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 001-38738

ETON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**37-1858472**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
21925 W. Field Parkway, Suite 235 Deer Park, IL	**60010-7278**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (847) 787-7361

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.001 par value	**ETON**	**The Nasdaq Global Market LLC**

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

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

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

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

The aggregate market value of all common stock (based upon the closing price on the Nasdaq Global Market) of the registrant held by non-affiliates as of June 30, 2025 was approximately $360.6 million.

As of March 17, 2026, the registrant had 27,284,491 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 Part III of this Annual Report on Form 10-K.

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Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties, many of which are beyond our control. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, these forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements as a result of various factors, including those set forth below under the caption "Risk Factors."

Forward-looking statements in this Annual Report and in our other reports with the Securities and Exchange Commission (the "SEC"), for example, may include statements regarding:

- our ability to submit our product candidates through the 505(b)(2) regulatory pathway for approval by the U.S. Food and Drug Administration (the "FDA");
- our ability to obtain FDA approval for our product candidates;
- our ability to comply with all U.S. and foreign regulations concerning the development, manufacture and sale of our product candidates;
- our ability to maintain, protect and enhance our intellectual property;
- costs associated with initiating and defending intellectual property infringement and other claims;
- future acquisitions of or investments in complementary companies or technologies; and
- our ability to comply with evolving legal standards and regulations, particularly concerning requirements for being a public company.

In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "continue," "could," "estimates," "expects," "hopes," "intends," "may," "plan," "potential," "predicts," "projects," "seeks," "should," "will," "would" or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements include, but are not limited to, statements under the captions "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as other sections in this Annual Report on Form 10-K. We discuss many of the risks associated with the forward-looking statements in this Annual Report on Form 10-K in greater detail under the heading "Risk Factors." Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. You should be aware that the occurrence of any of the events discussed under the caption "Risk Factors" and elsewhere in this report could substantially harm our business, results of operations and financial condition and that if any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock.

The cautionary statements made in this report are intended to be applicable to all related forward-looking statements wherever they may appear in this Annual Report on Form 10-K. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Except as required by law, we assume no obligation to update our forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for our product candidates, as well as data regarding market research, estimates and forecasts prepared by our management. 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. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. As used in this Annual Report on Form 10-K, unless the context indicates or otherwise requires, "Eton," "our company," "we," "us," "the Company" and "our" refer to Eton Pharmaceuticals, Inc., a Delaware corporation.

You should read the following together with the more detailed information regarding our company, our common stock and our financial statements and notes to those statements appearing elsewhere in this report or incorporated by reference. The SEC allows us to "incorporate by reference" information that we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this report.

PART I

Item 1. Business

About Eton

Eton is an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases. We currently have eight commercial rare disease products: INCRELEX®, ALKINDI SPRINKLE®, KHINDIVI™, GALZIN®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous, and Nitisinone. We have five additional product candidates in late-stage development: ET-600, Amglidia®, ET-700, ET-800 and ZENEO® hydrocortisone autoinjector.

INCRELEX® – This biologic product was approved by the FDA in August 2005 as a treatment for children who suffer from severe primary insulin-like growth factor 1 deficiency (SPIGFD). The product is approved in 40 territories, including the United States and the European Union. We acquired and launched the product in December 2024.

ALKINDI SPRINKLE® – This product was approved by the FDA in September 2020 as a replacement therapy for Adrenocortical Insufficiency ("AI") in children under 17 years of age. The product is the first and only FDA-approved granule hydrocortisone formulation designed to help provide accurate dosing for newborns and children with AI. We acquired U.S. marketing rights to the product in March 2020 and launched ALKINDI SPRINKLE® in December 2020 with a sales force targeting pediatric endocrinologists. We believe there are approximately 10,000 children currently suffering from AI in the United States. ALKINDI SPRINKLE® is protected by three issued patents that extend to 2032, 2033, and 2034.

