2022, (the "IRA"), includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket cap for Medicare Part D beneficiaries to $2,000 beginning in 2025; impose new manufacturer financial liability on certain drugs under Medicare Part D; allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs without generic competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the rebate rule that would limit the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. Further, judicial challenges to the IRA may have an impact on the implementation of the IRA's provisions; and the overall effects of the IRA on our business and the healthcare industry in general is not yet known. Adoption of further government controls, measures and tightening of restrictive policies in jurisdictions with existing controls and measures could limit payments for pharmaceuticals.

In European countries, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed to by the government. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert commercial pressure on pricing within a country.

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

***Other Healthcare Laws and Compliance Requirements***

If we obtain regulatory approval for any of our product candidates, we may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, ("HIPAA"), which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- the federal transparency laws, including the provision of the Affordable Care Act referred to as the federal Physician Payment Sunshine Act, that requires drug and biologics manufacturers to disclose payments and other transfers of value provided to physicians and teaching hospitals and ownership interests of physicians and their immediate family members;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The Affordable Care Act broadened the reach of the fraud and abuse laws by, among other things, amending the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. § 1320a-7b. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act or the civil monetary penalties statute. Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

We are also subject to the U.S. Foreign Corrupt Practices Act ("FCPA") which prohibits improper payments or offers of payments to foreign governments and their officials for the purpose of obtaining or retaining business. Safeguards we implement to discourage improper payments or offers of payments by our employees, consultants, and others may be ineffective, and violations of the FCPA and similar laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against us, any of which would likely harm our reputation, business, financial condition and result of operations.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, exclusion from participation in government healthcare programs, such as Medicare and Medicaid and imprisonment, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

**Employees**

As of March 13, 2026, Eledon had 33 employees, all of whom are full-time. 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.

**Corporate Information**

Otic Pharma, Ltd. ("Otic") was founded in the State of Israel in 2008. In 2015, Otic established U.S. operations and moved its corporate headquarters to Irvine, California. In 2017, Otic consummated a reverse merger with Tokai Pharmaceuticals, Inc. ("Tokai"), a Delaware corporation that was incorporated on March 26, 2004, pursuant to which, among other things, Tokai purchased from Otic and its stockholders all of the common and preferred shares of Otic in exchange for the issuance of a certain number of shares of common stock of Tokai (the "Reverse Merger"). Following the Reverse Merger, Tokai changed its name to Novus Therapeutics, Inc. On September 14, 2020, the Company acquired Anelixis Therapeutics, Inc. ("Anelixis"), a Delaware Corporation, after which Anelixis became a wholly owned subsidiary of the Company. On January 4, 2021, the Company changed its name from Novus Therapeutics, Inc. to Eledon Pharmaceuticals, Inc.

Our executive offices are located at 19800 MacArthur Boulevard, Suite 250, Irvine, California 92612. The Company also has a research and development office in Burlington, Massachusetts. Our telephone number is (949) 238-8090 and our website is www.eledon.com.

You are advised to read this Annual Report on Form 10-K in conjunction with other reports and documents that we file from time to time with the Securities and Exchange Commission ("SEC"). In particular, please read our definitive proxy statement, which will be filed with the SEC in connection with our 2026 annual meeting of stockholders, our quarterly reports on Form 10-Q and any current reports on Form 8-K that we may file from time to time. You may obtain copies of these reports after the date of this annual report directly from us or from the SEC at its website at www.sec.gov. We make our periodic and current reports available on our internet website, free of charge, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC.

**Item 1A. Risk Factors.**

*An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information in this Annual Report on Form 10-K and in our other public filings. The occurrence of any of these risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described in our public filings when evaluating our business.*

**Risks Related to Our Operations**

***Our short operating history and shifts in our business strategy may make it difficult to evaluate the success of our business to date and to assess our future viability.***

We are a clinical stage biopharmaceutical company. Our ongoing operations to date have been limited to organizing and staffing the Company, business planning, raising capital, acquiring and developing technology, identifying potential product candidates and pursuing non-clinical and clinical trials. We have not yet demonstrated our ability to successfully manufacture drug products in large enough quantities and with stability to support additional clinical trials, execute pivotal clinical trials, obtain marketing approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. It can take many years to develop a new medicine from the time it is discovered to when it is available for treating patients. Consequently, any predictions made about our future success or viability based on our short operating history to date may not be as accurate as they could be if we had a longer operating history.

In addition, as an early-stage business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. To successfully market any of our current or future product candidates, we will need to transition from a company with a clinical development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

***We have incurred significant operating losses since our inception and expect that we will continue to incur losses over the next several years and may never achieve or maintain profitability.***

We have incurred significant annual net operating losses in every year since our inception. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other general and administrative expenses related to our ongoing operations. If tegoprubart or any future product candidates we develop are not successfully developed and approved, we may never generate any revenue from sales of products. The Company has experienced recurring net losses and negative cash flows from operating activities since its inception. The Company's net loss for the year ended December 31, 2025 is $45.6 million. As of December 31, 2025, the Company had cash and cash equivalents and short-term investments of $133.3 million, working capital of $117.3 million and an accumulated deficit of $401.2 million. We have not generated any revenues from product sales, have not completed the development of any product candidate and may never have a product candidate approved for commercialization. We expect it will be several years, if ever, before we have a product candidate ready for commercialization. We have financed our operations to date primarily through the sale of preferred and common stock, and the sale of warrants and have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and our clinical trials. Our net losses may fluctuate significantly from quarter to quarter and year to year and will depend, in part, on the rate at which we incur expenses and our ability to generate revenue. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

We anticipate that we will continue to incur significant expenses as we:

- conduct non-clinical and clinical development of our product candidates or any future product candidate;
- seek to identify and acquire additional product candidates;
- acquire or in-license other products and technologies;
- enter into collaboration arrangements with regards to product discovery or development;
- develop manufacturing processes and/or enter into manufacturing agreements with third-party manufacturers;
- seek marketing approvals for any of our product candidates that successfully complete clinical trials;

- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, expand, and protect our intellectual property portfolio;
- hire additional personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- operate as a public company.

To become and remain profitable, we must develop and eventually commercialize a product or products with significant market potential. This will require us to be successful in a range of challenging activities, including completing clinical trials of our product candidates, obtaining marketing approval for these product candidates and manufacturing, marketing and selling those products for which we obtain marketing approval. We may never succeed in these activities, including if we do not have available financial resources to allow us to pursue clinical trials and other clinical development activities, and, even if we are successful, we may never generate revenues that are significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of the Company, could impair our ability to raise capital, maintain our non-clinical and clinical development efforts, and expand our business or continue our operations and may require us to raise additional capital that may dilute the ownership interest of common stockholders. A decline in the value of the Company could also cause stockholders to lose all or part of their investment.

***We will require additional funding to be able to complete the development of our lead drug candidate. If we are unable to raise capital, we will be forced to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether.***

In view of our expectation to incur significant losses for the foreseeable future, we will be required to raise additional capital resources in the future in order to fund our operations. We can also provide no assurance that other funding will be available to us, will be obtained on terms favorable to us or will provide us with sufficient funds to meet our objectives. If we are unable to raise such capital, or if we are unable to do so on acceptable terms, we will be forced to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether. For example, we are currently unable to continue our clinical development of tegoprubart for people with ALS without additional financing, and we can provide no assurances that we will be able to obtain financing on acceptable terms or at all.

Our funding needs may fluctuate significantly based on a number of factors, such as:

- the scope, progress, results and costs of formulation development and manufacture of drug product to support non-clinical and clinical development of our product candidates;
- the extent to which we enter into additional collaboration arrangements regarding product discovery or development, or acquire or in-license products or technologies;
- our ability to establish additional collaborations with favorable terms, if at all;
- the costs, timing, and outcome of regulatory review of our product candidates;
- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; and
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

Identifying potential product candidates and conducting formulation development, non-clinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Even if we generate positive clinical data or are able to

successfully commercialize one or more of our product candidates, additional financing may not be available to us on acceptable terms, or at all.

***In addition to the dilution of our current stockholders' ownership as a result of the 2023 Private Placement, the 2024 Private Placement, the 2024 Underwritten Offering and the 2025 Underwritten Offering, we currently have a significant number of securities outstanding that are exercisable for our common stock, which could result in significant additional dilution and downward pressure on our stock price. Future issuances of our common stock, including common stock that may be issuable pursuant to outstanding warrants or other convertible securities, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall..***

As of December 31, 2025, there were 75,430,033 shares of our common stock outstanding and pre-funded warrants and common stock warrants to purchase 51,781,090 shares of our common stock outstanding. The issuance of shares of common stock in the 2023 Private Placement, the 2024 Private Placement, the 2024 Underwritten Offering and the 2025 Underwritten Offering (each as defined and described in *Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations*), diluted the ownership interests of our existing stockholders. The issuance of shares of common stock pursuant to our "at-the-market" equity offering program or upon exercise of pre-funded warrants or common warrants issued in the initial closing of the 2023 Private Placement, the pre-funded warrants issued in the 2024 Private Placement, the pre-funded warrants issued in the 2024 Underwritten Offering and the pre-funded warrants issued in the 2025 Underwritten Offering would result in significant additional dilution to our current stockholders, which could adversely affect the price of our common stock and the terms on which we could raise additional capital. If we sell additional shares of common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

***Our product candidates are in the early stages of clinical development and may not be successfully developed. If we are unable to successfully develop and commercialize these or any other product candidate, or if we experience significant delays in doing so, our business will be materially harmed.***

We currently do not have any products that have gained regulatory approval. We have invested substantially all of our efforts and financial resources in the development of our lead drug candidate tegoprubart, including funding non-clinical studies, clinical trials, drug formulation and the manufacturing of clinical trial materials. Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of one or more drug candidates. As a result, our business is substantially dependent on our ability to successfully complete the development of and obtain approval for one of our potential future additional product candidates.

We have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical area. For example, to execute our business plan, we will need to successfully:

- obtain additional financing in order to advance our drug product through clinical development, and to manufacture, obtain regulatory approval for and commercialize our product candidates;
- execute formulation, manufacturing, clinical, and non-clinical development activities;
- manufacture drug products at commercial scale;
- establish and confirm commercially acceptable stability (shelf-life) of our drug products;
- in-license or acquire other product candidates and advance them through clinical development;
- obtain required regulatory approvals for the development and commercialization of tegoprubart or other product candidates;
- maintain, leverage, and expand our intellectual property portfolio;
- build and maintain robust sales, distribution and marketing capabilities, either on our own or in collaboration with strategic partners;
- gain market acceptance for any approved and marketed drug products;
- obtain and maintain adequate product pricing and reimbursement;

- develop and maintain any strategic relationships we elect to enter; and
- manage our spending as costs and expenses increase due to product manufacturing, non-clinical development, clinical trials, regulatory approvals, post-marketing commitments, and commercialization.

If we are unsuccessful in accomplishing these objectives, we may not be able to successfully develop and commercialize our or other product candidates, and our business will suffer.

***Public health crises, including pandemics or epidemics could adversely affect our business.***

Our business and operations, including but not limited to ongoing or planned research and development activities may be impacted by public health crises. For example, our business was adversely affected by the COVID-19 pandemic, which also caused significant disruption in the operations of third parties upon whom we rely. Other future public health crises, including any future pandemics or epidemics could have a similar impact on our business. We may experience, as we did with the COVID-19 pandemic, disruptions as a result of future public health crisis, such as a future pandemic or epidemic, that could severely impact our operations and development activities, including, but not limited to:

- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- delays in manufacturing of our drug candidates due to increased competition for manufacturing capacity as a result of the pandemic;
- limitations in employee resources that would otherwise be focused on the conduct of our development activities, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- refusal of the U.S. Food and Drug Administration ("FDA") to accept data from clinical trials in affected geographies;
- delays in procuring drug substance and/or in manufacturing drug product due to limitations in employee resources or forced furloughs at our contract manufacturing organizations;
- delays in initiation of future clinical trials, including delays in receiving authorization from local regulatory authorities to initiate such clinical trials; and
- delays or disturbances in enrollment and trial execution, for example, because clinical trial sites may be unable to operate normally, or patients may elect to forego visits to medical facilities or undertake voluntary medical procedures.

Any of the foregoing factors, or other effects of any public health crisis, including any future pandemic or epidemic, could materially affect our business, possibly to a significant degree. The severity and duration of any such impacts cannot be predicted.

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

The global economy, including the financial and credit markets, continues to experience extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, elevated inflation and interest rates, changes in U.S. trade policy and uncertainty about economic stability. Likewise, the current conflicts in Ukraine and the Middle East have created volatility in the global capital markets and global economic consequences, including disruptions of the global supply chain and energy markets. A severe or prolonged economic downturn or continued volatility in the financial and credit markets could negatively impact our ability to obtain necessary debt or equity financing in a timely manner or on favorable terms, if at all. The severity and duration of any such impacts cannot be predicted. Any such failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies or cause us to delay our clinical development plans, research and development programs or commercialization efforts, out-license intellectual property rights to our product candidates or sell unsecured assets, or a combination of the above. Any of these actions could materially harm our business. For example, we do not currently have sufficient liquidity to fund the continued clinical development of tegoprubart for people with ALS without additional financing, notwithstanding the positive topline results of our Phase 2a study of tegoprubart for adult subjects with ALS.

In addition, as a result of high levels of inflation, we have experienced and may continue to experience cost increases, including costs of clinical trials and research and development of our product candidates, production costs, the price of labor, administration and other costs of doing business. Although we may continue to take measures to mitigate the impact of this inflation, if these measures are not effective, our business, financial condition, results of operations and liquidity could be materially adversely affected. Further, in an inflationary environment, cost increases may outpace our expectations, causing us to use our cash and other liquid assets faster than forecasted. If this happens, we may need to raise more capital to fund our operations than expected, and such capital may not be available in sufficient amounts or on reasonable terms, if at all.

***Adverse conditions in the financial markets, including bank failures, could adversely affect our liquidity and financial performance.***

We currently maintain domestic cash deposits, for short term operating requirements, in Federal Deposit Insurance Corporation ("FDIC") insured banks, which exceed the FDIC insurance limits. Our additional cash and cash equivalents are held in accounts managed by third-party financial institutions and consist primarily of cash invested in money market funds and government bonds. Bank failures, events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, or concerns or rumors about such events, may lead to widespread demands for customer withdrawals and liquidity constraints that may result in market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank failed and was taken into receivership by the FDIC. At that time, we maintained deposits amounting to approximately 78% of our total cash at Silicon Valley Bank. On March 26, 2023, the assets, deposits and loans of Silicon Valley Bank were acquired by First-Citizens Bank & Trust Company. In response to the failure of Silicon Valley Bank, we diversified our cash deposits into money market funds, U.S. treasuries and U.S. government agency securities and, as of the date of this report, our total cash maintained in FDIC insured banking accounts is less than 5% of our total cash and cash equivalents and short-term investments. The failure of a bank, or other adverse conditions in the financial or credit markets impacting financial institutions at which we maintain balances, could adversely impact our liquidity and financial performance. There can be no assurance that our deposits in excess of the FDIC or other comparable insurance limits will be backstopped by the U.S. or any applicable foreign government in the future or that any bank or financial institution with which we do business will be able to obtain needed liquidity from other banks, government institutions or by acquisition in the event of a future failure or liquidity crisis. Additionally, our cash investments outside of FDIC insured bank accounts are subject to general credit, liquidity, market, and interest rate risks. If the carrying value of an investment exceeds the fair value, and the decline in fair value is deemed to be other-than-temporary, we are required to write down the value of the investment, which could materially harm our results of operations and financial condition and could limit our access to liquidity.

***Drug development involves a lengthy and expensive process with an uncertain outcome, including failure to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the formulation and commercialization of our product candidates.***

Given the early stage of development for our product candidates, the risk of failure is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must conduct non-clinical trials and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Formulation and device development, non-clinical and clinical testing are all expensive activities, difficult to design and implement, and can take years to complete. Failure can occur at any time during the development program, including during the clinical trial process. Further, the results of non-clinical studies and early clinical trials of our product candidates, as well as earlier generation formulations may not be predictive of the results of later-stage clinical trials. Interim results of a clinical trial do not necessarily predict final results. Moreover, non-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in non-clinical and clinical trials have nonetheless failed to obtain marketing approval of their products. There is a risk that additional non-clinical and/or clinical safety studies will be required by the FDA or similar regulatory authorities outside the United States and/or that subsequent studies will not match results seen in prior studies. It is impossible to predict when or if any of our product candidates will prove effective, safe and well-tolerated in humans or will receive regulatory approval.

We may experience delays in our clinical trials, and we do not know whether planned clinical trials will begin or enroll subjects on time, need to be redesigned or be completed on schedule, if at all. There can be no assurance that the FDA or equivalent foreign regulatory bodies will approve investigational new drug applications and allow us to start clinical trials for any of our product candidates in the future, including for islet cell transplant. Once a clinical trial has commenced, there is also no assurance that the FDA or equivalent foreign regulatory body will not put any of our product candidates on clinical hold. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our

ability to receive marketing approval or commercialize our product candidates. Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design that we want to execute;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- delays in reaching, or failure to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- delays in completing formulation development and manufacturing as a prerequisite to commencing clinical work;
- inability, delay, or failure in identifying and maintaining a sufficient number of trial sites, many of which may already be engaged in other clinical programs;
- delay or failure in recruiting and enrolling suitable subjects to participate in a trial;
- delay or failure in having subjects complete a trial or return for post-treatment follow-up;
- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical trials and increased expenses associated with the services of our contract research organizations ("CROs") and other third parties;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- we may experience delays or difficulties in the enrollment of patients that our product candidates are designed to target;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have difficulty partnering with experienced CROs and study sites that can identify patients that our product candidates are designed to target and run our clinical trials effectively;
- regulators or institutional review boards ("IRBs") may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; or
- there may be changes in governmental regulations or administrative actions. For example, in January 2025 the Trump administration issued an Executive Order that paused the FDA's rulemaking ability and could affect recently finalized FDA rules that have not yet taken effect. The extent to which such existing or future executive orders impact the healthcare regulatory environment remains uncertain and could materially impact our development and commercialization activities. In addition, our development and commercialization activities could be harmed or delayed by a shutdown of the U.S. government or reduction in funding or staffing at U.S. government agencies, including the FDA and SEC. For example, a prolonged shutdown or the reduction of funding or staffing at the FDA may significantly delay the FDA's ability to timely review and process any submissions we may file or cause other regulatory delays, which could materially and adversely affect our business. Further, government shutdowns and/or employee terminations or resignations at the SEC could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings that would reduce the potential market for our products or inhibit our ability to successfully commercialize our products;
- be subject to additional post-marketing restrictions and/or testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our non-clinical studies or clinical trials will need to be restructured or will be completed on schedule, or at all. Significant non-clinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or may allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

***If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented and expenses for the development of our product candidates could increase.***

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to demonstrate safety and efficacy. We do not know whether the ongoing or planned clinical trials will enroll subjects in a timely fashion, require redesign of essential trial elements or be completed on its projected schedule. In addition, competitors may have ongoing clinical trials for product candidates that treat related or the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether.

Patient enrollment is affected by other factors including:

- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same disease indication;
- the patient referral practices of physicians;
- the proximity and availability of clinical trial sites for prospective patients;
- ambiguous or negative interim results of our clinical trials, or results that are inconsistent with earlier results;
- feedback from regulatory authorities, IRBs, ethics committees ("ECs"), or data safety monitoring boards, or results from earlier stage or concurrent non-clinical and clinical trials, that might require modifications to the protocol;
- decisions by regulatory authorities, IRBs, ECs, or the Company, or recommendations by data safety monitoring boards, to suspend or terminate clinical trials at any time for safety issues or for any other reason; and
- unacceptable risk-benefit profile or unforeseen safety issues or adverse effects.

Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of the Company to decline and limit our ability to obtain additional financing.

***Our ability to conduct clinical trials in some jurisdictions outside of the United States may be adversely affected.***

We currently have clinical trial sites in regions outside the United States, including Asia, the European Union and the United Kingdom, and we will continue to conduct future clinical trials in these markets. Our ability to conduct clinical trials at sites located outside the United States is subject to numerous risks unique to conducting business in jurisdictions outside the United States, including:

- difficulty in establishing or managing relationships with qualified CROs, physicians and clinical trial sites;
- different local standards for the conduct of clinical trials;
- difficulty in complying with various and complex import laws and regulations when shipping drugs to certain countries;
- the potential burden of complying with a variety of laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatments;
- lack of consistency in standard of care from country to country;
- diminished protection of intellectual property in some countries;
- instability in economic or political conditions, including inflation, recession and actual or anticipated military conflicts, social upheaval or political uncertainty;
- foreign exchange fluctuations;
- cultural differences in medical practice and clinical research; and
- changes in country or regional regulatory requirements.

The ongoing conflict in Ukraine and the resulting imposition of economic and other sanctions by the United States, European Union and many other nations on Russia, individuals in Russia, Russian businesses and the Russian central bank, or any escalation of tensions in the region, could have a broader impact that expands into other countries. The ongoing conflict in the Middle East could have similar impacts. Although the length and impact of any military action and expansion of the conflict into other countries are highly unpredictable, if either conflict spreads or has effects on additional countries, we may experience disruptions or delays in our plans to conduct clinical trial activities in affected regions outside the United States.

***If severe adverse events or unacceptable side effects are identified during the development of our product candidates, we may need to abandon or limit our development of some of our product candidates***.

If our product candidates are associated with severe adverse events or unacceptable side effects in non-clinical or clinical trials or have characteristics that are unexpected, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the adverse event or undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Any occurrences of clinically significant adverse events or unacceptable side effects with our product candidates may harm our business, financial condition and prospects significantly.

Tegoprubart is an early-product candidate, and the side effect profile in humans has not been fully established. Currently unknown, drug-related side effects may be identified through ongoing and future clinical trials and, as such, these possible drug-related side effects could affect patient recruitment, the ability of enrolled subjects to complete the trial, or result in potential product liability claims.