KHINDIVI™ – This product was approved by the FDA in May 2025 as a replacement therapy in pediatric patients five years of age and older for adrenocortical insufficiency. KHINDIVI is the only FDA-approved oral solution formulation of hydrocortisone. It comes in a 1mg/ml strength designed to eliminate the need to split or crush tablets, and to offer simple and accurate dosing specifically tailored to each patient's needs. It does not require refrigeration, mixing, or shaking – it is a ready-to-use oral liquid solution. KHINDIVI is designed to offer administration simplicity and dosing accuracy, and to provide a therapy option for patients who have difficulty swallowing tablets or with special administration needs, such as patients with a gastric tube.

GALZIN® is FDA-approved as a maintenance treatment for patients with Wilson disease who have been initially treated with a chelating agent. It is estimated that less than 5,000 patients in the U.S. are currently being treated for Wilson disease. We acquired the product in December 2024 and assumed the commercialization of the product in the U.S. in March 2025. We offer the product through our Eton Cares patient support program that provides high-touch, personalized service tailored for rare disease patients and their providers.

PKU GOLIKE® - In March 2024, we acquired the U.S. rights to PKU GOLIKE, which is a next generation medical formula product engineered with the patent protected, pharmaceutical grade Physiomimic™ technology for the dietary management of phenylketonuria ("PKU") under medical supervision. PKU GOLIKE's® taste-masked, odor-free coating technology is designed to provide a better taste and a superior experience compared to alternative PKU medical formulas. In addition, PKU GOLIKE's delayed amino acid release formulation is designed to keep patients full for a longer period of time.

Carglumic Acid Tablets – Our Carglumic Acid product is an FDA-approved generic version of Carbaglu®. Our product is approved for the treatment of acute and chronic hyperammonemia due to N-acetylglutamate synthase ("NAGS") deficiency. We acquired the marketing rights to the product in October 2021 and launched the product in December 2021. We promote the product with our internal sales force.

Betaine Anhydrous for Oral Solution – Our Betaine Anhydrous product is an FDA-approved generic version of Cystadane® for the treatment of homocystinuria, a rare inherited condition that is estimated to impact fewer than 2,000 patients in the United States. We acquired the product in September 2022 and launched the product in May 2023.

Nitisinone – Our Nitisinone product is an FDA-approved generic version of Orfadin® for the treatment of tyrosinemia type 1, an ultra-rare inherited condition that is estimated to impact fewer than 500 patients in the United States. We acquired the product in October 2023 and launched the product in February 2024.

ET-600 – In July 2025, ET-600's NDA was accepted for review by the FDA and assigned a PDUFA target action date of February 25, 2026. The Company has scheduled the production of launch inventory for the first quarter of 2026 in preparation for a commercial launch shortly after the anticipated approval. The Company recently held an ET-600 advisory meeting with leading healthcare practitioners within the pediatric endocrinology community.

Amglidia® - In November 2024, we entered into a licensing agreement with AMMTeK., pursuant to which we have agreed to acquire the U.S. rights to Amglidia® (glyburide oral suspension), which we also have a license to the issued patent on Amglidia®. Amglidia® is being developed for the treatment of neonatal diabetes mellitus, a rare condition estimated to impact approximately 300 patients in the U.S. The product was approved by the European Medicines Agency in 2018 and has been granted Orphan Drug Designation by the FDA. AMMTeK has conducted a post-approval study tracking five years of real-world safety and efficacy in European patients, which will be used to support Eton's NDA submission.

ET-700– We are scheduled to begin its proof-of-concept positron emission tomography ("PET") study during 2026. The study is expected to validate the efficacy of the Company's propriety, patent-pending extended-release formulation, and if positive, would support the initiation of a dose ranging and pivotal clinical trial in late 2026 or early 2027. We have also submitted a patent for ET-700, which is currently pending.

ET-800– We are developing this ready-to-use, injectable liquid hydrocortisone in a vial for the hospital market.