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

We are highly dependent on the product development, clinical and business development expertise of the principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our executives and key employees, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel is critical to our success. Due to the small size of the Company and the limited number of employees, each of our executives and key

employees serves in a critical role. The loss of the services of our executive officers or other key employees could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of, and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating drug product, non-clinical development, clinical development, regulatory strategy, and commercial strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to provide services to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

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

***If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, or the approvals may be for a narrow indication, we may not be able to commercialize our product candidates, and our ability to generate revenue may be materially impaired.***

Our product candidates must be approved by the FDA pursuant to a new drug application in the United States and by other regulatory authorities outside the United States prior to commercialization in the respective regions. The process of obtaining marketing approvals, both in the United States and outside the United States, is expensive and takes several years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any country. We have no experience in filing and supporting the applications necessary to gain marketing approvals for our products and may engage third-party consultants to assist in this process. Securing marketing approval requires the submission of extensive non-clinical and clinical data, and other supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product formulation and manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional non-clinical, clinical or other data. In addition, varying interpretations of the data obtained from non-clinical and clinical trials could delay, limit or prevent marketing approval of a product candidate. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may also cause delays in or prevent the approval of an application.

Any marketing approval we ultimately obtain may be for fewer or more limited indications than requested or subject to restrictions or post-approval commitments that render the approved product not commercially viable or its market potential significantly impaired. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

In order to market and sell our products in the EU and other international jurisdictions outside of the United States, we or our third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and may require additional non-clinical, clinical or health outcome data. In addition, the time required to obtain approval may differ substantially amongst international jurisdictions. The regulatory approval process outside the United States generally includes all the risks associated with obtaining FDA approval. In addition to regulatory approval, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country.

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

***Any product candidate for which we obtain marketing approval will be subject to extensive post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.***

Our product candidates and the activities associated with their development and commercialization, including their testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulations that are specific to those defined by regulatory authorities in the countries where the product is approved. In the United States and other countries that follow the International Conference on Harmonization, these requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, including periodic inspections by the FDA and other regulatory authorities, requirements regarding the distribution of samples to physicians and recordkeeping.

The FDA, or other regulatory authorities, may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products and if we promote our products beyond their approved indications, we may be subject to enforcement action for off-label promotion. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers, or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance with EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the EU's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

***Legislation regulating the pharmaceutical and healthcare industries may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.***

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes intended to contain healthcare costs and modify the regulation of drug and biologic products. These and other regulatory changes 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 candidates for which we obtain marketing approval.

For example, in 2022, the U.S. government enacted the Inflation Reduction Act of 2022, which, among other things, includes policies that are designed to have a direct impact on drug prices and reduce drug spending by the federal government, which took effect in 2023. The Inflation Reduction Act of 2022 requires drug manufacturers to pay rebates to Medicare if they increase prices faster than inflation for certain drugs used by Medicare beneficiaries. The mechanics of the rebate calculation are similar to those of the Medicaid rebate, but the expansion of inflation-based rebates may further complicate pricing strategies. In addition, in 2025, President Trump issued executive orders focused on lowering drug prices in the U.S. It is unclear how these drug pricing initiatives will affect what actions will be implemented by the Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS"), or FDA, and how those actions will impact our industry and our business. The Inflation Reduction Act of 2022 or other similar legislation could have the effect of reducing the prices we can charge and reimbursement we receive for our products, thereby reducing our profitability.

We expect that additional state and federal healthcare reform measures and regulations will be adopted in the future. Any of these measures and regulations could limit the amounts that federal and state governments will pay for healthcare products and services, result in reduced demand for our product candidates or additional pricing pressures and affect our product development, testing, marketing approvals and post-market activities.

Recent administrative law cases decided by the U.S. Supreme Court in 2024 may create uncertainty with respect to actions taken by regulatory agencies to interpret, implement and enforce federal legislation. For example, in its June 2024 decision in *Loper Bright Enterprises v. Raimondo* ("*Loper decision*"), the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper* decision could result in legal challenges to regulations and guidance issued by federal agencies that are currently applicable to or will be applicable to our business, including those issued by the FDA and the CMS. Further, the *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations and delays in or other impacts to the agency rulemaking process, which could have a material adverse effect on our business, financial condition and results of operations.

Laws, restrictions, and other regulatory measures imposed in international jurisdictions present similar challenges to those in the United States, including increased difficulty and cost in obtaining marketing approval and commercializing of our product candidates, as well as potential limitations on the prices we may obtain.

In some countries, particularly the countries of the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

***Our business operations and relationships with healthcare providers, physicians, third-party payers, and customers will be subject to applicable anti-kickback, fraud and abuse and other broadly applicable healthcare laws, which could expose us to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, physicians and third-party payers will play a primary role in the recommendation and prescription of any product candidates for which we receive marketing approval. Our current and future arrangements may expose us to broadly applicable fraud and abuse and other healthcare laws that may constrain the business or financial arrangements and relationships through which we would market, sell and distribute the products for which we receive marketing approval. Even though we will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payers, federal and state healthcare laws are and will be applicable to our business. Such laws include, but are not limited to federal false claims, false statements and civil monetary penalties laws, including the federal civil False Claims Act ("FCA"), the federal Anti-Kickback Statute, the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), patient data privacy and security regulation, including, in the United States, HIPAA, as amended by the Health Information Technology for Clinical Health Act of 2009 ("HITECH"), the federal transparency requirements under the Physician Payments Sunshine Act, and analogous state, local or foreign law.

Pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the

Medicaid Rebate Program to reduce liability for Medicaid rebates. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations.

If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, disgorgement, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Laws, restrictions, and other regulatory measures are also imposed by anti-kickback, fraud and abuse, and other healthcare laws and regulations in international jurisdictions, and in those jurisdictions we face the same issues as in the United States regarding exposure to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm, and diminished profits and future earnings.

***We depend on our information systems and those of our third-party collaborators, service providers, contractors or consultants, which may fail or suffer cybersecurity incidents that could result in a material disruption of our development programs or loss of data and have a material adverse effect on our reputation, business, financial condition or results of operations.***

We rely on our information systems and infrastructure to effectively manage our business, including our clinical trials and studies. Our information systems and infrastructure, and those of our current or future third-party collaborators, service providers, contractors and consultants are vulnerable to damage from cybersecurity incidents, including computer viruses, denial-of-service attacks, hacking, phishing and other social engineering attacks, unauthorized access or use resulting from malware, as well as disruptions due to natural disasters, terrorism, war, mistakes or technical errors, including due to software updates and telecommunication and electrical failures. We may also experience cybersecurity incidents stemming from persons inside our organizations (including employees or contractors), or other persons with access to information systems inside our organization. Attacks on information systems are increasing in their frequency, levels of persistence, sophistication and intensity, and they are being conducted by increasingly sophisticated and organized foreign governments, groups and individuals with a wide range of motives and expertise. Further, cybersecurity threats and the techniques used in cyberattacks change, develop and evolve rapidly, including from emerging technologies, such as advanced forms of artificial intelligence and quantum computing. In addition to extracting or accessing sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the security, confidentiality, integrity and availability of information. The prevalent use of mobile devices that access sensitive information also increases the risk of data security incidents which could lead to the loss of confidential information or other intellectual property. Information system disruptions, even if inadvertent, may limit or disable our access or important third parties' access to our systems. While to our knowledge none of the cybersecurity incidents we have experienced to date have had a material adverse impact on our business, financial condition or operations, if such an event were to occur and cause interruptions in our operations or the operations of third-party collaborators, service providers, contractors or consultants, it could result in a material disruption of our development programs and significant reputational, financial, legal, regulatory, business or operational harm. The costs to us to mitigate, investigate and respond to potential security incidents, breaches, disruptions, network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. Moreover, data security incidents and other security breaches can be difficult to detect, and any delay in identifying them may lead to increased harm.

***The compromise of privacy, security, integrity or confidentiality of sensitive information related to our business or failure to comply with confidentiality and data privacy obligations could have a material adverse effect on our business.***

In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any real or perceived

security breach affects our information systems (or those of our third-party collaborators, service providers, contractors or consultants), or results in the loss of or accidental, unlawful or unauthorized access to, use of, release of, or other processing of personally identifiable information or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could be found to have violated applicable U.S. and international privacy, data protection and other laws, which could subject us to litigation and governmental investigations and proceedings by federal, state and local regulatory entities in the U.S. and by international regulatory entities, resulting in exposure to material civil and/or criminal liability and the further development of our product candidates could be delayed. Such a breach may require notification to governmental agencies, the media or individuals pursuant to various foreign, domestic (federal and state) privacy and security laws, if applicable, including HIPAA, as amended by HITECH, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to cybersecurity incidents.

Any failure or perceived failure by us or any third-party collaborators, service providers, contractors or consultants to comply with our privacy, confidentiality, data security or similar obligations, or any data security incidents or other security breaches that result in the accidental, unlawful or unauthorized access to, use of, release of, processing of, or transfer of sensitive information, including personally identifiable information, may result in negative publicity, harm to our reputation, governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us, could cause third parties to lose trust in us or could result in claims by third parties, including those that assert that we have breached our privacy, confidentiality, data security or similar obligations, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations. To the extent we maintain individually identifiable health information, we could be subject to fines and penalties (including civil and criminal) under HIPAA for any failure by us or our business associates to comply with HIPAA's requirements.

***European data collection is governed by restrictive regulations governing the collection, use, processing and cross-border transfer of personal information.***

We may collect, process, use or transfer personal information from individuals located in the European Economic Area (the "EEA") in connection with our business, including in connection with conducting clinical trials in the EEA. Additionally, if any of our product candidates are approved, we may seek to commercialize those products in the EEA. The collection and use of personal health data in the EEA is governed by the provisions of the General Data Protection Regulation ((EU) 2016/679) (the "GDPR"), along with other European Union and country-specific laws and regulations. The United Kingdom and Switzerland have also adopted data protection laws and regulations. These legislative acts (together with regulations and guidelines) impose requirements relating to having legal bases for processing personal data relating to identifiable individuals and transferring such data outside of the EEA, including to the United States, providing details to those individuals regarding the processing of their personal data, keeping personal data secure, having data processing agreements with third parties who process personal data, responding to individuals' requests to exercise their rights in respect of their personal data, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers or corporate representatives, conducting data protection impact assessments and record-keeping. The GDPR imposes additional responsibilities and liabilities in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. Failure to comply with the requirements of the GDPR and related national data protection laws of the member states of the EEA and other states in the EEA may result in substantial fines, other administrative penalties and civil claims being brought against us, which could have a material adverse effect on our business, financial condition and results of operations. European data protection authorities may interpret the GDPR and national laws differently and may impose additional requirements, which adds to the complexity of processing personal data in or from the EEA or United Kingdom. Guidance on implementation and compliance practices are often updated or otherwise revised.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.***

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

## Risks Related to the Commercialization of Our Product Candidates

***Even if any of our product candidates receives marketing approval, we may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community necessary for commercial success.***

If any of our product candidates receives marketing approval, we may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payers and others in the medical community. In addition, physicians, patients and third-party payers may prefer other novel products to ours. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety and potential advantages and disadvantages compared to alternative treatments;
- the ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of our marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement, including patient cost-sharing programs such as copays and deductibles;
- the ability to develop or partner with third-party collaborators to develop companion diagnostics;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

***If our current product candidates, or a future product candidate receives marketing approval and we, or others, later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, the ability to market the product could be compromised.***

Clinical trials are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent beneficial effect of a product candidate that is greater than the actual positive effect in a broader patient population or alternatively fail to identify undesirable side effects. If, following approval of a product candidate, we, or others, discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following events could occur:

- regulatory authorities may withdraw their approval of the product or seize the product;
- the product may be required to be recalled or changes may be required to the way the product is administered;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the product;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- the creation of a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- additional restrictions may be imposed on the distribution or use of the product via a Risk Evaluation and Mitigation Strategy;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could have a material and adverse effect on our operations and business. The commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

***We currently have no marketing and sales force. If we are unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to effectively market and sell our product candidates, if approved, or generate product revenues.***

We currently do not have a marketing or sales team for the marketing, sales and distribution of any of our product candidates that are able to obtain regulatory approval. In order to commercialize any product candidates, we must build on a territory-by-territory basis marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our product candidates receive regulatory approval, we intend to establish an internal sales and marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time-consuming, will require significant attention of our executive officers to manage and may nonetheless fail to effectively market and sell our product candidates. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of any of our products that we obtain approval to market. With respect to the commercialization of all or certain of our product candidates, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements when needed on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may incur significant additional losses.

***We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.***

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are several large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our product candidates. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Specifically, there are a number of companies developing competing anti-CD40 and anti-CD40L therapeutics in clinical trials for transplant, autoimmune or central nervous system indications, including: Novartis, Sanofi, UCB, Amgen (post-acquisition of Horizon Therapeutics), Bristol Myers Squibb, Tonix Pharmaceuticals, Veloxis Pharmaceuticals and Kiniksa Pharmaceuticals. Most of these companies are larger than Eledon and have significantly greater resources to develop their drug candidates.

If approved, we expect that tegoprubart will face competition from numerous FDA-approved therapeutics for the prevention of transplant rejection, including PROGRAF®, ASTAGRAF XL®, ENVARSUS XR®, NULOJIX®, CELLCEPT®, MYFORTIC®, and numerous other branded and generic immunosuppressive agents. Multiple companies are working on islet cell and kidney transplant solutions that may ultimately potentially negate the need for immunosuppressive agents in these indications altogether.

We expect that tegoprubart will face competition from FDA-approved therapeutics for the treatment of ALS including RADICAVA®, riluzole, and numerous other branded and generic immunosuppressive agents. Multiple pharmaceutical and biotechnology companies, including but not limited to Biogen, Ionis Pharmaceuticals, Alexion Pharmaceuticals, Orion Pharma, Orphazyme, AZTherapies, Voyager Therapeutics, Apic Bio, Brainstorm Cell Therapeutics, Argenx, Ionis Pharmaceuticals, Coya Therapeutics and Cytokinetics, are also working on competing ALS pharmaceutical, gene therapy and cell therapy approaches.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. In addition, our ability to compete may be affected in many cases by insurers or other third-party payers seeking to encourage the use of generic products.

Generic products are currently available, with additional generic products expected to become available over the coming years, potentially creating pricing pressure. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic products.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, conducting non-clinical studies, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

***The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.***

The availability and extent of reimbursement by governmental and private payers is essential for most patients to be able to afford expensive treatments. Sales of our product candidates will depend substantially, both domestically and internationally, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payers. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payers tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. Reimbursement agencies in Europe may be more conservative than CMS. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payers, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. Increased expense is incurred to cover costs of health outcome focused research used to generate data necessary to justify the value of our products in order to secure reimbursement. We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market.

In addition, many private payers contract with commercial vendors who sell software that provide guidelines that attempt to limit utilization of, and therefore reimbursement for, certain products deemed to provide limited benefit to existing alternatives. Such organizations may set guidelines that limit reimbursement or utilization of our products.

***Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.***

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in decreased demand for any product candidates or products that we may develop; injury to our reputation and significant negative media attention; withdrawal of clinical trial participants; significant costs to defend the related litigation; substantial monetary awards to trial participants or patients; loss of revenue; reduced resources of our management to pursue our business strategy; and the inability to commercialize any products that we may develop.

We currently hold $10.0 million in product liability insurance coverage in the aggregate, with a per incident limit of $10.0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

## Risks Related to Our Dependence on Third Parties

***We contract with third parties for the manufacture of our product candidates for non-clinical and clinical trials and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products at an acceptable cost and quality, which could delay, prevent or impair our development or commercialization efforts.***

We have utilized, and intend to continue utilizing, third parties to formulate, manufacture, package, and distribute clinical supplies of our drug candidates. We have no experience in manufacturing and do not have any manufacturing facilities. Currently, we rely on third parties for the manufacturing of drug substance and drug product for non-clinical and clinical activities. Our manufacturing vendors utilize proprietary cell culture media, cell lines, buffers, manufacturing equipment, manufacturing supplies, and storage buffers for the manufacturing of tegoprubart and other product candidates. These materials are custom-made and available from only a limited number of sources. Although we believe that our third-party suppliers maintain a significant supply of these materials and equipment on hand, any sustained disruption in this supply, could adversely affect our operations. We do not have any long-term agreements in place with our current suppliers. If we are required to change manufacturers, we may experience delays associated with finding an alternate manufacturer that is properly qualified to produce supplies of our products and product candidates in accordance with regulatory requirements and our specifications. Any delays or difficulties in obtaining or in manufacturing, packaging or distributing approved product candidates could negatively impact our clinical trials.

We expect to rely on third-party manufacturers or third-party collaborators for the manufacture of commercial supply of any other product candidates for which our collaborators or we obtain marketing approval. Despite drug substance and product risk management, this reliance on third parties presents a risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. For example, these third parties experienced disruptions in their operations in conjunction with the COVID-19 pandemic. Additionally, on April 16, 2025, the U.S. Department of Commerce announced an investigation under Section 232 of the Trade Expansion Act of 1962 into imports of pharmaceuticals and pharmaceutical ingredients, including finished drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients, and key starting materials, and derivative products of those items. The investigation will examine the impact of these imports on U.S. national security culminating in a decision by the President whether to take action to remedy any identified threats, including by imposing additional tariffs. Further, the U.S. government has proposed a 100% tariff on branded and patented pharmaceutical products. All of these current and threatened tariffs are subject to implementation or change with little notice. Any delay, performance failure, or increase in costs on the part of our existing or future manufacturers of drug substance or drug products could delay or increase the cost of our clinical development or marketing approval. We do not currently have arrangements in place for redundant supply. If suppliers cannot supply us with our requirements, we may be required to identify alternative manufacturers, which would lead us to incur added costs and delays in identifying and qualifying any such replacement.

Formulations and devices used in early studies are not final formulations and devices for commercialization. Additional changes may be required by the FDA or other regulatory authorities on specifications and storage conditions. These may require additional studies and may result in a delay in our clinical trials and commercialization activities.

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

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

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

The third parties we rely on for manufacturing and packaging are also subject to regulatory review, and any regulatory compliance problems with these third parties could significantly delay or disrupt our clinical or commercialization activities. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. Additionally, macro-economic conditions may adversely affect these third parties, causing them to suffer liquidity or operational problems. If a key third-party vendor becomes insolvent or is forced to lay off workers assisting with our projects, our results and development timing could suffer.

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

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

***We depend on CROs and other contracted third parties to perform non-clinical and clinical testing and certain other research and development activities. As a result, the outcomes of the activities performed by these organizations will be, to a certain extent, beyond our control.***

The nature of outsourcing a substantial portion of our business will require that we rely on CROs and other contractors to assist us with research and development, clinical testing activities, patient enrollment, data collection, and regulatory submissions to the FDA or other regulatory bodies. As a result, our success will depend partially on the success of these third parties in performing their responsibilities. Although we intend to pre-qualify our CROs and other contractors and we believe that the contractors selected will be fully capable of performing their contractual obligations, we cannot directly control the adequacy and timeliness of the resources and expertise that they apply to these activities. Additionally, macro-economic conditions may affect our development partners and vendors, which could adversely affect their ability to timely perform their tasks. If our contractors do not perform their obligations in an adequate and timely manner, the pace of clinical development, regulatory approval and commercialization of our drug candidates could be significantly delayed, and our prospects could be adversely affected.

## Risks Related to Our Intellectual Property

***If we are unable to obtain and maintain intellectual property protection for our technology and products or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.***

Our success depends in large part on our ability to obtain and maintain patent protection in relevant countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing patent applications

in the United States and internationally that are related to our novel technologies and product candidates. This patent portfolio includes issued patents and pending patent applications covering pharmaceutical compositions and methods of use.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may choose not to seek patent protection for certain innovations and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope. It is also possible that we will fail to identify patentable aspects of our discovery and non-clinical development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, India and China do not allow patents for methods of treating the human body. 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 know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the EU, the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

The risks described pertaining to our patents and other intellectual property rights also apply to the intellectual property rights that we license, and any failure to obtain, maintain and enforce these rights could have a material adverse effect on our business. In some cases, we may not have control over the prosecution, maintenance or enforcement of the patents that we license, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain and enforce the licensed patents. Any inability on our part to protect adequately our intellectual property may have a material adverse effect on our business, operating results and financial position.

The United States Patent and Trademark Office ("USPTO") and various non-U.S. governmental patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In certain situations, non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

In addition, we have acquired rights to tegoprubart and other product candidates through a license agreement with The ALS Therapy Development Foundation, Inc. and a manufacturing know-how rights license agreement with Lonza Sales AG, Inc. for the use of certain processes and know-how related to the manufacture of tegoprubart, and may in the future enter into other license agreements with third parties for other intellectual property rights or assets. These license agreements may impose various diligence, milestone payment, royalty, and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, we may be required to make certain payments to the licensor, we may lose the exclusivity of our license, or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the milestone and other payments associated with these licenses will make it less profitable for us to develop our drug candidates than if we had developed the licensed technology internally.

In some cases, patent prosecution of our licensed technology may be controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we may control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

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

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 the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference or derivation proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our 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 be forced, including by court order, to cease commercializing the infringing technology or product. 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 product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Because competition in our industry is intense, competitors may infringe or otherwise violate our issued patents, patents of our licensors or other intellectual property. To counter infringement or 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. In addition, 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 in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could be significant. 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.

***We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.***

A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our products. 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 on commercially reasonable terms, or our business could be harmed, possibly materially. If we were not able to obtain a license or are not able to obtain a license on commercially reasonable terms, our business could be harmed, possibly materially.

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

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Any NDAs or similar agreements entered into by the Company may not be with all relevant parties, or adequately protect the confidentiality of our trade secrets. Moreover, to the extent we enter into such agreements, 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, we would have no right to prevent them, or those to whom they communicate 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, our competitive position would be harmed.

***We may be subject to claims of misappropriation of trade secrets from former employers of Company personnel.***

Many of our employees and certain of our directors were previously employed at or affiliated with research foundations or other biotechnology or pharmaceutical companies. Although we try to ensure that our employees and directors 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 employees or directors have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's or director's former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

## Risks Related to Our Common Stock

***We expect our stock price to be volatile, and the market price of our common stock may drop unexpectedly.***

The market price of our common stock could be subject to significant fluctuations. Market prices for securities of early-stage pharmaceutical, biopharmaceutical, and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- uncertainties regarding our financial condition and our ability to raise sufficient capital to fund our ongoing operations;
- our ability to obtain regulatory approvals for our product candidates or other product candidates, and delays or failures to obtain such approvals;
- failure of any of our product candidates, if approved, to achieve commercial success;
- issues in manufacturing our approved products, if any, or product candidates;
- the results of our current and any future clinical trials of our product candidates;
- uncertainties about the ability of tegoprubart to prevent rejection in connection with kidney, xeno or islet cell transplantations;
- the entry into, or termination of, key agreements, including key commercial partner agreements;
- the initiation of, material developments in, or conclusion of litigation to enforce or defend any of our intellectual property rights or defend against the intellectual property rights of others;
- announcements by commercial partners or competitors of new commercial products, clinical progress, or the lack thereof, significant contracts, commercial relationships, or capital commitments;
- the introduction of technological innovations or new therapies that compete with our potential products;
- the loss of key employees;
- changes in estimates or recommendations by securities analysts, if any, who cover our common stock;
- general and industry-specific economic conditions that may affect our research and development expenditures;
- changes in the structure of healthcare payment systems;
- period-to-period fluctuations in our financial results; and
- future issuances of shares of common stock.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

***We have previously identified and remediated a material weakness in our internal control over financial reporting. If we fail to maintain effective internal controls, we may conclude that our internal control over financial reporting is not effective, which could adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner.***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles ("GAAP"). Our management is likewise required, on a quarterly basis, to evaluate the effectiveness of our disclosure controls and procedures, and to disclose any material weaknesses and any changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, such controls. Ensuring that we will have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently.

We have previously identified and remediated a material weakness in our internal controls over financial reporting, including as described Part II Item 9A, Controls and Procedures of this Annual Report on Form 10-K. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis. Although the Company concluded that as of December 31, 2025 its internal control over financial reporting was effective, the Company cannot provide assurances that the remediated material weakness will not reoccur, or that a new material weakness will not occur in the future. The existence of any material weakness could require management to devote significant time and incur significant expense to remediate any such material weakness and management may not be able to remediate any such material weakness in a timely manner. If we fail to maintain effective internal controls or any such material weakness is not remediated effectively or in a sufficient amount time, our ability to report our results of operations and financial condition accurately and in a timely manner could be adversely impacted. Further, we could be impacted by a material misstatement of our annual or interim financial statements that was not prevented or detected on a timely basis, which could have a negative effect on our results of operations and/or the trading price of our securities.

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

Provisions in our corporate charter and bylaws may discourage, delay or prevent a merger, acquisition or other change in control of the Company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our Board is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by stockholders to replace or remove the current management by making it more difficult for stockholders to replace members of our Board. Among other things, these provisions:

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

***We do not expect to pay any cash dividends in the foreseeable future.***

We expect to retain our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain, if any, for any stockholders for the foreseeable future.

**Item 1B. Unresolved Staff Comments.**

Not applicable.

**Item 1C. Cybersecurity.**

**Strategy and Oversight**

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, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and data related to our clinical studies and employees, or our information systems and the data contained therein.

We retain a Chief Information Consultant to collaborate with the company, including the Chief Financial Officer, and Executive Leadership Team, to help identify, assess and manage the company's cybersecurity threats and risks. This group identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example, automated tools, subscribing to reports and services that identify cybersecurity threats, analyzing reports of threats and actors, and evaluating threats reported to us. We also use a third-party security management vendor to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our information systems, including, for example, incident detection and response policy, route risk assessments, data encryption, network security controls, data segregation, access controls, physical security, asset management, tracking and disposal, systems monitoring, penetration testing, and cybersecurity insurance. As part of our information security program, we provide mandatory periodic training for all employees on how to identify potential cybersecurity risks and protect our resources and information. This training is supplemented by firmwide testing initiatives, including periodic phishing tests.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, the Chief Information Consultant works with management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business. In addition, our Chief Financial Officer evaluates material risks from cybersecurity threats and, as appropriate, reports to the Audit Committee of the Board of Directors, which evaluates our overall enterprise risk.

To date, we do not believe that known risks from cybersecurity threats, including as a result of any previous cybersecurity incidents that we are aware of, have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition. However, we can give no assurance that we have detected or protected against all such cybersecurity incidents or threats. For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under Part I. Item 1A. *Risk Factors* in this Annual Report on Form 10-K, including the risk factor titled "We depend on our information systems and those of our third-party collaborators, service providers, contractors or consultants, which may fail or suffer cybersecurity incidents that could result in a material disruption of our development programs or loss of data and have a material adverse effect on our reputation, business, financial condition or results of operations."

**Governance**

Our Board addresses our cybersecurity risk management as part of its general oversight function. The Audit Committee is responsible for overseeing our cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats. Our cybersecurity risk assessment and management processes are implemented and maintained by our Chief Financial Officer who oversees the work performed by our Chief Information Consultant.

Our Chief Financial Officer is responsible for hiring appropriate consultants, helping to integrate cybersecurity risk considerations into our overall risk management strategy and communicating key priorities to relevant personnel. Our Chief Financial Officer, with support from our Chief Information Consultant, is responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

The Audit Committee receives periodic reports from our Chief Financial Officer concerning our significant cybersecurity threats and risks and the processes we have implemented to address them. The Audit Committee also receives various reports, summaries or presentations related to cybersecurity threats, risk and mitigation. The Chief Financial Officer also promptly informs and updates the Board about any information security incidents that may pose significant risk to our Company.

The Chief Financial Officer has over 20 years of operations and leadership experience, including experience in information technology strategy and execution. The Chief Information Consultant has over 20 years of experience managing and securing technology infrastructure.

**Item 2. Properties.**

Our executive offices are located in Irvine, California. We lease approximately 5,817 square feet of office space under an operating lease that expires on June 30, 2027. Additionally, we have an operating lease for approximately 6,138 square feet of office space in Burlington, Massachusetts, that expires on November 21, 2027. We believe our facilities are sufficient for our current needs.

**Item 3. Legal Proceedings.**

Neither we nor any of our subsidiaries is a party to, and none of their respective property is the subject of, any material legal proceeding, although we are from time-to-time party to legal proceedings that arise in the ordinary course of our business.

**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 is traded on the Nasdaq Capital Market under the symbol "ELDN".

As of March 13, 2026, there were approximately 23 stockholders of record of our common stock.

**Dividends**

We have never declared or paid, and do not anticipate declaring or paying in the foreseeable future, any cash dividends on our common stock. Future determination as to the declaration and payment of dividends, if any, will be at the discretion of our Board and will depend on then existing conditions, including our operating results, financial condition, contractual restrictions, capital requirements, business prospects and other factors that our Board may deem relevant.

### Item 6. [Reserved.]

**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

*Management's Discussion and Analysis of Financial Condition and Results of Operations is intended to help the reader understand the results of operations and financial condition of the Company. The Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with our audited consolidated financial statements and notes thereto for the year ended December 31, 2025. In addition to historical information, this Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") which are intended to be covered by the safe harbors created thereby. See "Special Note Regarding Forward-Looking Statements" in this Annual Report on Form 10-K. Our actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under the Part I, Item 1A. Risk Factors section and elsewhere in this report, as well as, in other reports and documents we file with the Securities and Exchange Commission from time to time. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances occurring after the date of this Annual Report on Form 10-K.*

## RECENT DEVELOPMENTS

### *Overview*

Our business strategy is to optimize the clinical and commercial value of tegoprubart and become a global biopharmaceutical company with a focused immunology franchise. Tegoprubart targets the CD40 ligand (also known as CD40L). Blocking CD40L has been shown to inhibit multiple costimulatory receptors including CD40 and CD11, key components of how immune cells communicate with one another. Blocking CD40L also increases polarization of lymphocytes into Tregs, a specialized subpopulation of T cells that act to suppress immune response.

We believe the central role of CD40L signaling in generating pro-inflammatory responses makes it an attractive candidate for therapeutic intervention in the protection of transplanted organs and the prevention of transplant rejection, as well as modulating immune responses in autoimmune disease, and in neuroinflammation. Blocking the activation of the CD40L pathway has been shown to slow disease progression and pathology in preclinical models of autoimmunity and neurodegeneration, and to prevent acute and long-term allograft transplant rejection in multiple animal species.

We continue to focus on the development of tegoprubart for the prevention of rejection of allograft (i.e., transplanting an organ from one human to another) and xenograft (i.e., transplanting an organ from an animal to a human) organs and cells. Our mission is to both extend the functional life of transplanted organ and reduce side effect of current immunosuppressive treatments such as kidney toxicity, high blood pressure, and tremor.

Tegoprubart is being evaluated in multiple kidney transplantation studies, including a Phase 1b trial and a Phase 2 open-label extension study, and was evaluated through our Phase 2 BESTOW trial, each designed to assess safety, pharmacokinetics, and efficacy compared to standard-of-care immunosuppression. Final and interim data suggest improved renal function and reduced immunosuppressive-related adverse events. Additionally, an investigator-initiated islet cell transplantation study has shown potential in achieving insulin independence without the use of calcineurin inhibitors, supporting further exploration in Type 1 diabetes. We also continue to explore xenotransplantation applications, an emerging area of scientific and commercial interest. Our collaboration with eGenesis, Inc. supports preclinical and clinical studies in kidney, heart, and islet cell transplantation. A more complete discussion of the Phase 2 BESTOW clinical data, as well as results from the investigator-initiated islet cell transplantation study, is included in Item 1, *Business* in Part I of this Annual Report on Form 10-K.

We plan to seek guidance from the FDA regarding the design of a potential Phase 3 clinical trial evaluating tegoprubart in kidney transplantation and, subject to regulatory feedback and alignment, may initiate a Phase 3 trial.

### *Financing Activities*

#### *2023 Securities Purchase Agreement*

On April 28, 2023, we entered into a Securities Purchase Agreement (the "2023 Securities Purchase Agreement") with certain institutional and accredited investors, pursuant to which we agreed to issue and sell to the investors in a private placement (the "2023 Private Placement") (i) in an initial closing, (a) an aggregate of 15,151,518 shares (the "Shares") of our common stock, $0.001 par value per share ("common stock"), or pre-funded warrants in lieu thereof (the "Pre-Funded Warrants"), and (b) common stock warrants exercisable into an aggregate of 15,151,518 shares of common stock (or Pre-

Funded Warrants in lieu thereof) (the "Common Warrants" and, together with the Pre-Funded Warrants, the "Warrants"); (ii) in a second closing (the "Second Closing"), upon the satisfaction or waiver of specified conditions set forth in the 2023 Securities Purchase Agreement, an aggregate of 20,202,024 shares of common stock (or Pre-Funded Warrants); and (iii) in a third closing (the "Third Closing"), upon the satisfaction or waiver of specified conditions set forth in the 2023 Securities Purchase Agreement, an aggregate of 25,252,530 shares of common stock (or Pre-Funded Warrants), in each case subject to customary adjustments as provided in the 2023 Securities Purchase Agreement, Pre-Funded Warrant or Common Warrant, as applicable. Each Common Warrant has an exercise price of $3.00 per share and expires five years after issuance. The Pre-Funded Warrants are exercisable immediately and until exercised in full, with an exercise price of $0.001 per share. The Pre-Funded Warrants and Common Warrants are subject to specified beneficial ownership limitations, which are generally set at 9.99% of the total common stock then issued and outstanding immediately following the exercise of such warrants, and provided that any beneficial ownership limitation may not exceed 19.99% unless otherwise permitted. The Shares, the Warrants, and the shares of common stock issuable upon the exercise of the Warrants, have not been registered under the Securities Act and were offered pursuant to the exemption from registration provided in Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder.

On May 5, 2023, the initial closing occurred, and we received gross proceeds of $35.0 million, or net proceeds of approximately $33.0 million after deducting underwriting discounts and commissions and offering expenses, in exchange for 8,730,168 shares of common stock and Pre-Funded Warrants to purchase 6,421,350 shares of common stock.

On July 8, 2024, the Second Closing occurred, and the Company received gross proceeds of $2.1 million, or net proceeds of approximately $2.0 million after deducting underwriting discounts and commissions and offering expenses, in exchange for 909,088 shares of common stock.

On September 30, 2024, and October 1, 2024, the Third Closing occurred, and the Company received gross proceeds of $4.0 million, or net proceeds of approximately $3.8 million after deducting underwriting discounts and commissions and offering expenses, in exchange for 1,727,400 shares of common stock.

In connection with the 2023 Private Placement, the Company filed on May 18, 2023, a registration statement on Form S-3 (the "2023 Registration Statement") with the Securities and Exchange Commission ("SEC") to register for resale the Shares and the shares of common stock issuable upon the exercise of the Warrants. The 2023 Registration Statement became effective on June 2, 2023.

***Exercise of Pre-Funded Warrants from 2023 Securities Purchase Agreement***

On January 30, 2024, Armistice Capital Master Fund Ltd. (the "Exercising Stockholder") exercised Pre-Funded Warrants to purchase 600,000 shares of common stock at an exercise price of $0.001 per share, which were issued in conjunction with the 2023 Securities Purchase Agreement. On January 30, 2024, the Company issued 600,000 shares of common stock to the Exercising Stockholder in accordance with such exercise.

On May 7, 2024, the Exercising Stockholder exercised Pre-Funded Warrants to purchase 583,000 shares of common stock at an exercise price of $0.001 per share, which were issued in conjunction with the 2023 Securities Purchase Agreement. On May 9, 2024, the Company issued 583,000 shares of common stock to the Exercising Stockholder in accordance with such exercise.

On July 11, 2024, the Exercising Stockholder exercised their remaining Pre-Funded Warrants to purchase 240,000 shares of common stock at an exercise price of $0.001 per share, which were issued in conjunction with the 2023 Securities Purchase Agreement. On July 11, 2024, the Company issued 240,000 shares of common stock to the Exercising Stockholder in accordance with such exercise.

***2024 Securities Purchase Agreement***

On May 6, 2024, we entered into a Securities Purchase Agreement (the "2024 Securities Purchase Agreement") with certain institutional and accredited investors, pursuant to which we agreed to issue and sell to the investors in a private placement (the "2024 Private Placement") an aggregate of 13,110,484 shares (the "2024 Shares") of our common stock at a price of $2.37 per share, and pre-funded warrants (the "2024 Pre-Funded Warrants") at a price of $2.369 per underlying share, which are exercisable to purchase 7,989,516 shares of common stock at an exercise price of $0.001 per share. The 2024 Pre-Funded Warrants were issued in lieu of shares of common stock and are exercisable immediately and until exercised in full. The 2024 Pre-Funded Warrants are subject to specified beneficial ownership limitations (equal to 4.99% or

9.99% as determined by the holder of each such warrant) of the total common stock then issued and outstanding immediately following the exercise of such warrants, and provided that any beneficial ownership limitation may not exceed 19.99% unless otherwise permitted. The 2024 Shares, the 2024 Pre-Funded Warrants, and the shares of common stock issuable upon the exercise of the 2024 Pre-Funded Warrants, have not been registered under the Securities Act and were offered pursuant to the exemption from registration provided in Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder.

The 2024 Private Placement resulted in gross proceeds to the Company of $50.0 million, or net proceeds of approximately $48.1 million after deducting offering costs.

In connection with the 2024 Private Placement, on May 24, 2024, we filed a registration statement on Form S-3 (the "2024 Registration Statement") with the SEC to register for resale the 2024 Shares and the shares of common stock issuable upon the exercise of the 2024 Pre-Funded Warrants. The 2024 Registration Statement became effective on June 5, 2024.

***2024 Equity Distribution Agreement***

On September 20, 2024, we entered into an Open Market Sale Agreement (the "Sales Agreement") with Guggenheim Securities, LLC ("Guggenheim Securities") to sell shares of our common stock, having aggregate sales proceeds of up to $75.0 million, from time to time, through an "at the market" equity offering program under which Guggenheim Securities will act as sales agent. In connection with the Sales Agreement, we filed on September 20, 2024 a registration statement on Form S-3 containing a prospectus and prospectus supplement (the "Shelf Registration Statement") with the SEC. The Shelf Registration Statement became effective on October 2, 2024. As of December 31, 2025, we have not sold any shares under the Sales Agreement.

***2024 Underwritten Offering***

On October 29, 2024, we entered into an underwriting agreement with Leerink Partners, LLC, as representative of the several underwriters named therein in connection with the underwritten offering, issuance and sale by the Company (the "2024 Underwritten Offering") of 18,356,173 shares of our common stock, at an offering price of $3.65 per share, and pre-funded warrants at a price of $3.649 per pre-funded warrant, which are exercisable to purchase 4,931,507 shares of our common stock at an exercise price of $0.001 per share (the "2024 Offering Pre-Funded Warrants").

The 2024 Underwritten Offering closed on October 30, 2024 and resulted in gross proceeds of $85 million, or net proceeds of approximately $79.5 million after deducting underwriting discounts and commissions and offering expenses. The 2024 Underwritten Offering was made pursuant to the Shelf Registration Statement and a prospectus supplement relating to the 2024 Underwritten Offering dated October 29, 2024.

A holder of the 2024 Offering Pre-Funded Warrants (together with its affiliates) may not exercise any portion of a 2024 Offering Pre-Funded Warrant to the extent that the that, after giving effect to such exercise, the holder (together with the holder's affiliates, and any other persons acting as a group together with the holder or any of the holder's affiliates) would beneficially own in excess of 4.99% (or, at the holder's option upon issuance, 9.99%) of the number of shares of the our common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of such 2024 Offering Pre-Funded Warrants.

***2025 Underwritten Offering***

On November 12, 2025, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Leerink Partners, LLC, as representative of the several underwriters named therein (the "Underwriters"), in connection with the underwritten public offering and sale by the Company (the "2025 Underwritten Offering") of 15,152,485 shares of the Company's common stock at a public offering price of $1.65 per share (the "Common Stock Purchase Price"), and pre-funded warrants (the "2025 Offering Pre-Funded Warrants") at a public offering price of $1.649 per 2025 Offering Pre-Funded Warrant, which are exercisable to purchase up to 15,151,515 shares of common stock at an exercise price of $0.001 per share. In addition, pursuant to the Underwriting Agreement, the Company granted the Underwriters an option (the "Option"), exercisable for 30 days, to purchase up to 4,545,600 additional shares of common stock at the Common Stock Purchase Price less the underwriting discounts and commissions, which Option was exercised in full by the Underwriters.

The 2025 Underwritten Offering closed on November 13, 2025 and resulted in gross proceeds of $57.5 million or net proceeds of approximately $53.6 million after deducting the underwriting discounts and commissions and offering expenses.

The 2025 Underwritten Offering was made pursuant to the Shelf Registration Statement and a prospectus supplement relating to the 2025 Underwritten Offering dated November 12, 2025.

A holder of the 2025 Offering Pre-Funded Warrants (together with its affiliates) may not exercise any portion of a 2025 Offering Pre-Funded Warrant to the extent that, after giving effect to such exercise, the holder (together with the holder's affiliates, and any other persons acting as a group together with the holder or any of the holder's affiliates) would beneficially own in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of such 2025 Offering Pre-Funded Warrant. A holder, A holder, upon notice to the Company, may increase or decrease such beneficial ownership limitation provision, provided that in no event shall the limitation exceed 19.99% of the number of shares of the common stock outstanding immediately after giving effect to the issuance of shares of common stock upon exercise of the 2025 Offering Pre-Funded Warrant may increase or decrease such beneficial ownership limitation, provided that in no event shall the limitation exceed 19.99% of the number of shares of the common stock outstanding immediately after giving effect to the issuance of shares of common stock upon exercise of the 2025 Offering Pre-Funded Warrant.

***2025 Warrant Exchange Agreement***

On December 30, 2025, the Company entered into an exchange agreement (the "Warrant Exchange Agreement") with Coastlands Capital Partners LP, ("Coastlands Capital"), pursuant to which Coastlands Capital agreed to exchange 4,203,764 shares of common stock for a pre-funded warrant to purchase an aggregate of 4,203,764 shares of common stock (the "Exchange Warrant"), and the Company cancelled the 4,203,764 shares of common stock delivered in the exchange.

Coastlands Capital (together with its affiliates) may not exercise any portion of the Exchange Warrant to the extent that, after giving effect to such exercise, Coastlands Capital (together with its affiliates and any other persons acting as a group together with Coastlands Capital or any of the its affiliates) would beneficially own in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of the Exchange Warrant. Coastlands Capital may increase or decrease such beneficial ownership limitation, provided that in no event shall the limitation exceed 19.99% of the number of shares of the common stock outstanding immediately after giving effect to the issuance of shares of common stock upon exercise of the Exchange Warrant.

***Common Stock Warrants***

As of December 31, 2025, 15,151,518 warrants were exercisable into common stock (after rounding for fractional shares and subject to beneficial ownership conversion blockers). The shares of common stock underlying the registered direct and private placement warrants are registered for offer and sale under the Securities Act pursuant to our effective registration statements on Forms S-3.

***Financial Operations Overview***

***Operating Expenses***

Our operating expenses consist primarily of costs associated with research and development activities and general and administrative activities.

***Research and Development Expenses***

Research and development expenses, which consist primarily of costs associated with our product research and development efforts, are expensed as incurred. Research and development expenses consist primarily of:

- personnel costs, including salaries, benefits, stock-based compensation and travel expenses, for employees engaged in research and development functions;
- expenses incurred under agreements with contract research organizations, or ("CROs"), and sites that conduct our non-clinical studies and clinical trials;
- expenses associated with manufacturing materials for use in non-clinical studies and clinical trials and developing external manufacturing capabilities;
- costs of outside consultants engaged in research and development activities, including their fees and travel expenses;

- other expenses related to our non-clinical studies and clinical trials and expenses related to our regulatory activities; and
- payments made under our third-party license agreements.

***General and Administrative Expenses***

General and administrative expenses consist primarily of personnel costs that include salaries, benefits and travel expenses for our executive, finance, and other administrative functions, and stock-based compensation expense. General and administrative expenses also include professional fees for expenses incurred under agreements with third parties relating to public relations, audit, tax and legal services, including legal expenses to pursue patent protection of our intellectual property; and our information technology, facilities and other related expenses, including rent, maintenance of facilities, insurance and supplies.

***Change in fair value of warrant liabilities***

Change in fair value of warrant liabilities represents the initial recognition of warrant liabilities at fair value in excess of proceeds received, as well as subsequent period remeasurements of these warrant liabilities at fair value. These remeasurements reflect changes in market conditions, such as fluctuations in stock price, volatility, interest rates, and other valuation inputs that impact the fair value of the liability.