ZENEO® Hydrocortisone Autoinjector – Our ZENEO® hydrocortisone autoinjector product candidate is a proprietary needle-free autoinjector under development for the treatment of adrenal crisis.

Eton Pharmaceuticals
Products Summary

Product	Eton Category	Indication	FDA Status
INCRELEX®	Endocrinology	Severe Primary IGF-1 Deficiency	Commercial
ALKINDI SPRINKLE®	Endocrinology	Adrenal Insufficiency	Commercial
KHINDIVI™	Endocrinology	Adrenal Insufficiency	Commercial
GALZIN®	Metabolic	Wilson Disease	Commercial
PKU GOLIKE®	Metabolic	Phenylketonuria	Commercial
Carglumic Acid Tablets	Metabolic	NAGS deficiency	Commercial
Betaine Anhydrous	Metabolic	Homocystinuria	Commercial
Nitisinone	Metabolic	Tyrosinemia Type 1	Commercial
ET-600	Endocrinology	Diabetes Insipidus	PDUFA goal date of February 25, 2026
Amglidia®	Endocrinology	Neonatal diabetes mellitus	Under Development
ET-700	Metabolic	Wilson Disease	Under Development
ET-800	Endocrinology	Adrenal Insufficiency	Under Development
ZENEO® Hydrocortisone	Endocrinology	Adrenal Crisis	Under Development

Goals and Strengths

Our goal is to become a leading pharmaceutical company focused on developing and commercializing treatments for rare diseases. We believe we are unique in the pharmaceutical industry in our ability to identify, acquire, and advance products through the development and regulatory process. Our biggest competitive strengths are:

- Business development experience – our ability to identify and execute transactions on under-appreciated development assets. Our team has completed over 150 business development transactions throughout their careers and their industry connections and track record provide the Company with proprietary deal flow. We typically avoid participating in broker led transactions or auction processes.

- Regulatory expertise – our knowledge and experience in gaining FDA approval, and particularly our knowledge within the 505(b)(2) regulatory pathway, provides drug sponsors with the opportunity to leverage existing data or literature to drastically expedite drug development timelines and reduce investment.

- Established commercial operations – our sales and marketing teams have developed strong relationships with healthcare professionals and patient advocacy groups in multiple therapeutic areas. These relationships allow us to commercialize new products quickly and effectively.

Sales and Marketing

We currently commercialize eight products under our own label with our internal infrastructure and sales force. We market and sell INCRELEX®, ALKINDI SPRINKLE®, KHINDIVI™, GALZIN®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous, and Nitisinone in the United States consistent with applicable laws. These products are distributed to patients via specialty pharmacies, which support customer service and reimbursement activities.

Research and Development

We currently have twelve employees that support our product research and development ("R&D") priorities and strategy. In addition, we utilize external sources for various product development activities, including the resources of our product development partners for certain product candidates and through the use of contract laboratory services on a fee for service model. Our R&D priorities include:

- developing, manufacturing and delivering a pipeline of innovative products to patients living with rare diseases;

- advancing our capabilities that can position us for long-term R&D leadership; and

- pursuing multiple development pathways through acquisitions, joint ventures, partnerships, and product licensing with creativity, flexibility and urgency to deliver innovative products to patients as quickly as possible.

Manufacturing and Suppliers

We rely on third-party contract manufacturing organizations ("CMOs") to manufacture our products. The majority of our finished product manufacturing partners are based in the United States or Europe. We seek to work with CMOs that have a long history of quality and FDA compliance. All products are manufactured in compliance with current Good Manufacturing Processes ("GMP"), and our internal quality system requires us to enter quality agreements with and audit all of our manufacturers prior to commercializing the product. Our choice to rely on external manufacturers significantly reduces the amount of capital required to be invested in our business and allows us the flexibility to pursue a broad range of opportunities beyond the specific capabilities of a single facility.