## CRITICAL ACCOUNTING ESTIMATES

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amount of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities as of the date of the financial statements. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

***Accrued Research and Development Expenses***

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts, communicating with our personnel and vendors to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- CROs in connection with performing research and development services on our behalf;
- other providers in connection with clinical trials;
- vendors in connection with non-clinical development activities; and
- vendors related to product manufacturing, development and distribution of clinical supplies.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. When determining accruals, we estimate the time period over which services will be performed, enrollment of patients, number of sites activated and level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly. Although

we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting expenses that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

***Stock-Based Compensation***

The Company recognizes compensation expense for all stock-based awards based on the grant-date estimated fair value.

The fair value of stock options is determined using the Black-Scholes option pricing model, using assumptions which are subjective and require significant judgment and estimation by management. The risk-free rate assumption was based on observed yields from governmental zero-coupon bonds with an equivalent term. The expected volatility assumption was based on historical volatilities of a group of comparable industry companies whose share prices are publicly available. The peer group was developed based on publicly traded biotechnology and pharmaceutical companies with comparable business characteristics, clinical stages of development, and organizational scale, including employee headcount, primarily consisting of companies with Phase II or Phase III clinical programs. The expected term of stock options represents the weighted-average period that the stock options are expected to be outstanding. Because the Company does not have historical exercise behavior, the Company determined the expected life assumption using the simplified method for stock options granted to employees, which is an average of the options ordinary vesting period and the contractual term. The expected dividend assumption was based on the Company's history and expectation of dividend payouts. The Company has not paid and does not expect to pay dividends at any time in the foreseeable future. The Company recognizes forfeitures on an actual basis and as such did not estimate forfeitures to calculate stock-based compensation.

Restricted Stock Units ("RSU") are measured and recognized based on the quoted market price of our common stock on the date of grant.

***Warrant Liabilities***

Warrants are accounted for as either derivative liabilities or as equity instruments depending on the specific terms of the underlying agreement. Warrants classified as derivative liabilities are initially recorded at fair value on the issuance date and are remeasured at each reporting period, with changes in fair value recognized in the consolidated statements of operations. Warrants classified as equity instruments are recorded in additional paid-in capital at issuance and are not subject to remeasurement. The Common Warrants are recorded at fair value using the Black-Scholes option-pricing model at issuance, with any subsequent changes in fair value recognized in the consolidated statements of operations. To determine the fair value of the liability classified warrants, a Black-Scholes option-pricing model is used, which considers assumptions that are subjective and require significant judgment and estimation by management. The risk-free rate assumption was based on observed yields from governmental zero-coupon bonds with an equivalent term. The expected volatility assumption was based on a peer group of publicly traded biotechnology and pharmaceutical companies with comparable business characteristics, clinical stages of development, and organizational scale, including employee headcount, primarily consisting of companies with Phase II or Phase III clinical programs. We periodically evaluate changes in facts and circumstances that could impact the classification of warrants.

***Recently Issued and Adopted Accounting Pronouncements***

A description of recently issued and recently adopted accounting pronouncements that may potentially impact our financial position and results of operations is set forth in *Note 2. Summary of Significant Accounting Policies*, of the Notes to Financial Statements included in this Annual Report on Form 10-K.

***Market Trends and Uncertainties***

The global economy, including the financial and credit markets, has recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, elevated inflation and interest rates, changes in U.S. trade policy and uncertainty about economic stability. Likewise, the current conflicts in Ukraine and the Middle East have created volatility in the global capital markets and global economic consequences, including disruptions of the global supply chain and energy markets. A severe or prolonged economic downturn or continued volatility in the financial and credit markets could negatively impact our ability to obtain necessary debt or equity financing in a timely manner or on favorable terms, if at all.

The severity and duration of any such impacts cannot be predicted. Any such failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies or cause us to delay our clinical development plans, research and development programs or commercialization efforts, out-license intellectual property rights to our product candidates or sell unsecured assets, or a combination of the above. Any of these actions could materially harm our business.

Any of the foregoing items could materially affect our business, possibly to a significant degree. The severity and duration of any such impacts cannot be predicted. See Item 1A, "Risk Factors" in Part I of this Annual Report on Form 10-K for additional information

## RESULTS OF OPERATIONS

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

The following table provides comparative results of operations for the years ended December 31, 2025 and 2024 (in thousands):

| | Year Ended December 31, | | | |
|---|---|---|---|---|
| | 2025 | 2024 | $ Variance | % Variance |
| **Operating expenses:** | | | | |
| Research and development | $ 66,267 | $ 51,964 | $ 14,303 | 28% |
| General and administrative | 16,984 | 18,613 | (1,629) | -9% |
| Total operating expenses | 83,251 | 70,577 | 12,674 | 18% |
| Loss from operations | (83,251) | (70,577) | (12,674) | -18% |
| Other income, net | 4,220 | 3,924 | 296 | 8% |
| Change in fair value of warrant liabilities | 33,449 | 30,900 | 2,549 | 8% |
| Loss before income taxes | (45,582) | (35,753) | (9,829) | -27% |
| Provision for income taxes | (35) | (431) | 396 | 92% |
| Net loss | $ (45,617) | $ (36,184) | $ (9,433) | -26% |
| Other comprehensive loss: | | | | |
| Unrealized loss on available-for-sale securities, net | (2) | — | (2) | -100% |
| Comprehensive loss | $ (45,619) | $ (36,184) | $ (9,435) | -26% |

*Research and Development Expenses*

The following table summarizes the period-over-period changes in research and development expenses for the periods presented (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2025 | 2024 | Change |
| Tegoprubart - kidney transplantation programs | $ 35,994 | $ 27,452 | $ 8,542 |
| Tegoprubart - other development programs | (168) | 306 | (474) |
| Manufacturing | 14,974 | 12,448 | 2,526 |
| Personnel-related | 10,993 | 7,292 | 3,701 |
| Stock-based compensation | 4,241 | 4,277 | (36) |
| Other expenses | 233 | 189 | 44 |
| Total research and development expenses | $ 66,267 | $ 51,964 | $ 14,303 |

Research and development expenses increased $14.3 million for the year ended December 31, 2025, compared to the year ended December 31, 2024. The increase was primarily attributable to:

- an increase of $8.5 million in Tegoprubart - kidney transplantation programs, primarily driven by higher external CRO costs, related to increased activities in our Phase 1b, Phase 2 BESTOW and Phase 2 open-label extension trials for kidney transplantation;
- a decrease of $0.5 million in Tegoprubart - other development programs, primarily external CRO costs, related to the close-out of activities of our terminated IgAN program in 2024;
- an increase of $2.5 million in manufacturing costs, primarily contract manufacturing organization expenses, associated with increased production of drug substance and drug product clinical trial supply; and
- an increase of $3.7 million in personnel-related expenses, driven by increased headcount supporting ongoing clinical development programs.

*General and Administrative Expenses*

The following table summarizes the period-over-period changes in general and administrative expenses for the periods presented (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2025 | 2024 | Change |
| Professional Fees | $ 5,141 | $ 4,212 | $ 929 |
| Personnel-related | 3,533 | 3,414 | 119 |
| Stock-based compensation | 6,210 | 8,845 | (2,635) |
| Other expenses | 2,100 | 2,142 | (42) |
| Total general and administrative expenses | $ 16,984 | $ 18,613 | $ (1,629) |

General and administrative expenses decreased $1.6 million for the year ended December 31, 2025, compared to the year ended December 31, 2024. The decrease was primarily attributable to:

- an increase of $0.9 million in professional and consulting fees, primarily due to increased audit and legal service costs;
- an increase of $0.1 million in personnel-related expenses driven by higher headcount; and partially offset by;
- a decrease of $2.6 million in stock-based compensation expense, attributable to performance-based stock options granted in 2024.

*Other Income, Net*

The $0.3 million increase in other income, net was primarily due to an increase in interest income, driven by higher balances of our cash and cash equivalents and short-term investments during the year ended December 31, 2025 as compared to the year ended December 31, 2024.

*Change in fair value of warrant liabilities*

For the year ended December 31, 2025, the fair value of warrant liabilities decreased by $33.4 million. This change was primarily driven by a decrease in the fair value of the Common Warrants, reflecting a decline in the Company's stock price during the period. The warrant liability declined from $44.9 million as of December 31, 2024 to $11.4 million as of December 31, 2025.

*Provision for Income Taxes*

The provision for income taxes for the year ended December 31, 2025 and 2024 was $35 thousand and $0.4 million, respectively. The higher income tax expense in 2024 versus income tax expense in 2025 was the result of a larger change in the effective state tax rate used to remeasure the deferred tax liability related to indefinite-lived assets in 2024.

## LIQUIDITY AND CAPITAL RESOURCES

### *Sources of Liquidity*

As of December 31, 2025, the Company had cash and cash equivalents and short-term investments of $133.3 million, working capital of $117.3 million and an accumulated deficit of $401.2 million.

We do not have any approved products for commercial sale and have never generated revenue from product sales and have incurred significant net losses since our inception and expect to continue to incur net operating losses for the foreseeable future. We do not expect to receive any revenue from any product candidates that we develop unless and until we obtain regulatory approval and commercialize our product candidates or enter into collaborative arrangements with third parties. We currently have no credit facility or committed sources of capital. To date, our operations have been financed primarily by net proceeds from the sale of preferred and common stock, and the sale of warrants. Additionally, in view of our expectation to incur significant losses for the foreseeable future we will be required to raise additional capital resources in the future in order to fund our operations, although the availability of, and our access to, such resources is not assured.

Based on our liquidity estimates and our current resources, we have concluded that we have sufficient cash resources to meet our anticipated cash needs through at least the next 12 months from the date of this report. We have based this estimate on assumptions that may prove to be incorrect, and we could utilize our available resources sooner than we currently expect. To finance our operations beyond that point we will need to raise additional capital, which cannot be assured. Further, from time to time, our operating plans may change, and we may need additional funds to meet operational needs for clinical studies sooner than planned or to fund additional clinical studies. For example, we do not currently have sufficient liquidity to fund the continued clinical development of tegoprubart for people with ALS without additional financing. We will continue to monitor our liquidity position in light of various financing alternatives and may pursue additional financing or other alternatives to allow us to continue our product development. However, there can be no assurance such financing or other alternatives will be available to us on acceptable terms, or at all, which could force us to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether.

### *Material Cash Requirements*

Our primary use of cash is to fund operating expenses, which consist of clinical research and development expenses, manufacturing expenses, legal and compliance expenses, compensation and related expenses, and general overhead costs. Cash used to fund operating expenses is impacted by the timing of when we pay or prepay these expenses.

We expect our expenses to increase in connection with our ongoing activities, particularly as we expand our clinical program with tegoprubart and, continue the research and development of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution.

We will continue to require additional financing in order to advance our drug product through clinical development, to manufacture, obtain regulatory approval for and to commercialize our product candidates, to develop, acquire or in-license other potential product candidates, and to fund operations for the foreseeable future. Therefore, we will seek to raise additional capital through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. The ability to raise substantial additional capital will depend on many factors, including:

- the initiation, progress, timing, costs and results of our ongoing and future clinical trials of tegoprubart, including as such activities may be adversely impacted by global events or macroeconomic conditions;
- the impact of global macroeconomic trends and uncertainties, which continue to experience volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates, rising interest rates and uncertainty about economic stability;

- the number and scope of indications we decide to pursue for tegoprubart development;
- the cost, timing and outcome of regulatory review of any biologics license application, or BLA, we may submit for tegoprubart;
- the costs and timing of manufacturing for tegoprubart, if approved;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of tegoprubart;
- the costs associated with being a public company;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- the extent to which we acquire or in-license other product candidates and technologies; and
- the cost associated with commercializing tegoprubart, if approved for commercial sale.

Conditions in the financial and credit markets may also limit the availability of funding or increase the cost of funding. As a result of any of the foregoing factors, adequate additional funding may not be available to us on acceptable terms on a timely basis, or at all. The severity and duration of any such impacts cannot be predicted. Any such failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies or cause us to delay our clinical development plans, research and development programs or commercialization efforts, out-license intellectual property rights to our product candidates or sell unsecured assets, or a combination of the above. Any of these actions could materially harm our business. The issuance of shares of common stock in the 2023 Private Placement, the 2024 Private Placement, the 2024 Underwritten Offering and the 2025 Underwritten Offering diluted the ownership interests of our existing stockholders, and to the extent that we raise additional capital through the sale of additional equity, including through our "at the market" equity offering program, or convertible debt securities in the future, our stockholders' ownership interests may be further diluted, and the terms of these securities may also include liquidation or other preferences that adversely affect our stockholders' rights. Debt financing, if available, would 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 or declaring dividends, that could adversely impact our ability to conduct our business. If we raise funds through collaborations, licenses and other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. Please see Part I, Item 1A. *Risk Factors* of this Annual Report on Form 10-K for additional risks associated with our substantial capital requirements and the challenges we may face in raising capital.

We lease our office facilities in Irvine, California and Burlington, Massachusetts under non-cancelable operating leases that expire in June 2027 and November 2027, respectively. As of December 31, 2025, we expect to make total lease payments of $0.7 million through November 2027.

We enter into contracts in the normal course of business with third-party contract organizations for preclinical and clinical studies, manufacture and supply of our preclinical and clinical materials and providing other services and products for operating purposes. Contracts for preclinical and clinical studies and other services generally provide for termination following a certain period after notice, and therefore we believe that our non-cancelable obligations under these agreements are not material. We do not have any long-term manufacturing and supply agreements with our third-party contract manufacturers but enter into specific contracts on an as needed basis for individual batch production runs (See *Note 7. Commitments and Contingencies* of the Notes to Financial Statements included in this Annual Report on Form 10-K for contract obligations due within the next year).

***Cash Flows***

The following table provides a summary of our net cash flow activity for the years ended December 31, 2025 and 2024 (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2025 | 2024 | Change |
| Net cash used in operating activities | $ (62,341) | $ (47,271) | $ (15,070) |
| Net cash provided by (used in) investing activities | 10,793 | (70,314) | 81,107 |
| Net cash provided by financing activities | 53,807 | 133,522 | (79,715) |
| Net change in cash and cash equivalents | $ 2,259 | $ 15,937 | $ (13,678) |

*Operating Activities*

Net cash used in operating activities was $62.3 million for the year ended December 31, 2025, reflecting a net loss of $45.6 million. Adjustments for certain non-cash items including a $33.4 million change in fair value of warrant liabilities due to decreased stock price and $10.5 million of stock-based compensation. The change in cash used in operating assets and liabilities was $7.7 million, primarily driven by an increase in accrued expenses as a result of kidney transplantation programs.

Net cash used in operating activities was $47.3 million for the year ended December 31, 2024, reflecting a net loss of $36.2 million. Operating activities include adjustments for certain non-cash charges including $30.9 million due to a change in fair value of warrant liabilities and fair value of financial instruments issued in excess of proceeds and $13.1 million of stock-based compensation. Net operating assets and liabilities changed by $8.7 million, primarily driven by an increase in accounts payable and accrued expense as of result of kidney transplantation programs.

*Investing Activities*

Net cash provided by investing activities for the year ended December 31, 2025 was $10.8 million. We purchased $161.1 million of short-term investments, which was offset by the maturing of $171.9 million of our short-term investments during the year.

Net cash used in investing activities for the year ended December 31, 2024 was $70.3 million. We purchased $156.1 million of short-term investments, which was partially offset by the maturing of $85.8 million of our short-term investments during the year.

*Financing Activities*

Net cash provided by financing activities for the year ended December 31, 2025 was $53.8 million, which consisted of the 2025 Underwritten Offering, totaling $53.6 million in net proceeds from the sale of 19.7 million shares of common stock and 15.2 million pre-funded warrants to purchase common stock and $0.2 million from exercise of stock options.

Net cash provided by financing activities for the year ended December 31, 2024 was $133.5 million, which consisted of the following: $79.5 million in net proceeds from the 2024 Underwritten Offering, involving the sale of 18.4 million shares of the common stock and pre-funded warrants to purchase 4.9 million shares of common stock; $48.1 million in net proceeds from the 2024 Private Placement, involving the sale of 13.1 million shares of common stock and pre-funded warrants to purchase 8.0 million shares of common stock; $1.9 million in net proceeds from the Second Closing, involving the sale of 0.9 million shares of common stock; $3.8 million in net proceeds from the Third Closing, involving the sale of 1.7 million shares of common stock; and $0.2 million from exercise of stock options.

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

Per §229.305 of Regulation S-K, the Company, designated a Smaller Reporting Company as defined in §229.10(f)(1) of Regulation S-K, is not required to provide the disclosure required by this Item.

**Item 8. Financial Statements and Supplementary Data.**

The Report of Independent Registered Public Accounting Firm, our consolidated financial statements and accompanying notes listed under Part IV, Item 15. *Exhibits and Financial Statement Schedules* of this Annual Report on Form 10-K are set forth beginning on page F-1 immediately following the signature page hereof and incorporated by reference herein.

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

Not applicable

**Item 9A. Controls and Procedures.**

***Evaluation of Disclosure Controls and Procedures***

As of the end of the period covered by this Annual Report on Form 10-K, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures.

Based on this evaluation, management concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2025.

**Internal Control Over Financial Reporting**

***Management's Report on Internal Control Over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control system is designed to provide reasonable assurance to our management and Board regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Our management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO Framework") in its 2013 *Internal Control—Integrated Framework.* Management believes that the COSO Framework is a suitable framework for its evaluation of financial reporting because it is free from bias, permits reasonably consistent qualitative and quantitative measurements of our internal control over financial reporting, is sufficiently complete so that those relevant factors that would alter a conclusion about the effectiveness of our internal control over financial reporting are not omitted and is relevant to an evaluation of internal control over financial reporting.

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

As a non-accelerated filer, this Annual Report on Form 10-K does not include an attestation report on our internal control over financial reporting issued by the Company's independent registered public accounting firm.

***Completed Remediation of Prior Years' Material Weakness***

In the course of preparing our unaudited condensed consolidated financial statements as of and for the three and six months ended June 30, 2025, our management concluded that the Series X and Series $X^1$ non-voting convertible preferred stock, $0.001 par value ("Preferred Stock") should be treated as a separate class of common stock for purposes of calculating earnings per share in accordance with Accounting Standards Codification ("ASC") 260-10, "Earnings Per Share" and the Company must instead present earnings per share under the two-class method. Additionally, our management concluded that the Preferred Stock does not meet the criteria for permanent equity classification and must be classified as temporary equity under ASC 480-10-S99-3A.

This determination resulted in the restatements of our financial statements in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2025 (as to the three and nine months ended September 30, 2024), our Quarterly Report on Form 10-Q for the quarter ended June 30, 2025 (as to the three and six months ended June 30, 2024), our Quarterly Report on Form 10-Q/A for the three months ended March 31, 2025, and our Annual Report on Form 10-K/A for the year ended December 31, 2024 (together, the "Impacted Reports").

As a result, as previously disclosed in our Annual Report on Form 10-K/A for the year ended December 31, 2024, our management, including our principal executive officer and principal financial officer, determined that there existed a material weakness in our internal control over financial reporting related to our accounting for equity instruments for the periods covered by each of the Impacted Reports. A material weakness is a deficiency, or a combination of deficiencies, in the internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis. Specifically, our management determined that we did not maintain effective controls to timely identify and account for equity instruments with complex terms, including certain provisions within our Preferred Stock. This material weakness resulted in the material misstatement of each of the Impacted Reports.

As previously disclosed, in August 2025, the Company immediately implemented a plan to address and remediate the material weakness described above and to improve our internal control over financial reporting. As part of the remediation plan, management identified and implemented a number of actions including, but not limited to, the following actions:

- Engaged with external technical accounting experts to advise and review all equity instruments, ensuring appropriate technical analysis, documentation, and oversight prior to the preparation of our financial statements.
- Implemented an accounting standards compliance process to ensure timely adoption and assessment of evolving accounting standards.
- Strengthened financial disclosure and technical guidance resources.

During the fourth quarter of the year ended December 31, 2025, we successfully completed the testing necessary to conclude that the material weakness has been remediated. As such, management, including our principal executive officer and principal financial officer, have concluded that the plan and actions described above were satisfactorily executed and the related policies, procedures and controls have been implemented, operated effectively and tested satisfactorily for a sufficient period of time to demonstrate that the previously identified material weakness has been remediated as of December 31, 2025. The Company is committed to evaluating and monitoring adherence to the established policies and procedures listed above.

***Changes in Internal Control over Financial Reporting***

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) or 15d-15(f) of the Exchange Act) during the quarter ended December 31, 2025, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information.**

*Insider Trading Arrangements*

None.

**Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspection.**

Not applicable.

## PART III

### Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 is incorporated herein by reference to information in our proxy statement for our 2026 Annual Meeting of Stockholders (the "2026 Proxy Statement"), which we expect to be filed with the SEC within 120 days of the end of our fiscal year ended December 31, 2025, including under headings "Proposal 1: Board of Directors and Corporate Governance—Election of Class III Directors," "Executive Officers," "Corporate Governance—Director Nomination Process," " Corporate Governance—Committees of the Board," and "Corporate Governance—Insider Trading Policy and Procedures."

We have adopted a written 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 copy of the code is available on the Corporate Governance section of our website, which is located at *http://ir.eledon.com/corporate-governance/governance-overview*. We intend to disclose on our website any amendments to, or waivers from, the code of business conduct and ethics that are required to be disclosed pursuant to the disclosure requirements of Item 5.05 of Form 8-K within four business days following the date of the amendment or waiver.

### Item 11. Executive Compensation.

The information required by this Item 11 is incorporated herein by reference to information in our 2026 Proxy Statement, including under headings "Executive Compensation," and "Director Compensation."

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

The information required by this Item 12 is incorporated herein by reference to information in our 2026 Proxy Statement, including under headings "Stock Ownership and Reporting—Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance Under Equity Compensation Plans."

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

The information required by this Item 13 is incorporated herein by reference to information in our 2026 Proxy Statement, including under headings "Corporate Governance—Policies and Procedures for Related Person Transactions," "Corporate Governance," and "Corporate Governance—Committees of the Board."

### Item 14. Principal Accountant Fees and Services.

The information required by this Item 14 is incorporated herein by reference to information in our 2026 Proxy Statement, including under headings "Independent Registered Public Accounting Firm—Audit Fees and Services" and "Independent Registered Public Accounting Firm—Pre-Approval Policies and Procedures."

## PART IV

**Item 15. Exhibits and Financial Statement Schedules.**

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Financial Statements:

The Report of Independent Registered Public Accounting Firm, our consolidated financial statements and accompanying notes are set forth beginning on page F-1 immediately following the signature page of this Annual Report on Form 10-K.

(2) Financial Statement Schedules:

The financial statement schedules are omitted as they are either not applicable or the information required is presented in the financial statements and notes thereto under Part II, Item 8. *Financial Statements and Supplementary Data*.

(3) Exhibits:

| Exhibit Number | Exhibit Description | Incorporated by Reference | | | Filing Date | Filed Herewith |
|---|---|---|---|---|---|---|
| | | Form | File No. | Exhibit | | |
| 3.1 | Restated Certificate of Incorporation of Novus Therapeutics, Inc., a Delaware corporation, dated September 22, 2014 | 8-K | 001-36620 | 3.1 | September 26, 2014 | |
| 3.2 | Certificate of Amendment to Certificate of Incorporation of Novus Therapeutics, Inc. (effecting, among other things a reverse stock-split), filed with the Secretary of the State of Delaware on May 9, 2017 | 8-K | 001-36620 | 3.1 | May 15, 2017 | |
| 3.3 | Certificate of Amendment to Certificate of Incorporation of Novus Therapeutics, Inc. (effecting, among other things a change in the corporation's name to "Novus Therapeutics, Inc."), filed with the Secretary of the State of Delaware on May 9, 2017 | 8-K | 001-36620 | 3.2 | May 15, 2017 | |
| 3.4 | Certificate of Amendment to the Restated Certificate of Incorporation of Novus Therapeutics, Inc., (effecting, among other things a reverse stock-split) effective as of October 5, 2020 | 8-K | 001-36620 | 3.1 | October 6, 2020 | |

| | | | | | | |
|---|---|---|---|---|---|---|
| 3.5 | Certificate of Amendment to the Restated Certificate of Incorporation of Novus Therapeutics, Inc., (effecting, among other things a change in the corporation's name to "Eledon Pharmaceuticals, Inc.") effective as of January 5, 2021 | 8-K | 001-36620 | 3.1 | January 5, 2021 | |
| 3.6 | Certificate of Amendment to the Restated Certificate of Incorporation, as amended, of Eledon Pharmaceuticals, Inc., (effecting an increase in authorized shares of common stock) | 8-K | 001-36620 | 3.1 | June 12, 2025 | |
| 3.7 | Certificate of Amendment to the Restated Certificate of Incorporation, as amended, of Eledon Pharmaceuticals, Inc., (providing for exculpation of certain officers) | 8-K | 001-36620 | 3.2 | June 12, 2025 | |
| 3.8 | Amended and Restated Bylaws of Eledon Pharmaceuticals, Inc. | 8-K | 001-36620 | 3.4 | January 5, 2021 | |
| 3.9 | Certificate of Designations of Series X Convertible Preferred Stock | 8-K | 001-36620 | 3.1 | February 19, 2020 | |
| 3.10 | Certificate of Designations of Series $X^1$ Convertible Preferred Stock | 8-K | 001-36620 | 3.1 | September 15, 2020 | |
| 4.1 | Form of Common Stock Purchase Warrant | 8-K | 001-36620 | 4.1 | January 16, 2020 | |
| 4.2 | Form of Pre-Funded Warrant to Purchase Common Stock | 8-K | 001-36620 | 4.1 | May 1, 2023 | |
| 4.3 | Form of Tranche A Warrant to Purchase Common Stock or Pre-Funded Warrants | 8-K | 001-36620 | 4.2 | May 1, 2023 | |
| 4.4 | Form of Pre-Funded Warrant to Purchase Common Stock | 8-K | 001-36620 | 4.1 | May 7, 2024 | |
| 4.5 | Form of Pre-Funded Warrant to Purchase Common Stock | 8-K | 001-36620 | 4.1 | October 30, 2024 | |
| 4.6 | Form of Pre-Funded Warrant to Purchase Common Stock | 8-K | 001-36620 | 4.1 | November 13, 2025 | |
| 4.7 | Form of Exchange Warrant | 8-K | 001-36620 | 4.1 | January 2, 2026 | |
| 4.8 | Description of Securities | | | | | X |

| | | | | | |
|---|---|---|---|---|---|
| 10.1 | Open Market Sales Agreement by and between the Registrant and Guggenheim Securities, LLC dated September 20, 2024 | S-3 | 333-282260 | 1.2 | September 20, 2024 |
| 10.2* | Form of Indemnification Agreement to be entered into with each of the directors and officers of Eledon | 8-K | 001-36620 | 10.1 | September 21, 2023 |
| 10.3 | Fourth Amendment to Lease Agreement, dated March 12, 2024, by and between Newport Gateway Office LLC and Eledon Pharmaceuticals, Inc. | 10-K | 001-36620 | 10.7 | March 20, 2025 |
| 10.4 | Lease Agreement, dated September 4, 2024, by and between Blanchard Group LLC and Eledon Pharmaceuticals, Inc. | 10-K | 001-36620 | 10.8 | March 20, 2025 |
| 10.5* | Tokai Pharmaceuticals, Inc. 2014 Stock Incentive Plan | 10-Q | 001-36620 | 10.2 | August 7, 2018 |
| 10.6* | Novus Therapeutics, Inc., 2014 Employee Stock Purchase Plan | 10-Q | 001-36620 | 10.3 | August 7, 2018 |
| 10.7* | Executive Employment Agreement, dated September 9, 2020, between Novus Therapeutics, Inc. and David-Alexandre C. Gros, M.D. | 10-K | 001-36620 | 10.8 | March 31, 2021 |
| 10.8* | David-Alexandre Gros, M.D. Letter Agreement, dated April 27, 2023 | 8-K | 001-36620 | 10.3 | May 1, 2023 |
| 10.9* | David-Alexandre Gros, M.D. Letter Agreement, dated December 16, 2024 | 10-K | 001-36620 | 10.14 | March 20, 2025 |
| 10.10* | Executive Employment Agreement, dated March 15, 2021, between Eledon Pharmaceuticals, Inc. and Paul Little | 10-K | 001-36620 | 10.10 | March 31, 2021 |
| 10.11* | Steve Perrin, Ph.D. Letter Agreement, dated April 27, 2023 | 8-K | 001-36620 | 10.4 | May 1, 2023 |
| 10.12* | Novus Therapeutics, Inc., 2020 Long Term Incentive Plan | 10-K | 001-36620 | 10.11 | March 31, 2021 |
| 10.13* | Eledon Pharmaceuticals, Inc. 2020 Long Term Incentive Plan, as amended | 8-K | 001-36620 | 10.1 | July 10, 2024 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 10.14* | Performance Stock Option Agreement, dated February 1, 2022, between Eledon Pharmaceuticals, Inc. and David-Alexandre C. Gros, M.D. | 10-K | 001-36620 | 10.12 | March 24, 2022 | |
| 10.15 | Amended and Restated License Agreement by and between ALS Therapy Development Foundation, Inc. and Anelixis Therapeutics, Inc, dated February 18, 2020 | 10-Q | 001-36620 | 10.1 | August 11, 2022 | |
| 10.16 | First Amendment to Restated License Agreement between ALS Therapy Development Foundation, Inc. and Anelixis Therapeutics, Inc. dated September 5, 2020 | 10-Q | 001-36620 | 10.2 | August 11, 2022 | |
| 10.17 | License Agreement between Lonza Sales AG and Anelixis Therapeutics, LLC, dated September 11, 2018 | 10-Q | 001-36620 | 10.3 | August 11, 2022 | |
| 10.18* | Form of Stock Option Agreement, dated May 1, 2023, between Eledon Pharmaceuticals, Inc. and each of David-Alexandre C. Gros, M.D., Steve Perrin, Ph D., Bryan Smith and Paul Little | 10-K | 001-36620 | 10.22 | March 28, 2024 | |
| 10.19* | Form of Amendment to Stock Option Agreement, dated December 30, 2023, between Eledon Pharmaceuticals, Inc. and David-Alexandre C. Gros, M.D., Steve Perrin, Ph D., Bryan Smith and Paul Little | 10-K | 001-36620 | 10.23 | March 28, 2024 | |
| 10.20* | Form of Amendment to Stock Option Agreement, dated June 13, 2024, between Eledon Pharmaceuticals, Inc. and David-Alexandre C. Gros, M.D., Steve Perrin, Ph D., Bryan Smith and Paul Little | 10-K | 001-36620 | 10.25 | March 20, 2025 | |
| 10.21* | Form of Amendment to Stock Option Agreement, dated November 20, 2024, between Eledon Pharmaceuticals, Inc. and David-Alexandre C. Gros, M.D., Steve Perrin, Ph D., Bryan Smith and Paul Little | 10-K | 001-36620 | 10.26 | March 20, 2025 | |
| 10.22* | Stock Option Forfeiture Agreement date December 30, 2025, between Eledon Pharmaceuticals, Inc. and David-Alexandre C. Gros, M.D. | | | | | X |

| | | | | | | |
|---|---|---|---|---|---|---|
| 10.23* | Stock Option Forfeiture Agreement date December 30, 2025, between Eledon Pharmaceuticals, Inc. and Steve Perrin, Ph.D | | | | | X |
| 10.24 | Underwriting Agreement, dated November 12, 2025, by and between Eledon Pharmaceuticals, Inc. and Leerink Partners LLC, as representative of the several underwriters named therein | 8-K | 001-36620 | 1.1 | November 13, 2025 | |
| 19.1 | Eledon Pharmaceuticals, Inc. Insider Trading Policy | 10-K | 001-36620 | 19.1 | March 20, 2025 | |
| 21.1 | Subsidiaries of the Registrant | 10-K | 001-36620 | 21.1 | March 17, 2020 | |
| 23.1 | Consent of Deloitte & Touche LLP, independent registered public accounting firm | | | | | X |
| 23.2 | Consent of Crowe LLP, independent registered public accounting firm | | | | | X |
| 31.1 | Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | | | | | X |
| 31.2 | Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | | | | | X |
| 32.1# | Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | | | | | X |
| 32.2# | Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | | | | | X |
| 97.1* | Incentive Compensation Recoupment Policy | 10-K | 001-36620 | 97.1 | March 28, 2024 | |

| | | |
|---|---|---|
| 101.INS | INLINE XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document | X |
| 101.SCH | INLINE XBRL Taxonomy Extension Schema with Embedded Linkbase Documents | X |
| 104 | Cover page formatted as INLINE XBRL and contained in Exhibit 101 | X |
| * | Indicates a management contract or compensatory plan | |
| # | These certifications are not deemed filed by the SEC and are not to be incorporated by reference in any filing we make under the Securities Act of 1933 or the Securities Exchange Act of 1934, irrespective of any general incorporation language in any filings. | |

**Item 16. Form 10-K Summary.**

None.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**Eledon Pharmaceuticals, Inc.**

Date: March 19, 2026 By: /s/ David-Alexandre C. Gros, M.D.

**David-Alexandre C. Gros, M.D.**
**Chief Executive Officer**
**and Director (Principal**
**Executive Officer and Duly Authorized Officer)**

Date: March 19, 2026 By: /s/ Paul Little

**Paul Little**
**Chief Financial Officer**
**(Principal Financial and Accounting Officer)**

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/ David-Alexandre C. Gros, M.D.<br>**David-Alexandre C. Gros, M.D.** | Chief Executive Officer and Director<br>(Principal Executive Officer) | March 19, 2026 |
| /s/ Paul Little<br>**Paul Little** | Chief Financial Officer<br>(Principal Financial and Accounting Officer) | March 19, 2026 |
| /s/ Keith A. Katkin<br>**Keith A. Katkin** | Chairman of the Board of Directors | March 19, 2026 |
| /s/ Jan Hillson, M.D.<br>**Jan Hillson, M.D.** | Director | March 19, 2026 |
| /s/ James Robinson<br>**James Robinson** | Director | March 19, 2026 |
| /s/ Allan Kirk, M.D.<br>**Allan Kirk, M.D.** | Director | March 19, 2026 |
| /s/ John S. McBride<br>**John S. McBride** | Director | March 19, 2026 |
| /s/ June Lee, M.D.<br>**June Lee, M.D.** | Director | March 19, 2026 |
| /s/ Steven Perrin<br>**Steven Perrin** | President, Director | March 19, 2026 |

**ELEDON PHARMACEUTICALS, INC.**
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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Eledon Pharmaceuticals, Inc.

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheet of Eledon Pharmaceuticals, Inc. (the "Company") as of December 31, 2025, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity, and cash flows, for the year ended December 31, 2025, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025, and the results of its operation and its cash flows for the year ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

**Basis for Opinion**

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

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

**Critical Audit Matter**

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

**Classification of Pre-Funded Warrants – Refer to Notes 2 and 9 to the financial statements**

*Critical Audit Matter Description*

On November 13, 2025, the Company closed an underwritten offering, which included the sale of pre-funded warrants (the “2025 Offering Pre-Funded Warrants”), and on December 30, 2025, the Company entered into an agreement to exchange shares of the Company's common stock for pre-funded warrants (the “2025 Warrant Exchange Agreement”). The Company accounts for pre-funded warrants as either a liability or equity in accordance with Accounting Standards Codification (ASC) Topic 480-10, Distinguishing liabilities from equity, and ASC 815-40, Derivatives and Hedging - Contracts in Entity’s Own Equity.

We identified the assessment of the classification of the 2025 Offering Pre-Funded Warrants and the 2025 Warrant Exchange Agreement (collectively, the “2025 Pre-Funded Warrant Agreements”) as a critical audit matter. The assessment of the terms and provisions to determine the classification of the 2025 Pre-Funded Warrant Agreements as a liability or equity is complex

and required a high extent of effort, including the need for us to involve professionals in our firm with expertise in accounting for financial instruments.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the classification of the 2025 Pre-Funded Warrant Agreements, included the following, among others:

- We read the 2025 Pre-Funded Warrant Agreements, and compared the terms and provisions to the Company's accounting analysis.
- With the assistance of professionals in our firm having expertise in accounting for financial instruments, we evaluated the terms and provisions of the 2025 Pre-Funded Warrant Agreements to assess the appropriate classification as a liability or equity.

/s/ Deloitte & Touche LLP

Costa Mesa, CA
March 19, 2026

We have served as the Company's auditor since 2025.

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Shareholders and the Board of Directors of Eledon Pharmaceuticals, Inc.
Irvine, California

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Eledon Pharmaceuticals, Inc. (the "Company") as of December 31, 2024, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity, and cash flows, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

### Basis for Opinion

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

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

### Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

*Classification and Valuation of Pre-Funded Warrants*

As described in Note 2, Summary of Significant Accounting Policies, and Note 9, Stockholder's Equity, to the consolidated financial statements, the Company accounts for issued pre-funded warrants either as a liability or equity in accordance with ASC 815-40, Derivatives and Hedging - Contracts in Entity's Own Equity. Liability-classified warrants are measured at fair value on the issuance date and at the end of each reporting period with any change in the fair value of the warrants recorded in the consolidated statements of operations and comprehensive loss as a gain or loss. The Common Warrants and the Subsequent Closing Warrants (as defined in Note 9) issued in the 2023 Private Placement are liability classified and recorded at fair value using the Black-Scholes option-pricing model at issuance, with any subsequent changes in fair value recognized in the consolidated statements of operations. Determining the proper classification of pre-funded warrants as either a derivative liability or as equity instruments requires significant management judgment in assessing the specific terms and

conditions. The valuation of the derivative liability for liability classified pre-funded warrants also requires management judgment in determining the fair value.

The classification and valuation of warrants was determined to be a critical audit matter because of the complexity and significant judgment involved in determining the accounting for the pre-funded warrants and the significant audit effort, including the use of specialists, in assessing management's conclusions and inputs to its calculation of fair value.

Our audit procedures to evaluate the classification and fair market value of the pre-funded warrants included:

- Obtaining and inspecting the securities purchase agreements to evaluate the contractual terms of the pre-funded warrants.
- Evaluating management's technical accounting analysis on the classification of the pre-funded warrants.
- Consulting with specialists on the classification and valuation of the pre-funded warrants.
- Developing an independent expectation of the valuation of the liability-classified warrants to compare to management's valuation.

/s/ Crowe LLP

We served as the Company's auditor from 2024 to 2024.

Los Angeles, California
March 20, 2025, Except for Note 9, as to which the date is August 14, 2025

**ELEDON PHARMACEUTICALS, INC.**
**CONSOLIDATED BALANCE SHEETS**
**(In thousands, except share and per share data)**

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 22,808 | $ 20,549 |
| Short-term investments | 110,528 | 119,629 |
| Prepaid expenses and other current assets | 2,352 | 3,552 |
| Total current assets | 135,688 | 143,730 |
| Operating lease right-of-use asset, net | 613 | 926 |
| In-process research and development | 32,386 | 32,386 |
| Other assets | 322 | 363 |
| Total assets | $ 169,009 | $ 177,405 |
| **LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 3,627 | $ 5,833 |
| Current operating lease liability | 358 | 314 |
| Accrued expenses and other liabilities | 14,359 | 5,430 |
| Total current liabilities | 18,344 | 11,577 |
| Deferred tax liability | 2,187 | 2,183 |
| Non-current operating lease liability | 283 | 640 |
| Warrant liabilities | 11,416 | 44,865 |
| Total liabilities | 32,230 | 59,265 |
| | | |
| Commitments and contingencies (Note 7) | | |
| | | |
| Convertible preferred stock, 5,000,000 shares authorized at December 31, 2025 and 2024: | | |
| Series X non-voting convertible preferred stock, $0.001 par value, 10,000 shares designated; 4,422 shares issued and outstanding at December 31, 2025 and 2024 | 2,151 | 2,151 |
| Series X[1] non-voting convertible preferred stock, $0.001 par value, 515,000 shares designated; 110,086 shares issued and outstanding at December 31, 2025 and 2024 | 53,543 | 53,543 |
| Stockholders' equity: | | |
| Common stock, $0.001 par value, 300,000,000 and 200,000,000 shares authorized at December 31, 2025 and 2024, respectively; 75,430,033 and 59,789,275 shares issued and outstanding at December 31, 2025 and 2024, respectively | 75 | 60 |
| Additional paid-in capital | 482,189 | 417,946 |
| Accumulated other comprehensive income | 24 | 26 |
| Accumulated deficit | (401,203) | (355,586) |
| Total stockholders' equity | 81,085 | 62,446 |
| Total liabilities, convertible preferred stock and stockholders' equity | $ 169,009 | $ 177,405 |

See accompanying notes to consolidated financial statements.

**ELEDON PHARMACEUTICALS, INC.**
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**
**(In thousands, except share and per share data)**

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| **Operating expenses** | | |
| Research and development | $ 66,267 | $ 51,964 |
| General and administrative | 16,984 | 18,613 |
| Total operating expenses | 83,251 | 70,577 |
| Other income, net | 4,220 | 3,924 |
| Change in fair value of warrant liabilities | 33,449 | 30,900 |
| Loss before income taxes | (45,582) | (35,753) |
| Provision for income taxes | (35) | (431) |
| Net loss | $ (45,617) | $ (36,184) |
| Other comprehensive loss: | | |
| Unrealized loss on available-for-sale securities, net | (2) | — |
| Comprehensive loss | $ (45,619) | $ (36,184) |
| Basic and diluted earnings per share of common stock | $ (0.52) | $ (0.66) |
| Weighted-average common shares outstanding, basic and diluted | 81,836,246 | 48,543,787 |
| Basic and diluted earnings per share of Series X and Series X[1] non-voting convertible preferred stock | $ (28.73) | $ (36.61) |
| Weighted-average shares outstanding of Series X and Series X[1] non-voting convertible preferred stock, basic and diluted | 114,508 | 114,508 |

See accompanying notes to consolidated financial statements.

## ELEDON PHARMACEUTICALS, INC.
## CONSOLIDATED STATEMENTS OF CONVERTIBLE STOCK AND STOCKHOLDERS' EQUITY
## (In thousands, except share data)

| | Convertible Preferred Stock | | | | Stockholders' Equity | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Series X[1] Non-Voting Convertible Preferred Stock | | Series X Non-Voting Convertible Preferred Stock | | Common Stock | | Additional Paid-In Capital | Accumulated Other Comprehensive Income | Accumulated Deficit | Total Stockholders' Equity |
| | Shares | Amount | Shares | Amount | Shares | Amount | | | | |
| **Balance as of December 31, 2023** | 110,086 | $ 53,543 | 4,422 | $ 2,151 | 24,213,130 | $ 24 | $ 270,892 | $ — | $ (319,402) | $ (48,486) |
| Issuance of common stock and pre-funded warrants in connection with 2024 Securities Purchase Agreement, net of issuance costs | — | — | — | — | 13,110,484 | 13 | 48,051 | — | — | 48,064 |
| Issuance of common stock with the completion of the Second Closing and Third Closing in connection with 2023 Securities Purchase Agreement, net of issuance costs | — | — | — | — | 2,636,488 | 3 | 6,152 | — | — | 6,155 |
| Issuance of common stock in connection with exercise of pre-funded warrants | — | — | — | — | 1,423,000 | 1 | — | — | — | 1 |
| Issuance of common stock and pre-funded warrants in connection with 2024 Underwritten Offering, net of issuance costs. | — | — | — | — | 18,356,173 | 18 | 79,515 | — | — | 79,533 |
| Stock option exercise | — | — | — | — | 50,000 | 1 | 214 | — | — | 215 |
| Share-based compensation | — | — | — | — | — | — | 13,122 | — | — | 13,122 |
| Accumulated other comprehensive income | — | — | — | — | — | — | — | 26 | — | 26 |
| Net loss | — | — | — | — | — | — | — | — | (36,184) | (36,184) |
| **Balance as of December 31, 2024** | 110,086 | $ 53,543 | 4,422 | $ 2,151 | 59,789,275 | $ 60 | $ 417,946 | $ 26 | $ (355,586) | $ 62,446 |
| Issuance of common stock and pre-funded warrants in connection with 2025 Underwritten Offering, net of issuance costs | — | — | — | — | 19,698,085 | 19 | 53,558 | — | — | 53,577 |
| Cancellation of common stock in exchange of common stock for pre-funded warrants | — | — | — | — | (4,203,764) | (4) | 4 | — | — | — |
| Issuance of common stock in connection with vesting of restricted stock units | — | — | — | — | 46,000 | — | — | — | — | — |
| Stock option exercise | — | — | — | — | 100,437 | — | 230 | — | — | 230 |
| Share-based compensation | — | — | — | — | — | — | 10,451 | — | — | 10,451 |
| Accumulated other comprehensive loss | — | — | — | — | — | — | — | (2) | — | (2) |
| Net loss | — | — | — | — | — | — | — | — | (45,617) | (45,617) |
| **Balance as of December 31, 2025** | 110,086 | $ 53,543 | 4,422 | $ 2,151 | 75,430,033 | $ 75 | $ 482,189 | $ 24 | $ (401,203) | $ 81,085 |

See accompanying notes to consolidated financial statements.