Intellectual Property

Our success depends in part on our ability to obtain patents, to protect trade secrets, to operate without infringing upon the proprietary rights of others and to prevent others from infringing on our proprietary rights. Our policy is to seek to protect our proprietary position 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 of our business. We also rely on our trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary position. We vigorously defend our intellectual property to preserve our rights and gain the benefit of our technological investments. Our business is not dependent, however, upon any single patent, trademark, or contract.

ALKINDI SPRINKLE® is protected by three issued patents that extend to 2034. KHINDIVI™ is protected by two issued patents that extend to 2043, and there are additional patent applications related to this product under review with the U.S. Patent and Trademark Office ("USPTO"). ET-600 is protected by an issued patent that extends to 2044 and there are additional patent applications related to this product under review with the USPTO. We intend to seek patent protection on our internally developed products as circumstances warrant.

Government Regulation

The FDA and comparable regulatory agencies in federal, state and local jurisdictions impose substantial requirements upon the development, manufacture, and marketing of pharmaceutical products. These agencies regulate the research, testing, manufacture, quality, control, storage, distribution, marketing and sale of our pharmaceutical products. Additionally, in the United States, we must follow rules and regulations established by the FDA requiring the presentation of data indicating that our products are safe and efficacious and are manufactured in accordance with GMP regulations. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or allow us to manufacture or market our products, and we may be criminally prosecuted. We, and our manufacturers and contract research organizations ("CROs"), may also be subject to regulations under other foreign, federal, state and local laws, including, but not limited to, the U.S. Occupational Safety and Health Act, the Resource Conservation and Recovery Act, the Clean Air Act and import, export and customs regulations as well as the laws and regulations of other countries. The U.S. government has increased its enforcement activity regarding marketing practices domestically and internationally. As a result, pharmaceutical companies must ensure their compliance with the Foreign Corrupt Practices Act and federal healthcare fraud and abuse laws, including the False Claims Act.

FDA Market Approval Process

The steps required to be taken before a new drug may be marketed in the United States generally include:

- completion of pre-clinical laboratory and animal testing under current good laboratory practices;
- completion of required chemistry, manufacturing and controls testing;
- submission to the FDA of an Investigational New Drug ("IND") application, which must be evaluated and found acceptable by the FDA before human clinical trials may commence;
- performance of adequate and well-controlled human clinical trials to establish the safety, pharmacokinetics and efficacy of the proposed drug for its intended use;
- approval by an independent institutional review board ("IRB") or ethics committee before each human clinical trial may be initiated;
- submission and approval of an NDA by the FDA; and
- compliance with any post-approval requirements, including agreement with FDA of the language on the package insert.

The testing and approval process require substantial time, effort, and financial resources, and we cannot be certain that any approval will be granted on a timely basis, if at all. Preclinical development of a drug candidate can take several years to complete, with no guarantee that an IND application based on those studies will become effective to even permit clinical testing to begin. Even though several of our pharmaceutical product candidates utilize active drug ingredients that are commercially marketed in the United States in other dosage forms, we need to establish safety and effectiveness of those active ingredients in the formulation and dosage forms that we are developing.

Clinical studies are conducted under protocols detailing, among other things, the objectives of the study, what types of patients may enter the study, schedules of tests and procedures, drugs, dosages, and length of study, as well as the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical study and any subsequent protocol amendments must be submitted to the FDA as part of the IND process.

Clinical trials are usually conducted in three phases. Phase 1 clinical trials are conducted in small groups of healthy volunteers to assess safety of various dosing regimens and pharmacokinetics. After a safe dose has been established, in Phase 2 clinical trials the drug is administered to a limited patient population with the target disease or condition to identify possible adverse events and safety risks, and to conduct a preliminary evaluation of the efficacy of the product candidate in treating the targeted disease or condition. Phase 3 clinical trials are usually multi-center, double-blind controlled trials in larger numbers of subjects to assess as fully as possible both the safety and effectiveness of the drug, establish the overall risk-benefit of the product candidate, and provide adequate information for the labeling of the product.