**ELEDON PHARMACEUTICALS, INC.**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**
**(In thousands)**

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| **Cash flows used in operating activities:** | | |
| Net loss | $ (45,617) | $ (36,184) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Gain on lease termination | — | (10) |
| Non-cash lease expense | 313 | 359 |
| Accretion of investment discounts | (1,696) | (2,799) |
| Stock-based compensation | 10,451 | 13,122 |
| Change in fair value of warrant liabilities | (33,449) | (30,900) |
| Deferred tax provision | 5 | 431 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other assets | 1,241 | 1,298 |
| Accounts payable, accrued expenses and other liabilities | 6,724 | 7,751 |
| Operating lease liabilities | (313) | (339) |
| Net cash used in operating activities | (62,341) | (47,271) |
| **Cash flows from investing activities:** | | |
| Purchase of available-for-sale short-term investments | (161,132) | (156,131) |
| Proceeds from maturities of available-for-sale short-term investments | 171,925 | 85,817 |
| Net cash provided by (used in) investing activities | 10,793 | (70,314) |
| **Cash flows from financing activities:** | | |
| Proceeds from issuances of common stock and pre-funded warrants, net | 53,577 | 133,307 |
| Proceeds from exercise of stock options | 230 | 215 |
| Net cash provided by financing activities | 53,807 | 133,522 |
| Net change in cash and cash equivalents | 2,259 | 15,937 |
| Cash and cash equivalents at beginning of year | 20,549 | 4,612 |
| Cash and cash equivalents at end of year | $ 22,808 | $ 20,549 |
| **Supplemental disclosure of non-cash investing and financing activities** | | |
| Non-cash activities: | | |
| Unrealized gain (loss) on available-for-sale securities | $ (2) | $ 26 |
| Common stock exchange for warrants | $ 4 | $ — |
| Offering costs accrued but not yet paid | $ 4 | $ — |
| Increase in operating right-of-use lease asset and liability due to new lease | $ — | $ 920 |
| Settlement of warrant liability into common stock due to exercise | $ — | $ 446 |

See accompanying notes to consolidated financial statements.

## Note 1. Description of Business

Eledon Pharmaceuticals, Inc. is a clinical stage biotechnology company using its immunology expertise in targeting the CD40 Ligand ("CD40L") pathway to develop therapies to protect transplanted organs and prevent rejection, and to treat amyotrophic lateral sclerosis ("ALS"). The Company's lead compound in development is tegoprubart, an IgG1, anti-CD40L antibody with high affinity for the CD40L, a well-validated biological target that we believe has broad therapeutic potential. Unless otherwise indicated, references to the terms "Eledon," "our," "us," "we," or the "Company" refer to Eledon Pharmaceuticals, Inc. and its wholly owned subsidiaries, on a consolidated basis.

On September 14, 2020, Eledon acquired Anelixis Therapeutics, Inc. ("Anelixis"), a privately held clinical stage biotechnology company developing a next generation anti-CD40L antibody as a potential treatment for organ and cellular transplantation, autoimmune diseases, and neurodegenerative diseases. The Company maintains its corporate headquarters in Irvine, California and has research and development facilities in Burlington, Massachusetts.

## Note 2. Summary of Significant Accounting Policies

### *Basis of Presentation and Principles of Consolidation*

The consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). Eledon, a Delaware corporation, owns 100% of the issued and outstanding common stock or other ownership interest in Anelixis Therapeutics, LLC, a Delaware limited liability company, and Otic Pharma, Ltd., a private limited company organized under the laws of the State of Israel ("Otic"). Otic owns 100% of the issued and outstanding common stock or other ownership interest in its U.S. subsidiary, Otic Pharma, Inc. The functional currency of the Company's foreign subsidiary is the U.S. Dollar; however, certain expenses, assets and liabilities are transacted at the local currency. These transactions are translated from the local currency into U.S. Dollars at exchange rates during or at the end of the reporting period. The activities of the Company's foreign subsidiary are not significant to the consolidated financial statements. All significant intercompany accounts and transactions among the entities have been eliminated in consolidation.

### *Reclassifications*

Certain reclassifications have been made to the prior year balances in *Note 5. Prepaid Expenses and Other Current Assets* and *Note 6. Accrued Expenses and Other Liabilities* to conform to the current year presentation. These reclassifications had no impact on prior period results.

### *Use of Estimates*

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make informed estimates and assumptions that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes. The most significant estimates in the Company's consolidated financial statements relate to stock-based compensation expense, warrant liabilities, the fair value of right-of-use ("ROU") assets and liabilities, accruals for liabilities, impairment of long-lived assets, and other matters that affect the consolidated financial statements and related disclosures. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could differ materially from those estimates under different assumptions or conditions and the differences may be material to the consolidated financial statements.

### *Concentration of Credit Risk*

Financial instruments which potentially subject the Company to significant concentration of credit risk consists of cash, cash equivalents and short-term investments. The Company maintains deposits in federally insured institutions in excess of federally insured limits and invests in short-term investments with the primary objective of seeking to preserve principal, achieve liquidity requirements and safeguard invested funds. We believe that the Company is not exposed to significant credit risk due to the financial position of the depository institution in which those deposits are held and the nature, including the credit ratings, of our cash equivalents and short-term investments, but we have not eliminated all credit risk.

***Cash and Cash Equivalents***

The Company considers all highly liquid investments with original maturities of three months or less when purchased to be cash equivalents. Cash and cash equivalents include cash in readily available checking accounts, money market funds, U.S. government securities and U.S. government agency securities. Cash and cash equivalents are valued at cost, which approximates their fair value due to the short-term maturities of these investments.

***Risks and Liquidity***

Since inception, the Company devoted substantially all of its resources to its research and development efforts, pre-clinical studies and clinical trials, establishing and maintaining its intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations. The Company has experienced recurring net losses and negative cash flows from operating activities since its inception. The Company's net loss for the year ended December 31, 2025 is $45.6 million. As of December 31, 2025, the Company had cash and cash equivalents and short-term investments of $133.3 million, working capital of $117.3 million and an accumulated deficit of $401.2 million. Due to continuing research and development activities, the Company expects to continue to incur net losses into the foreseeable future. In order to continue these activities, the Company will need to raise additional funds through public or private debt and equity financings including the possible issuance of shares of common stock pursuant to the Company's "at-the-market" equity offering program, and may need to pursue strategic collaboration and licensing arrangements. The Company's ability to raise additional capital in the equity and debt markets is dependent on a number of factors, including, but not limited to, the market demand for the Company's common stock, which itself is subject to a number of development and business risks and uncertainties, as well as the uncertainty that the Company would be able to raise such additional capital at a price or on terms that are favorable to the Company. If the Company issues equity or convertible debt securities to raise additional funding, its existing stockholders may experience dilution, it may incur significant financing costs, and the new equity or convertible debt securities may have rights, preferences and privileges senior to those of its existing stockholders. If the Company issues debt securities to raise additional funding, it would incur additional debt service obligations, it could become subject to additional restrictions limiting its ability to operate its business, and it may be required to further encumber its assets.

The Company expects that, based on its current operating plans, the Company's existing cash, cash equivalents and marketable securities will be sufficient to fund its currently planned operations for at least the next 12 months from the filing date of these consolidated financial statements. The Company anticipates it will require additional financing to fund its future operations. Even if the Company believes it has sufficient funds for its current or future operating plans, the Company may seek to raise additional capital if market conditions are favorable or in light of other strategic considerations.

***Reportable Segments***

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources and in assessing performance. The Company operates as one operating and one reportable segment, focused on the development of tegoprubart, to develop therapies to protect transplanted organs and prevent rejection, and to treat ALS. The Company's measure of segment profit or loss is net loss. The CODM is the chief executive officer. The CODM manages and allocates resources to the operations of the Company on a total company basis. Managing and allocating resources on a consolidated basis enables the CODM to assess the overall level of resources available and how to best deploy these resources across functions, therapeutic areas and research and development projects that are in line with the Company's long-term company wide strategic goals. Consistent with this decision-making process, the CODM uses consolidated net income for purposes of evaluating performance, forecasting future period financial results, allocating resources and setting incentive targets. Operating expenses are used to monitor budget versus actual results. The measure of segment assets is reported on the balance sheet as total consolidated assets.

The following table is representative of the significant expense categories regularly provided to the CODM when managing the Company's single reporting segment. A reconciliation to the consolidated net loss for the years ended December 31, 2025 and 2024 is included at the bottom of the table below (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Operating expenses: | | |
| Tegoprubart - kidney transplantation programs | $ 35,994 | $ 27,452 |
| Tegoprubart - other development programs | $ (168) | 306 |
| Manufacturing | $ 14,974 | 12,448 |
| Personnel-related expenses | $ 14,526 | 10,706 |
| Stock-based compensation | $ 10,451 | 13,122 |
| Other segment items* | $ 7,474 | 6,543 |
| Other income, net | $ 4,220 | 3,924 |
| Change in fair value of warrant liabilities | $ 33,449 | 30,900 |
| Provision for income taxes | $ (35) | (431) |
| Net loss | $ (45,617) | $ (36,184) |

** Other segment items included in total operating expenses primarily consist of consulting, professional fees, facilities, insurance and information technology.*

***In-Process Research and Development***

Amounts allocated to in-process research and development ("IPR&D") in connection with a business combination are recorded at fair value and are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. If and when development is complete, which generally occurs when regulatory approval to market a product is obtained, the associated assets are deemed finite-lived and amortized over a period that best reflects the economic benefits provided by these assets. During the period the assets are considered indefinite-lived, they will not be amortized but will be tested annually for impairment or more frequently if indicators of impairment exist.

The Company first assesses qualitative factors to determine whether it is more likely than not that the fair value of the IPR&D is less than its carrying amount as a basis for determining whether it is necessary to perform a quantitative assessment. If, after assessing qualitative factors, the Company determines it is not more likely than not that the fair value is less than its carrying amount, then a quantitative assessment is unnecessary. If the quantitative assessment is deemed necessary, the excess of the carrying value over fair value will be recorded as an impairment. The qualitative assessment focuses on the key inputs, assumptions and rationale utilized in the establishment of the carrying value and related changes since the last quantitative assessment. Based on the results of the Company's annual qualitative assessment, the Company concluded that it is not more likely than not that IPR&D was impaired for any of the periods presented.

***Research and Development Expenses***

Research and development expenses include personnel and facility-related expenses, outside contracted services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services and non-cash stock-based compensation. Research and development costs are expensed as incurred. Amounts due under contracts with third parties may be either fixed fee or fee for service, and may include upfront payments, monthly payments and payments upon the completion of milestones or receipt of deliverables. Non-refundable advance payments under agreements are capitalized and expensed as the related goods are delivered or services are performed.

The Company contracts with third parties to perform various clinical trial activities in the on-going development of potential products. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows to its vendors. Payments under the contracts depend on factors such as the achievement of certain events, successful enrollment of patients, and completion of portions of the clinical trial or similar conditions. The Company's accrual for clinical trials is based on estimates of the services received and efforts expended pursuant to contracts with clinical trial centers and clinical research organizations. These contracts may be terminated by the Company upon written notice and the Company is generally only liable for actual effort expended by the organizations to the date of termination, although in certain instances the Company may be further responsible for termination fees and penalties. The

Company estimates its research and development expenses and the related accrual as of each balance sheet date based on the facts and circumstances known to the Company at that time.

***Net Loss Per Share***

Basic and diluted net loss per share are calculated using the two-class method in accordance with Accounting Standards Codification ("ASC") Topic 260, Earnings Per Share. The two-class method allocates undistributed losses to the Company's outstanding common stock, and the Series X and Series $X^1$ non-voting convertible preferred stock, $0.001 par value (the "Preferred Stock"), based on each class's proportionate share of the total weighted-average shares outstanding. Since the Company has never declared dividends, net loss and undistributed losses are equivalent. The process is used for both common stock and Preferred Stock.

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period determined using the treasury-stock and if-converted methods. As the rights and preferences of the Preferred Stock are substantially identical to each other, they are considered a single class of common stock for earnings per share purposes.

For purposes of the diluted net loss per share calculation, incentive stock options, restricted stock units and warrants are considered to be potentially dilutive securities and are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. Therefore, basic and diluted net loss per share was the same for the periods presented due to the Company's net loss position. Basic weighted average shares outstanding for the years ended December 31, 2025 and 2024 include 36,629,572 and 12,443,755 respectively, shares underlying pre-funded warrants to purchase common shares. As the shares underlying these pre-funded warrants can be issued for little consideration (an exercise price per share equal to $0.001 per share), these shares are deemed to be issued for purposes of basic earnings per share.

***Employee Benefit Plan***

The Company maintains a defined contribution retirement savings plan under Section 401(k) of the Internal Revenue Code covering all employees who meet eligibility requirements. Participants may contribute a portion of their compensation subject to IRS limitations. The Company provides matching contributions in accordance with the terms of the plan.

The Company recognized expense related to employer contributions to the plan of $0.5 million and $0.3 million for the years ended December 31, 2025 and 2024, respectively.

***Stock-Based Compensation***

The Company recognizes compensation expense for all stock-based awards based on the grant-date estimated fair value.

The fair value of stock options is determined using the Black-Scholes option pricing model, using assumptions which are subjective and require significant judgment and estimation by management. The risk-free rate assumption was based on observed yields from governmental zero-coupon bonds with an equivalent term. The expected volatility assumption was based on historical volatilities of a group of comparable industry companies whose share prices are publicly available. The peer group was developed based on publicly traded biotechnology and pharmaceutical companies with comparable business characteristics, clinical stages of development, and organizational scale, including employee headcount, primarily consisting of companies with Phase II or Phase III clinical programs. The expected term of stock options represents the weighted-average period that the stock options are expected to be outstanding. Because the Company does not have historical exercise behavior, the Company determined the expected life assumption using the simplified method for stock options granted to employees, which is an average of the options ordinary vesting period and the contractual term. The expected dividend assumption was based on the Company's history and expectation of dividend payouts. The Company has not paid and does not expect to pay dividends at any time in the foreseeable future. The Company recognizes forfeitures on an actual basis and as such did not estimate forfeitures to calculate stock-based compensation.

Restricted Stock Units ("RSUs") are measured and recognized based on the quoted market price of our common stock on the date of grant.

***Income Taxes***

Significant judgment is required in determining the Company's provision for income taxes, deferred tax assets and liabilities and the valuation allowance recorded against net deferred tax assets. We assess the likelihood that deferred tax assets will be recovered as deductions from future taxable income. The evaluation of the need for a valuation allowance is performed on a jurisdiction-by-jurisdiction basis and includes a review of all available positive and negative evidence. Factors reviewed include projections of pre-tax book income for the foreseeable future, determination of cumulative pre-tax book income after permanent differences, earnings history, and reliability of forecasting. We have provided a valuation allowance on our deferred tax assets as of December 31, 2025 and 2024 because we believe it is more likely than not that a majority of our deferred tax assets will not be realized as of this date.

The Company evaluates the accounting for uncertainty in income tax recognized in its consolidated financial statements and determines whether it is more likely than not that a tax position will be sustained upon examination by the appropriate taxing authorities before any part of the benefit is recorded in its consolidated financial statements. For those tax positions where it is "not more likely than not" that a tax benefit will be sustained, no tax benefit is recognized. Where applicable, associated interest and penalties are also recorded. The Company has not accrued any liabilities for any such uncertain tax positions as of December 31, 2025 and 2024. The Company is subject to U.S. federal and state tax authority examinations for all the years since inception due to net operating loss and tax credit carryforwards. The net operating losses and tax credits are subject to adjustment until the statute closes on the year the attributes are ultimately utilized.

The Company's income tax returns are based on calculations and assumptions that are subject to examination by the Internal Revenue Service and other tax authorities. In addition, the calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax regulations. The Company recognizes liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While the Company believes it has appropriate support for the positions taken on its tax returns, the Company regularly assesses the potential outcomes of examinations by tax authorities in determining the adequacy of its provision for income taxes. The Company continually assesses the likelihood and amount of potential revisions and adjusts the income tax provision, income taxes payable and deferred taxes in the period in which the facts that give rise to a revision become known. For additional information, see *Note 8. Income Taxes* of the Notes to Financial Statements.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted into law. The OBBBA makes permanent key elements of the Tax Cuts and Jobs Act 2017, including 100% bonus depreciation and immediate expensing of domestic research and development costs, among other tax changes. The Company had no impact on its consolidated financial statements as a result of the enactment of OBBBA.

***Common Stock Warrants and Pre-Funded Warrants***

The Company accounts for issued common stock warrants and pre-funded warrants either as a liability or equity in accordance with ASC 480-10, Distinguishing Liabilities from Equity ("ASC 480-10") and ASC 815-40, Derivatives and Hedging — Contracts in Entity's Own Equity ("ASC 815-40"). The Company first evaluates the warrants under ASC 480-10 to determine whether the instruments should be classified as liabilities, including whether the warrants embody an obligation to repurchase the Company's shares, require or may require cash settlement, or represent obligations to issue a variable number of shares with a monetary value that is fixed or indexed to something other than the Company's stock. If liability classification is not required under ASC 480-10, the Company then applies ASC 815-40. Under ASC 815-40, contracts that may require settlement for cash are liabilities, regardless of the probability of the occurrence of the triggering event. Liability-classified warrants are measured at fair value on the issuance date and at the end of each reporting period. Any change in the fair value of the warrants after the issuance date is recorded in the consolidated statements of operations and comprehensive loss as a gain or loss. If warrants do not require liability classification under ASC 815-40, in order to conclude warrants should be classified as equity, the Company assesses whether the warrants are indexed to its common stock and whether the warrants are classified as equity under ASC 815-40 or other applicable GAAP standard. Equity-classified warrants are accounted for at fair value on the issuance date with no changes in fair value recognized after the issuance date.

***Recent Adopted Accounting Pronouncements***

In December 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. This update requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. ASU 2023-09 is effective for public entities with annual periods beginning after December 15, 2024, with early adoption permitted. The Company adopted ASU 2023-09, effective December 31, 2025, in these consolidated financial statements. ASU 2023-09 only impacted the disclosures and did not impact the consolidated financial statements. See *Note 8*, *Income Taxes*, for disclosures related to the adoption of ASU 2023-09.

***Recent Accounting Pronouncements Issued But Not Adopted***

In November 2024, the FASB issued ASU No. 2024-03, "Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40) Disaggregation of Income Statement Expenses," which requires disaggregated disclosure of income statement expenses for public business entities ("PBEs"). In January 2025, the FASB issued ASU No. 2025-01 "Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40)," which clarified the effective date for ASU 2024-03. These amendments are intended to provide more information about types of expenses in commonly presented expense captions. The amendments in this update are effective for annual periods beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, and early adoption is permitted. The Company is currently evaluating the impact on its consolidated financial statements and related disclosures.

Other recent accounting pronouncements issued by the FASB (including its Emerging Issues Task Force), the American Institute of Certified Public Accountants, and the Securities and Exchange Commission ("SEC") did not, or are not believed by management to, have a material impact on the Company's present or future financial position, results of operations or cash flows.

**Note 3. Short-Term Investments**

The objectives of the Company's investment policy are to preserve principal, meet the Company's liquidity requirements and safeguard invested funds. Short-term investments consist of U.S. treasuries and U.S. government securities. The Company has classified these investments as available-for-sale securities, as the sale of such investments may be required prior to maturity to implement management strategies, and therefore has classified all investments with maturity dates beyond three months at the date of purchase as current assets in the accompanying consolidated balance sheets. Any premium or discount arising at purchase is amortized and/or accreted to interest income as an adjustment to yield using the straight-line method over the life of the instrument. The amortized cost of available-for-sale securities is adjusted for amortization of premiums and accretion of discounts to maturity. Investments are reported at their estimated fair value. Unrealized gains and losses are included in accumulated other comprehensive loss as a component of stockholders' equity until realized.

The following is a summary of short-term investments, which were classified as available-for-sale securities as of December 31, 2025 and 2024 (in thousands):

| | December 31, 2025 | | | |
|---|---|---|---|---|
| | Amortized Cost | Unrealized Gains | Unrealized Losses | Fair Value |
| U.S. treasuries | $ 59,839 | $ 27 | $ (5) | $ 59,861 |
| U.S. government securities | 50,667 | 9 | (9) | 50,667 |
| Total short-term investments | $ 110,506 | $ 36 | $ (14) | $ 110,528 |

| | December 31, 2024 | | | |
|---|---|---|---|---|
| | Amortized Cost | Unrealized Gains | Unrealized Losses | Fair Value |
| U.S. government securities | $ 119,603 | $ 55 | $ (29) | $ 119,629 |
| Total short-term investments | $ 119,603 | $ 55 | $ (29) | $ 119,629 |

All of the Company's available-for-sale securities have a stated maturity of less than one year.

**Note 4. Fair Value Measurements**

Financial assets and liabilities are recorded at fair value.

The Company classifies fair value measurements using a three-level hierarchy that prioritizes the inputs used to measure fair value. This hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- Level 1—Quoted market prices (unadjusted) in active markets for identical assets and liabilities.
- Level 2—Observable inputs other than quoted market prices included in Level 1, such as quoted market prices for markets that are not active or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities, including certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs. These fair values are obtained from independent pricing services which utilize Level 1 and Level 2 inputs.

***Financial Assets***

The following table summarizes the Company's financial asset instruments measured at fair value on a recurring basis as of December 31, 2025 and 2024 (in thousands). Included within cash and cash equivalents on the consolidated balance sheets, but excluded from the fair value hierarchy table, are cash deposits held at financial institutions.

| | December 31, 2025 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| **Assets:** | | | | |
| Cash equivalents: | | | | |
| Money market funds | $ 6,734 | $ — | $ — | $ 6,734 |
| U.S. treasuries | — | 14,955 | — | 14,955 |
| Total cash equivalents | 6,734 | 14,955 | — | 21,689 |
| **Short-term investments:** | | | | |
| U.S. treasuries | — | 59,861 | — | 59,861 |
| U.S. government securities | — | 50,667 | — | 50,667 |
| Total short-term investments | — | 110,528 | — | 110,528 |
| **Total financial assets** | $ 6,734 | $ 125,483 | $ — | $ 132,217 |

| | December 31, 2024 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| **Assets:** | | | | |
| Cash equivalents: | | | | |
| Money market funds | $ 1,215 | $ — | $ — | $ 1,215 |
| U.S. treasuries | — | 17,464 | — | 17,464 |
| Total cash equivalents | 1,215 | 17,464 | — | 18,679 |
| **Short-term investments:** | | | | |
| U.S. government securities | — | 119,629 | — | 119,629 |
| Total short-term investments | — | 119,629 | — | 119,629 |
| **Total financial assets** | $ 1,215 | $ 137,093 | $ — | $ 138,308 |

***Warrant Liabilities***

The following table summarizes the Company's warrant liabilities (see *Note 9. Preferred Stock and Stockholders' Equity*) measured at fair value on a recurring basis as of December 31, 2025 and 2024 (in thousands) and was based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy.

| | December 31, 2025 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Warrant liabilities | $ — | $ — | $ 11,416 | $ 11,416 |

| | December 31, 2024 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Warrant liabilities | $ — | $ — | $ 44,865 | $ 44,865 |

The following table provides a roll-forward of the aggregate fair value of the warrant liabilities categorized with Level 3 inputs (in thousands):

| | Warrant Liability |
|---|---|
| Balance as of December 31, 2024 | $ 44,865 |
| Change in fair value of warrant liabilities | (33,449) |
| Settlement of warrant liability | — |
| Balance as of December 31, 2025 | $ 11,416 |

**Note 5. Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consisted of the following as of December 31, 2025 and 2024 (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Prepaid clinical | $ 578 | $ 1,768 |
| Interest income receivable | 514 | 625 |
| Prepaid insurance | 688 | 693 |
| Prepaid other | 221 | 215 |
| Prepaid manufacturing | 340 | 147 |
| Other current assets | 11 | 104 |
| Total prepaid expenses and other current assets | $ 2,352 | $ 3,552 |

**Note 6. Accrued Expenses and Other Liabilities**

Accrued expenses and other liabilities consisted of the following as of December 31, 2025 and 2024 (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Accrued clinical | $ 6,531 | $ 3,021 |
| Accrued compensation and related expenses | 4,176 | 1,601 |
| Accrued manufacturing | 2,525 | 621 |
| Accrued professional services | 495 | 140 |
| Accrued other | 632 | 47 |
| Total accrued expenses and other liabilities | $ 14,359 | $ 5,430 |

## Note 7. Commitments and Contingencies

### *Contract Obligations*

As of December 31, 2025, the Company has non-cancelable purchase obligations related to manufacturing totaling $9.3 million. The Company expects to fulfill its commitments within the next twelve months under these agreements in the normal course of business, therefore, no related liability has been recorded on the consolidated balance sheets as of that date.

### *Operating Leases*

The Company leases office space under various operating leases. Total rent expense for all operating leases in the consolidated statements of operations and comprehensive loss was $0.4 million for each of the years ended December 31, 2025 and 2024.

On April 19, 2024, the Company entered into a 38-month operating lease for 5,817 square feet of office space in Irvine, California, that expires on June 30, 2027 (the "Irvine Lease Agreement"). On April 19, 2024, in conjunction with the Irvine Lease Agreement, the Company terminated an existing operating lease for 5,197 square feet of office space in Irvine, California, that was set to expire on December 31, 2024. On April 19, 2024, the effective date of the Irvine Lease Agreement, the Company recognized additional net ROU assets and lease liabilities in the amount of $0.5 million.

On September 4, 2024, the Company entered into a 36-month operating lease for 6,138 square feet of office space in Burlington, Massachusetts, that expires on November 21, 2027 (the "Burlington Lease Agreement"). The prior lease expired on November 20, 2024. On November 21, 2024, the effective date of the Burlington Lease Agreement, the Company recognized additional net ROU assets and lease liabilities in the amount of $0.5 million.

The Company determines if a contract contains a lease at inception. Our office leases have a remaining term of approximately 2 years and do not include options to extend the leases for additional periods.

Operating lease assets and liabilities are recognized at the lease commencement date. Operating lease liabilities represent the present value of lease payments not yet paid. Operating lease assets represent our right to use an underlying asset and are based upon the operating lease liabilities as adjusted for prepayments or accrued lease payments, initial direct costs, lease incentives, and impairment of operating lease assets. To determine the present value of lease payments not yet paid, we estimate incremental secured borrowing rates corresponding to the maturities of the leases. As we have no outstanding debt nor committed credit facilities, secured or otherwise, we estimate this rate based on prevailing financial market conditions, comparable company and credit analysis, and management's judgment.

Our leases contain rent escalations over the lease term. We recognize expense for these leases on a straight-line basis over the lease term. Additionally, tenant incentives used to fund leasehold improvements are recognized when earned and reduce our ROU asset related to the lease. These are amortized through the ROU asset as reductions of expense over the lease term. Our lease agreements do not contain any material residual value guarantees or material restrictive covenants.

While we do not currently have any lease agreement with lease and non-lease components, we elected to account for lease and non-lease components as separate components.

We have elected the short-term lease recognition exemption for all applicable classes of underlying assets. Short-term disclosures include only those leases with a term greater than one month and 12 months or less, and expense is recognized on a straight-line basis over the lease term. Leases with an initial term of 12 months or less, that do not include an option to purchase the underlying asset that we are reasonably certain to exercise, are not recorded on the consolidated balance sheet.

The components of lease expense were as follows (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Operating lease cost[(a)] | $ 394 | $ 407 |

[(a)] Includes variable operating lease expenses, which are immaterial.

Other supplemental cash flow information related to leases were as follows (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Cash paid for amounts included in the measurement of lease liability: | | |
| Operating cash flows from operating leases | $ 391 | $ 378 |

Other supplemental balance sheet information related to our operating leases (in thousands, except lease term and discount rate):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Operating leases | | |
| Operating lease right-of-use assets | $ 613 | $ 926 |
| | | |
| Operating lease liabilities (current) | (358) | (314) |
| Operating lease liabilities (non-current) | (283) | (640) |
| Total lease obligations under operating leases | $ (641) | $ (954) |
| | | |
| Weighted-average remaining lease term (in years) | 1.7 | 2.7 |
| Weighted-average discount rate | 9.44% | 9.46% |

As of December 31, 2025, future minimum payments under non-cancelable operating leases, were as follows (in thousands):

| | Year Ended December 31, |
|---|---|
| | 2025 |
| 2026 | $ 403 |
| 2027 | 294 |
| Total minimum lease payments | 697 |
| Less imputed interest | (56) |
| Present value of lease liabilities | 641 |
| Less current portion of operating lease liabilities | (358) |
| Non-current operating lease liabilities | $ 283 |

***Grants and Licenses***

*ALS Therapy Development Foundation, Inc. License Agreement*

In May 2015, Anelixis executed a License Agreement (the "Agreement"), which is an exclusive patent rights agreement with ALS Therapy Development Foundation, Inc. ("ALS TDI") for certain patents and "know-how" of ALS TDI. This Agreement continues until the licensee terminates the agreement with ninety days written notice. The Agreement requires license fees payable to ALS TDI, subject to the achievement of certain milestones and other conditions.

The first and second milestones of the Agreement are the dosing of the first subjects in a first toxicity study in non-human primates and the dosing of the first patient in a Phase I Clinical Trial, respectively. Both of these milestones were achieved prior to 2024. The fee due upon achievement of each milestone was $1.0 million, and as the payments became due, the Company settled the obligations through the issuance of common stock in lieu of cash payments.

The Agreement was amended and restated in February 2020, and a first amendment to the restated license agreement was executed in September 2020. As amended in September 2020, the remaining milestone payments for a first licensed

product total $6.0 million. In the event that the Company develops a second licensed product, the Company is obligated to pay up to $2.5 million in additional milestone payments.

In addition to the milestone payments, the Company is required to pay ALS TDI an amended annual license maintenance fee of $0.1 million beginning on the earlier of January 1, 2022, the Company's first sublicense, or change in control, as defined in the Agreement. The Company has made a $0.1 million annual license maintenance fee each year since 2022.

Furthermore, the Company is required to pay ALS TDI fees based on reaching certain levels of annual net sales of any product produced with the patent rights. A royalty in the low single digits will be due on aggregate net sales. Upon the first calendar year of reaching $500.0 million in aggregate net sales, the Company will be required to pay ALS TDI a one-time milestone payment of $15.0 million. Upon the first calendar year of reaching $1.0 billion in aggregate net sales, the Company is obligated to pay ALS TDI a one-time milestone payment of $30.0 million.

There were no milestones achieved during the years ended December 31, 2025 or 2024.

*Lonza Sales AG Inc. License Agreement*

In September 2018, Anelixis executed a License Agreement (the "Lonza Agreement"), which is a manufacturing know-how rights agreement with Lonza Sales AG Inc. ("Lonza") for the use of certain processes and know-how related to the manufacture of tegoprubart. The Lonza Agreement continues until the later of the last Valid Claim (as defined therein) or ten years from the First Commercial Sale of tegoprubart, as defined and subject to the conditions therein. A royalty in the low single digits will be due on aggregate net sales of tegoprubart that is manufactured by Lonza or any other third-party or licensee. For the years ended December 31, 2025 and 2024, the Company has not paid any royalties under the Lonza Agreement.

***Legal Matters***

The Company and its subsidiaries are not a party to or the subject of any claim or lawsuit that individually or in the aggregate is anticipated to have a material effect on the Company's results of operations, financial condition or cash flows.

***Indemnifications***

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves future claims that may be made against the Company but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future because of these indemnification obligations. No amounts associated with such indemnifications have been recorded to date.

***Contingencies***

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. There have been no contingent liabilities requiring accrual at December 31, 2025 and 2024.

**Note 8. Income Taxes**

Loss before income taxes are as follows (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| **Losses before income taxes:** | | |
| U.S. | $ (45,781) | $ (35,951) |
| Non-U.S. | 199 | 198 |
| Total | $ (45,582) | $ (35,753) |

The provision for income taxes are as follows (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Current: | | |
| Federal | $ — | $ — |
| State | 30 | — |
| Foreign | — | — |
| Total current income tax provision | 30 | — |
| Deferred: | | |
| Federal | — | — |
| State | 5 | 431 |
| Foreign | — | — |
| Total deferred income tax provision | 5 | 431 |
| Total provision for income taxes | $ 35 | $ 431 |

Significant judgment is required in determining the Company's provision for income taxes, deferred tax assets and liabilities and the valuation allowance recorded against net deferred tax assets. Deferred tax assets and liabilities are determined using the enacted tax rates in effect for the years in which those tax assets are expected to be realized. A valuation allowance is established when it is more likely than not the future realization of all or some of the deferred tax assets will not be achieved. The evaluation of the need for a valuation allowance is performed on a jurisdiction-by-jurisdiction basis, and includes a review of all available positive and negative evidence. Factors reviewed include projections of pre-tax book income for the foreseeable future, determination of cumulative pre-tax book income after permanent differences, earnings history, and reliability of forecasting.

Based on its review, the Company concluded that it was more likely than not that they would not realize the benefit of a portion of its deferred tax assets in the future. This conclusion was based on historical and projected operating performance, as well as the Company's expectation that its operations will not generate sufficient taxable income in future periods to realize the tax benefits associated with the deferred tax assets within the statutory carryover periods. Therefore, the Company has a valuation allowance on its deferred tax assets as of December 31, 2025.

The Company will continue to assess the need for a valuation allowance on its deferred tax assets by evaluating both positive and negative evidence that may exist. Any adjustment to the net deferred tax asset valuation allowance would be recorded in the statement of operations for the period that the adjustment is determined to be required.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows (in thousands):

| | Year Ended December 31, 2025 | |
|---|---|---|
| | $ | % |
| Expected benefit at statutory federal income tax rate | $ (9,572) | 21.00% |
| State income taxes, net of federal tax benefits* | 35 | -0.08% |
| Tax credits: | | |
| Research and development credits | (3,512) | 7.70% |
| Nontaxable and nondeductible items: | | |
| Stock-based compensation | 3,574 | -7.84% |
| Other permanent items | 19 | -0.04% |
| Change in fair value of warrant liabilities | (7,024) | 15.41% |
| Changes in unrecognized tax benefits | 1,756 | -3.85% |
| Other | 12 | -0.03% |
| Change in valuation allowance | 14,747 | -32.35% |
| Total provision for income taxes | $ 35 | -0.08% |

*State taxes in Massachusetts made up the majority (greater than 50%) of the tax effect in this category. The Company paid a majority of cash taxes in Massachusetts.

As previously disclosed for the years ended December 31, 2024, prior to the adoption of ASU 2023-09, the table below is a reconciliation of the components that caused the Company's provision (benefit) for income taxes to differ from amounts computed by applying the U.S. Federal statutory rate of 21% (in thousands):

| | Year Ended December 31, 2024 |
|---|---|
| Statutory federal income tax rate | $ (7,508) |
| State income taxes, net of federal tax benefits | (908) |
| Tax credits | (2,358) |
| Stock-based compensation | 2,819 |
| Permanent items | 12 |
| Change in fair value of warrant liabilities | (7,273) |
| State rate differential | 490 |
| Net operating loss true-up | (4) |
| Other | 24 |
| Change in valuation allowance | 15,137 |
| Total provision for income taxes | $ 431 |

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2025 and 2024 consisted of the following (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Net operating loss carryforwards | $ 29,509 | $ 22,740 |
| Research and development tax credits | 7,616 | 5,560 |
| Accruals and reserves | 699 | 366 |
| Research expenditures | 28,232 | 18,809 |
| Stock-based compensation | 1,591 | 3,281 |
| Depreciation and amortization | 795 | 1,056 |
| Lease liability | 151 | 225 |
| Total deferred tax assets | 68,593 | 52,037 |
| Right-of-use asset | (144) | (218) |
| Acquired IPR&D | (7,628) | (7,623) |
| Total deferred tax liabilities | (7,772) | (7,841) |
| Less: valuation allowance | (63,008) | (46,379) |
| Net deferred tax liabilities | $ (2,187) | $ (2,183) |

The following table reconciles the beginning and ending amounts of unrecognized tax benefits for the years presented (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Gross unrecognized tax benefits at the beginning of the year | $ 6,232 | $ 3,636 |
| Additions from tax positions taken in the current year | 2,017 | 2,596 |
| Additions from tax positions taken in prior years | 12 | — |
| Prior year adjustment | (238) | — |
| Gross unrecognized tax benefits at the end of the year | $ 8,023 | $ 6,232 |

The following table summarizes the income taxes paid, net of refunds, for the year ended December 31, 2025 (in thousands).

| | Year Ended December 31, 2025 |
|---|---|
| U.S. Federal | $ — |
| Massachusetts | 26 |
| Other | 2 |
| Total income taxes paid | $ 28 |

The deferred income tax assets have been offset by a valuation allowance, as realization is dependent on future earnings, if any, the timing and amount of which are uncertain. The net valuation allowance increased by $16.6 million from December 31, 2024 to December 31, 2025. The net valuation allowance increased by $15.6 million from December 31, 2023 to December 31, 2024.

The Company's accounting for deferred taxes involves the evaluation of a number of factors concerning the realizability of its net deferred tax assets. The Company primarily considered such factors as its history of operating losses, the nature of the Company's deferred tax assets, and the timing, likelihood, and amount, if any, of future taxable income during the periods in which those temporary differences and carryforwards become deductible. At present, the Company does not believe that it is more likely than not that the deferred tax assets will be realized; accordingly, a valuation allowance has been established.

As of December 31, 2025 and 2024, the Company had federal net operating loss carryforwards of approximately $117.5 million and $88.7 million, respectively, available to reduce future taxable income. As of December 31, 2025 and 2024, the Company also had state net operating loss carryforwards of $49.1 million and $37.7 million, respectively. Both the federal and state net operating loss carryforwards incurred before 2018 begin expiring in 2035, if not utilized. The federal net operating losses incurred since 2018 of $116.7 million do not expire. The state net operating losses begin to expire in 2035. As of December 31, 2025 and 2024, the Company had Israel net operating losses of $7.9 million, respectively, which carryforward indefinitely.

As of December 31, 2025 and 2024, the Company had federal research and development tax credit carryforwards of approximately $11.5 million and $8.0 million, respectively. If not utilized, the carryforwards will begin expiring in 2035. As of December 31, 2025 and 2024, the Company had state research and development credit carryforwards of approximately $3.4 million and $2.6 million, respectively, which will begin expiring in 2030 if not utilized.

Pursuant to the Internal Revenue Code of 1986, as amended ("IRC") Sections 382 and 383, annual use of the Company's net operating loss and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has not completed an IRC Section 382/383 analysis regarding the limitation of net operating loss and research and development credit carryforwards. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact the Company's effective tax rate.

The Company's ability to use its remaining net operating loss and tax credit carryforwards may be further limited if the Company experiences an IRC Section 382 ownership change in connection with future changes in our stock ownership.

In the United States, the Company files income tax returns in the U.S. Federal jurisdiction, California and Massachusetts. The Company's tax years for 2019 and forward are subject to examination by the Federal and California tax authorities due to the carryforward of unutilized net operating losses and research and development credits.

The Company's policy is to recognize interest expense and penalties related to income tax matters as a component of income tax expense. There was no accrued interest and penalties associated with uncertain tax positions as of December 31, 2025 and 2024. The Company has not recorded any interest or penalties as of December 31, 2025 or 2024.

On July 4, 2025, the OBBBA was signed into law. The legislation includes several changes to federal tax law that generally allow for more favorable deductibility of certain business expenses beginning in 2025, including the restoration of immediate expensing of domestic research and development expenditures, reinstatement of 100% bonus depreciation, and

more favorable rules for determining the limitation on business interest expense. OBBBA changes effective for 2025 were determined to have no impact to the income tax provision for year ended December 31, 2025.

**Note 9. Preferred Stock and Stockholders' Equity**

***Convertible Preferred Stock***

The Company has 5,000,000 authorized shares of preferred stock with a par value of $0.001 per share:

- Series $X^1$ non-voting convertible preferred stock, 515,000 shares designated; 110,086 shares issued and outstanding at December 31, 2025 and 2024, and
- Series X non-voting convertible preferred stock, 10,000 shares designated; 4,422 shares issued and outstanding at December 31, 2025 and 2024.

Each share of Preferred Stock is convertible into 55.5556 shares of common stock, at the option of the holder at any time, subject to certain limitations, including, that the holder will be prohibited from converting the Preferred Stock into common stock if, as a result of such conversion, the holder, together with its affiliates, would beneficially own a number of shares of common stock above a conversion blocker, which is initially set at 9.99% or 9.9% of the total common stock then issued and outstanding immediately following the conversion of such shares of Series X Preferred Stock or Series $X^1$ Preferred Stock, respectively. The holder of the Preferred Stock is entitled to receive dividends on shares of the Preferred Stock equal (on an as-if-converted-to-common-stock basis and without regard to any beneficial ownership limitations) to and in the same form as dividends actually paid on shares of the common stock. No other dividends will be paid on shares of the Preferred Stock. In the event of any liquidation, dissolution or winding up, the holder of the Preferred Stock will be entitled to receive out of the assets, whether capital or surplus, the same amount that a holder of common stock would receive if the Preferred Stock were fully converted to common stock, which amounts shall be paid pari passu with all holders of common stock. Shares of the Preferred Stock will generally have no voting rights, except as required by law and except that the consent of a majority of the holders of either series of outstanding Preferred Stock will be required to amend the terms of such series.

The Preferred Stock includes a provision that, in the event of a tender or exchange offer by a third party in which more than 50% of the common stockholders receive cash or other assets, allows holders of Preferred Stock, upon any subsequent conversion, to redeem their shares for the same form of consideration. In August 2025, the Company concluded that because this redemption right may be triggered by an event outside the Company's control and could result in settlement in cash, the Preferred Stock is classified as temporary equity. As of the current reporting date, a tender offer is not probable, and the preferred stock is not deemed probable of becoming redeemable. Because redemption is not considered probable, the Preferred Stock is not subsequently remeasured to its redemption value.

***Common Stock***

On June 10, 2025, the Company held its 2025 Annual Meeting of Stockholders (the "2025 Annual Meeting"). At the 2025 Annual Meeting, the Company's stockholders approved an amendment (the "Authorized Share Increase Amendment") to the Company's Restated Certificate of Incorporation (as amended, the "Certificate of Incorporation") to increase the number of authorized shares of common stock from 200,000,000 to 300,000,000 shares.

***2023 Securities Purchase Agreement***

On April 28, 2023, the Company entered into a Securities Purchase Agreement (the "2023 Securities Purchase Agreement") with certain investors, pursuant to which the Company agreed to issue and sell to the investors in a private placement (the "2023 Private Placement") (i) in an initial closing, (a) an aggregate of 15,151,518 shares (the "Shares") of the Company's common stock, $0.001 par value per share ("common stock"), or pre-funded warrants in lieu thereof (the "Pre-Funded Warrants"), and (b) common stock warrants exercisable into an aggregate of 15,151,518 shares of common stock (or Pre-Funded Warrants in lieu thereof) (the "Common Warrants" and, together with the Pre-Funded Warrants, the "Warrants"); (ii) in a second closing (the "Second Closing"), upon the satisfaction or waiver of specified conditions set forth in the 2023 Securities Purchase Agreement, an aggregate of 20,202,024 shares of common stock (or Pre-Funded Warrants); and (iii) in a third closing (the "Third Closing"), upon the satisfaction or waiver of specified conditions set forth in the 2023 Securities Purchase Agreement, an aggregate of 25,252,530 shares of common stock (or Pre-Funded Warrants), in each case subject to customary adjustments as provided in the 2023 Securities Purchase Agreement, Pre-Funded Warrant or Common Warrant, as

applicable. Each Common Warrant has an exercise price of $3.00 per share and expires five years after issuance. The Pre-Funded Warrants are exercisable immediately and until exercised in full, with an exercise price of $0.001 per share.

The Pre-Funded Warrants and Common Warrants are subject to specified beneficial ownership limitations, which are generally set at 9.99% of the total common stock then issued and outstanding immediately following the exercise of such warrants, and provided that any beneficial ownership limitation may not exceed 19.99% unless otherwise permitted. The Shares, the Warrants, and the shares of common stock issuable upon the exercise of the Warrants, have not been registered under the Securities Act of 1933, as amended (the "Securities Act"), and were offered pursuant to the exemption from registration provided in Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder.

On May 5, 2023, the initial closing occurred, and the Company received $35.0 million, or net proceeds of approximately $33.0 million after deducting offering costs, in exchange for 8,730,168 shares of common stock and Pre-Funded Warrants to purchase 6,421,350 shares of common stock.

On July 8, 2024, the Second Closing occurred, and the Company received gross proceeds of $2.1 million, or net proceeds of approximately $2.0 million after deducting offering costs, in exchange for 909,088 shares of common stock.

On September 30, 2024, and October 1, 2024, the Third Closing occurred, and the Company received gross proceeds of $4.0 million, or net proceeds of approximately $3.8 million after deducting offering costs, in exchange for 1,727,400 shares of common stock.

In connection with the 2023 Private Placement, the Company filed on May 18, 2023, a registration statement on Form S-3 (the "2023 Registration Statement") with the SEC to register for resale the Shares and the shares of common stock issuable upon the exercise of the Warrants. The 2023 Registration Statement became effective on June 2, 2023.

In August 2024, the Company concluded that the Common Warrants, and the potential issuance of Pre-Funded Warrants in lieu of additional shares of common stock in the Second Closing and Third Closing (the "Subsequent Closing Warrants") do not meet the conditions to be classified as equity instruments under ASC 815-40 and must instead be recorded as liabilities on the Company's consolidated balance sheets at their fair value and remeasured at fair value for each subsequent reporting period. As of October 2024, the Subsequent Closing Warrants either expired or were settled in connection with the Second Closing and Third Closing. Accordingly, the Company's consolidated balance sheets no longer include any fair value associated with the Subsequent Closing Warrants.

The valuation of the Common Warrants is adjusted to fair value (Level 3) at each balance sheet date until the Common Warrants are settled or expired.

The following table presents the assumptions used in the Black-Scholes option pricing model to determine the fair value of the Common Warrants as of December 31, 2025 and 2024 as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Expected stock price volatility | 110.5% | 96.4% |
| Risk-free interest rate | 3.6% | 4.4% |
| Expected term (in years) | 2.5 | 3.5 |
| Share price | $ 1.51 | $ 4.14 |

***2024 Securities Purchase Agreement***

On May 6, 2024, the Company entered into a Securities Purchase Agreement (the "2024 Securities Purchase Agreement") with certain institutional and accredited investors, pursuant to which the Company agreed to issue and sell to the investors in a private placement (the "2024 Private Placement") an aggregate of 13,110,484 shares (the "2024 Shares") of the Company's common stock, at a price of $2.37 per share, and pre-funded warrants (the "2024 Pre-Funded Warrants") at a price of $2.369 per underlying share, which are exercisable to purchase 7,989,516 shares of common stock at an exercise price of $0.001 per share. The 2024 Pre-Funded Warrants were issued in lieu of shares of common stock and are exercisable immediately and until exercised in full. The 2024 Pre-Funded Warrants are subject to specified beneficial ownership limitations (equal to 4.99% or 9.99% as determined by the holders of each such warrant) of the total common stock then issued and outstanding immediately following the exercise of such warrants, and provided that any beneficial ownership

limitation may not exceed 19.99% unless otherwise permitted. The 2024 Shares, the 2024 Pre-Funded Warrants, and the shares of common stock issuable upon the exercise of the 2024 Pre-Funded Warrants, have not been registered under the Securities Act and were offered pursuant to the exemption from registration provided in Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder.

The 2024 Pre-Funded Warrants were classified as a component of permanent stockholders' equity within additional paid-in-capital. The 2024 Pre-Funded Warrants are equity classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of common shares upon exercise, are indexed to the Company's common stock and meet the equity classification criteria. In addition, the 2024 Pre-Funded Warrants do not provide any guarantee of value or return.

The 2024 Private Placement resulted in gross proceeds to the Company of $50.0 million, or net proceeds of approximately $48.1 million after deducting offering costs. The Company is using the net proceeds from the 2024 Private Placement to fund pre-commercial activities for its products and general corporate purposes.

In connection with the 2024 Private Placement, the Company filed on May 24, 2024, a registration statement on Form S-3 (the "2024 Registration Statement") with the SEC to register for resale the 2024 Shares and the shares of common stock issuable upon the exercise of the 2024 Pre-Funded Warrants. The 2024 Registration Statement became effective on June 5, 2024.

***2024 Equity Distribution Agreement***

On September 20, 2024, the Company entered into an Open Market Sale Agreement (the "Sales Agreement") with Guggenheim Securities, LLC ("Guggenheim Securities") to sell shares of the Company's common stock, having aggregate sales proceeds of up to $75.0 million, from time to time, through an "at the market" equity offering program under which Guggenheim Securities will act as sales agent. In connection with the Sales Agreement, the Company filed on September 20, 2024 a registration statement on Form S-3 containing a prospectus and prospectus supplement (the "Shelf Registration Statement") with the SEC. The Shelf Registration Statement became effective on October 2, 2024. As of the year ended December 31, 2025, the Company has not sold any shares under the Sales Agreement.

***2024 Underwritten Offering***

On October 29, 2024, the Company entered into an underwriting agreement with Leerink Partners, LLC, as representative of the several underwriters named therein in connection with the underwritten offering, issuance and sale by the Company (the "2024 Underwritten Offering") of 18,356,173 shares of the Company's common stock, at an offering price of $3.65 per share, and pre-funded warrants at a price of $3.649 per pre-funded warrant, which are exercisable to purchase 4,931,507 shares of the Company's common stock at an exercise price of $0.001 per share (the "2024 Offering Pre-Funded Warrants").

The 2024 Offering Pre-Funded Warrants were classified as a component of permanent stockholders' equity within additional paid-in-capital. The 2024 Offering Pre-Funded Warrants are equity classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of common shares upon exercise, are indexed to the Company's common stock and meet the equity classification criteria. In addition, the 2024 Offering Pre-Funded Warrants do not provide any guarantee of value or return.

The 2024 Underwritten Offering closed on October 30, 2024 and resulted in gross proceeds of $85 million, or net proceeds of approximately $79.5 million after deducting underwriting discounts and commissions and offering expenses. The 2024 Underwritten Offering was made pursuant to the Shelf Registration Statement and a prospectus supplement relating to the 2024 Underwritten Offering dated October 29, 2024.

A holder of the 2024 Offering Pre-Funded Warrants (together with its affiliates) may not exercise any portion of a 2024 Offering Pre-Funded Warrant to the extent that, after giving effect to such exercise, the holder (together with the holder's affiliates, and any other persons acting as a group together with the holder or any of the holder's affiliates) would beneficially own in excess of 4.99% (or, at the holder's option upon issuance, 9.99%) of the number of shares of the Company's common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of such 2024 Offering Pre-Funded Warrant.

***2025 Underwritten Offering***

On November 12, 2025, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Leerink Partners, LLC, as representative of the several underwriters named therein (the "Underwriters"), in connection with the underwritten public offering and sale by the Company (the "2025 Underwritten Offering") of 15,152,485 shares of the Company's common stock at a public offering price of $1.65 per share (the "Common Stock Purchase Price"), and pre-funded warrants (the "2025 Offering Pre-Funded Warrants") at a public offering price of $1.649 per 2025 Offering Pre-Funded Warrant, which are exercisable to purchase up to 15,151,515 shares of common stock at an exercise price of $0.001 per share. In addition, pursuant to the Underwriting Agreement, the Company granted the Underwriters an option (the "Option"), exercisable for 30 days, to purchase up to 4,545,600 additional shares of common stock at the Common Stock Purchase Price less the underwriting discounts and commissions, which Option had been exercised in full by the Underwriters.

The 2025 Underwritten Offering closed on November 13, 2025 and resulted in gross proceeds of $57.5 million or net proceeds of approximately $53.6 million after deducting the underwriting discounts and commissions and offering expenses. The 2025 Underwritten Offering was made pursuant to the Shelf Registration Statement and a prospectus supplement relating to the 2025 Underwritten Offering dated November 12, 2025.

The 2025 Offering Pre-Funded Warrants were classified as a component of permanent stockholders' equity within additional paid-in-capital. The 2025 Offering Pre-Funded Warrants are equity classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of common shares upon exercise, are indexed to the Company's common stock and meet the equity classification criteria. In addition, the 2025 Offering Pre-Funded Warrants do not provide any guarantee of value or return.

A holder of the 2025 Offering Pre-Funded Warrants (together with its affiliates) may not exercise any portion of a 2025 Offering Pre-Funded Warrant to the extent that, after giving effect to such exercise, the holder (together with the holder's affiliates, and any other persons acting as a group together with the holder or any of the holder's affiliates) would beneficially own in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of such 2025 Offering Pre-Funded Warrant. A holder may increase or decrease such beneficial ownership limitation, provided that in no event shall the limitation exceed 19.99% of the number of shares of the common stock outstanding immediately after giving effect to the issuance of shares of common stock upon exercise of the 2025 Offering Pre-Funded Warrant.

***2025 Warrant Exchange Agreement***

On December 30, 2025, the Company entered into an exchange agreement (the "Warrant Exchange Agreement") with Coastlands Capital Partners LP, ("Coastlands Capital"), pursuant to which Coastlands Capital agreed to exchange 4,203,764 shares of the Company's common stock for a pre-funded warrant to purchase an aggregate of 4,203,764 shares of common stock (the "Exchange Warrant"), and the Company cancelled the 4,203,764 shares of common stock delivered in the exchange.

Coastlands Capital (together with its affiliates) may not exercise any portion of the Exchange Warrant to the extent that, after giving effect to such exercise, Coastlands Capital (together with its affiliates and any other persons acting as a group together with Coastlands Capital or any of the its affiliates) would beneficially own in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of the Exchange Warrant. Coastlands Capital may increase or decrease such beneficial ownership limitation, provided that in no event shall the limitation exceed 19.99% of the number of shares of the common stock outstanding immediately after giving effect to the issuance of shares of common stock upon exercise of the Exchange Warrant.

***Exercise of Pre-Funded Warrants from 2023 Securities Purchase Agreement***

On January 30, 2024, Armistice Capital Master Fund Ltd. (the "Exercising Stockholder") exercised Pre-Funded Warrants to purchase 600,000 shares of common stock at an exercise price of $0.001 per share, which were issued in conjunction with the 2023 Securities Purchase Agreement. On January 30, 2024, the Company issued 600,000 shares of common stock to the Exercising Stockholder in accordance with such exercise.

On May 7, 2024, the Exercising Stockholder exercised Pre-Funded Warrants to purchase 583,000 shares of common stock at an exercise price of $0.001 per share, which were issued in conjunction with the 2023 Securities Purchase Agreement. On May 9, 2024, the Company issued 583,000 shares of common stock to the Exercising Stockholder in accordance with such exercise.

On July 11, 2024, the Exercising Stockholder exercised their remaining Pre-Funded Warrants to purchase 240,000 shares of common stock at an exercise price of $0.001 per share, which were issued in conjunction with the 2023 Securities Purchase Agreement. On July 11, 2024, the Company issued 240,000 shares of common stock to the Exercising Stockholder in accordance with such exercise.

***Common Stock Warrants and Pre-Funded Warrants***

As of December 31, 2025, 51,781,090 warrants and pre-funded warrants exercisable into common stock. The Company has issued both common stock warrants and pre-funded warrants. The pre-funded warrants are exercisable for shares of common stock at a nominal exercise price and were fully paid for at issuance, except for the nominal exercise amount. The pre-funded warrants are intended to be economically equivalent to the Company's common stock.

The following table shows the warrants to purchase common stock activity:

| | Roll-Forward of Warrant Activity | | |
|---|---|---|---|
| | Common Stock Warrants | Pre-Funded Warrants | Total |
| Balance as of December 31, 2024 | 15,778,451 | 17,274,293 | 33,052,744 |
| Issued | — | 19,355,279 | 19,355,279 |
| Cancelled/Expired | (626,933) | — | (626,933) |
| Balance as of December 31, 2025 | 15,151,518 | 36,629,572 | 51,781,090 |

As of December 31, 2025, the Company's outstanding warrants to purchase shares of common stock consisted of the following:

| Date Issued | Number of Shares of Common Stock Issuable | Exercise Price | Expiration Date |
|---|---|---|---|
| 2023 Securities Purchase Agreement common warrants | 15,151,518 | $ 3.00 | May 5, 2028 |
| January 2021 pre-funded warrants | 509,117 | $ 0.001 | December 31, 2030 |
| 2023 Securities Purchase Agreement pre-funded warrants | 3,844,153 | $ 0.001 | N/A |
| 2024 Securities Purchase Agreement pre-funded warrants | 7,989,516 | $ 0.001 | N/A |
| 2024 Underwritten Offering pre-funded warrants | 4,931,507 | $ 0.001 | N/A |
| 2025 Underwritten Offering pre-funded warrants | 15,151,515 | $ 0.001 | N/A |
| 2025 Warrant Exchange Agreement | 4,203,764 | $ 0.001 | N/A |
| Balance as of December 31, 2025 | 51,781,090 | | |

***Preferred Stock Warrants***

As of December 31, 2025, all warrants exercisable for shares of Series $X^1$ Preferred Stock expired in accordance with their original terms.

| | Roll-Forward of Series $X^1$ Convertible Preferred Warrant Activity |
|---|---|
| | Total |
| Balance as of December 31, 2024 | 50,207.419 |
| Assumed and replaced | — |
| Exercised | — |
| Cancelled/Expired | (50,207.419) |
| Balance as of December 31, 2025 | — |

**Note 10. Stock-Based Compensation**

***Stock Option Plans***

The Company recognizes compensation expense for all stock-based awards based on the grant-date estimated fair value.

The fair value of stock options is determined using the Black-Scholes option pricing model, using assumptions which are subjective and require significant judgment and estimation by management. The risk-free rate assumption was based on observed yields from governmental zero-coupon bonds with an equivalent term. The expected volatility assumption was based on historical volatilities of a group of comparable industry companies whose share prices are publicly available. The peer group was developed based on companies in the pharmaceutical industry. The expected term of stock options represents the weighted-average period that the stock options are expected to be outstanding. Because the Company does not have historical exercise behavior, the Company determined the expected life assumption using the simplified method for stock options granted to employees, which is an average of the options ordinary vesting period and the contractual term. For stock options granted to the Company's board of directors (the "Board"), the Company determined the expected life assumption using the simplified method as the starting point with an average period of 12 months added to take into account the extended range of time of 12 to 18 months that vested stock options granted to Board members may be exercised upon termination. The expected dividend assumption was based on the Company's history and expectation of dividend payouts. The Company has not paid and does not expect to pay dividends at any time in the foreseeable future. The Company recognizes forfeitures on an actual basis and as such did not estimate forfeitures to calculate stock-based compensation.

Restricted Stock Units ("RSUs") are measured and recognized based on the quoted market price of our common stock on the date of grant.

On July 10, 2024, the Company held its 2024 Annual Meeting of Stockholders (the "2024 Annual Meeting"). At the 2024 Annual Meeting, the Company's stockholders approved an amendment to the Company's 2020 Long Term Incentive Plan (the "2020 Plan"). The 2020 Plan, as amended, (i) reflects an increase in the limit on the aggregate number of shares of the Company's common stock that may be delivered pursuant to all awards granted under the 2020 Incentive Plan by an additional 3,500,000 shares so that the new aggregate share limit under the 2020 Plan is 17,960,000 shares, and (ii) extends the date through which the Company may grant new awards under the 2020 Plan from November 15, 2030 to April 28, 2034.

On May 1, 2023, the Company issued stock option awards to its employees with both time-based and performance-based vesting requirements, totaling 7,381,857 stock options, with 1,476,372 of the granted stock options subject to the Company's customary time-based vesting schedule. The remaining 5,905,485 stock options granted are subject to both customary time-based vesting requirements and performance-based vesting requirements that are based on the same clinical development milestones applicable to the Second Closing and Third Closing of the 2023 Private Placement as specified in the 2023 Securities Purchase Agreement.

In December 2023, the Company amended the performance-based vesting requirements with its named executive officers and other employees that upon the Second Closing and Third Closing, a full or prorated amount of each closing installment shall vest based on the percentage of funding received relative to the total funding opportunity represented by the investors' Second Closing and Third Closing subscription amounts. On June 13, 2024 and November 20, 2024, the performance-based vesting requirement based on the milestones applicable to the Second Closing and Third Closing were satisfied, and 5,763,085 stock options were issued.

The Company's 2014 Stock Incentive Plan (the "2014 Plan") was closed to new grants following the approval of the 2020 Plan, and therefore, there were no shares reserved for issuance under the 2014 Plan as of December 31, 2025. The number of shares reserved for issuance under the 2020 Plan and the Company's Employee Stock Purchase Plan was 3,961,166 and 24,077 shares, respectively, as of December 31, 2025.

The following table summarizes all option activity under the 2014 Plan, 2020 Plan and inducement grants, including 2,713,083 shares forfeited by certain Company's executive officers and directors on December 30, 2025:

| | Shares Issuable Under Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (In years) | Aggregate Intrinsic Value (in thousands) |
|---|---|---|---|---|
| Outstanding as of January 1, 2024 | 15,381,853 | $ 4.21 | 8.9 | $ 235 |
| Granted | 622,000 | 2.22 | | |
| Exercised | (50,000) | 2.30 | | |
| Forfeited / Canceled | (316,465) | 7.29 | | |
| Outstanding as of December 31, 2024 | 15,637,388 | $ 4.02 | 7.5 | $ 20,628 |
| Granted | 2,495,025 | 4.01 | | |
| Exercised | (100,437) | 2.30 | | |
| Forfeited / Canceled | (2,804,477) | 8.66 | | |
| Outstanding as of December 31, 2025 | 15,227,499 | $ 3.17 | 7.3 | $ 357 |
| Options vested and expected to vest as of December 31, 2025 | 15,227,499 | $ 3.17 | 7.3 | $ 357 |
| Options exercisable as of December 31, 2025 | 9,189,825 | $ 3.31 | 6.8 | $ 179 |

Intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of the common stock for the options that had exercise prices that were lower than the fair value per share of the common stock on the date of exercise. The aggregate intrinsic value of options exercised during the year ended December 31, 2025 was $0.2 million.

The Company estimates the fair value of stock option awards on the grant date using the Black-Scholes option pricing model with the following weighted-average assumptions:

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Expected stock price volatility | 97.8% | 101.3% |
| Risk-free interest rate | 4.5% | 4.2% |
| Expected term (in years) | 6.0 | 6.9 |
| Estimated dividend yield | —% | —% |

The per share weighted average grant date fair value of stock options granted during the years ended December 31, 2025 and 2024 was $3.25 and $1.93, respectively.

***Restricted Stock Units***

The following table shows the RSU activity, as follows:

| | Shares Issuable Under RSUs | Weighted Average Grant Date Fair Value |
|---|---|---|
| Outstanding as of January 1, 2024 | — | $ — |
| Granted | 46,000 | 1.97 |
| Exercised | — | — |
| Forfeited / Canceled | — | — |
| Outstanding as of December 31, 2024 | 46,000 | $ 1.97 |
| Granted | 336,225 | 4.04 |
| RSUs Vested | (46,000) | 1.97 |
| Forfeited / Canceled | — | — |
| Outstanding as of December 31, 2025 | 336,225 | $ 4.04 |

***Stock-based Compensation Expense***

Total compensation expense related to all of the Company's stock-based awards for the years ended December 31, 2025 and 2024 was comprised of the following (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Stock-based compensation classified as: | | |
| Research and development expense | $ 4,241 | $ 4,277 |
| General and administrative expense | 6,210 | 8,845 |
| Total stock-based compensation expense | $ 10,451 | $ 13,122 |

As of December 31, 2025, total unrecognized stock-based compensation expense related to non-vested equity awards was $13.8 million, which is expected to be recognized over an estimated weighted-average period of 2.1 years.

**Note 11. Net Loss Per Share**

Basic and diluted net loss per share are calculated using the two-class method in accordance with ASC Topic 260, Earnings Per Share. The two-class method allocates undistributed losses to the Company's outstanding common stock, and the Preferred Stock, based on each class's proportionate share of the total weighted-average shares outstanding. Since the Company has never declared dividends, net loss and undistributed losses are equivalent.

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period determined using the treasury-stock and if-converted methods. The process is used for both common stock and Preferred Stock. As the rights and preferences of the Preferred Stock are substantially identical to each other, they are considered a single class of common stock for earnings per share purposes.

For purposes of the diluted net loss per share calculation, incentive stock options, restricted stock units and common warrants are considered to be potentially dilutive securities and are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. Basic weighted average shares outstanding for the years ended and December 31, 2025 and 2024 include 36,629,572 and 12,443,755 respectively, shares underlying pre-funded warrants to purchase common shares. As the shares underlying these pre-funded warrants can be issued for little consideration (an exercise price per share equal to $0.001 per share), these shares are deemed to be issued for purposes of basic earnings per share.

The calculation of basic and diluted earnings per share for our common stock and Preferred Stock is as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| **(In thousands, except share and per share data)** | | |
| Weighted-average common shares outstanding, basic and diluted | 81,836,246 | 48,543,787 |
| Weighted-average shares outstanding of Series X and Series X[1] non-voting convertible preferred stock, basic and diluted | 114,508 | 114,508 |
| Net loss used in the calculation of basic and diluted loss per share | $ (45,617) | $ (36,184) |
| Net loss available to common stock | $ (42,328) | $ (31,992) |
| Net loss per share, common stock, basic and diluted | $ (0.52) | $ (0.66) |
| Net loss available to Series X and Series X[1] non-voting convertible preferred stock | $ (3,290) | $ (4,192) |
| Basic and diluted earnings per share of Series X and Series X[1] non-voting convertible preferred stock | $ (28.73) | $ (36.61) |

The following table presents potentially dilutive securities outstanding based on the market price of the Company's common stock as of December 31, 2025 and 2024 that were excluded from the computation of diluted net loss per share because their inclusion would have been anti-dilutive. These securities consist of incentive stock options, restricted stock units and common warrants outstanding during the respective periods.

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Stock options outstanding and other equity awards | 1,333,225 | 6,007,789 |
| Common warrants | — | 18,567,751 |
| Total | 1,333,225 | 24,575,540 |

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