Clinical trials must be conducted in accordance with the FDA's current Good Clinical Practices ("GCP") requirements. The FDA may order the temporary or permanent discontinuation of a clinical study at any time or impose other sanctions if it believes that the clinical study is not being conducted in accordance with FDA requirements or that the participants are being exposed to an unacceptable health risk. An IRB generally must approve the clinical trial design and patient informed consent at study sites that the IRB oversees and may halt a study, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. Additionally, some clinical studies are overseen by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or committee. This group recommends whether or not a trial may move forward at designated checkpoints based on access to certain data from the study. The clinical study sponsor may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

As a product candidate moves through the clinical testing phases, manufacturing processes are further defined, refined, controlled, and validated. The level of control and validation required by the FDA increases as clinical studies progress. We and the third-party manufacturers on which we rely for the manufacture of our product candidates and their respective components (including the active pharmaceutical ingredient ("API")) are subject to requirements that drugs be manufactured, packaged, and labeled in conformity with GMP. To comply with GMP requirements, manufacturers must continue to spend time, money, and effort to meet requirements relating to personnel, facilities, equipment, production and process, labeling and packaging, quality control, recordkeeping, and other requirements.

After completion of all required testing in accordance with all applicable regulatory requirements, detailed information on the product candidate is submitted to the FDA in the form of an NDA, requesting approval to market the product for one or more indications, together with payment of a user fee, unless waived. An NDA includes all relevant data available from pertinent nonclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information on the chemistry, manufacture, controls, and proposed labeling, among other things. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the product candidate for its intended use to the satisfaction of the FDA.

If an NDA submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under a PDUFA, the FDA's goal is to complete its initial review and respond to the applicant within ten months of submission, unless the application relates to an unmet medical need, or is for a serious or life-threatening indication, in which case the goal may be within six months of NDA submission. However, the review process and the target response date under PDUFA may be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the NDA. During its review of an NDA, the FDA may refer the application to an advisory committee for review, evaluation, and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of the advisory committee, but it typically follows such recommendations. Data from clinical studies are not always conclusive and the FDA and/or any advisory committee it appoints may interpret data differently than the applicant.

After the FDA evaluates the NDA and inspects manufacturing facilities where the drug product and/or its API will be produced, it will either approve commercial marketing of the drug product with prescribing information for specific indications or issue a Complete Response Letter ("CRL") indicating that the application is not ready for approval and stating the conditions that must be met in order to secure approval of the NDA. If the CRL requires additional data and the applicant subsequently submits that data, the FDA nevertheless may ultimately decide that the NDA does not satisfy its criteria for approval. The FDA could also approve the NDA with a Risk Evaluation and Mitigation Strategies ("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 post-marketing testing. Such post-marketing testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and efficacy after approval.

If the FDA approves one of our product candidates, we will be required to comply with post-approval regulatory requirements, including record-keeping requirements and reporting of adverse reactions and production problems, and updated safety and efficacy information. Also, quality control and manufacturing procedures must continue to conform to GMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with GMP, which imposes extensive procedural, substantive and record-keeping requirements. If we seek to make certain changes to an approved product, such as certain manufacturing changes, we will need FDA review and approval before the change can be implemented. For example, if we change the manufacturer of a product or our API, the FDA may require stability or other data from the new manufacturer. Such data will take time and are costly to generate, and the delay associated with generating this data may cause interruptions in our ability to meet commercial demand, if any. While physicians may use products for indications that have not been approved by the FDA, we may not label or promote the product for an indication that has not been approved. Securing FDA approval for new indications is similar to the process for approval of the original indication and requires, among other things, submitting data from adequate and well-controlled studies that demonstrate the product's safety and efficacy in the new indication. Even if such studies are conducted, the FDA may not approve any change in a timely fashion, or at all.

The FDA may also require post-marketing testing or Phase 4 testing, as well as risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could otherwise restrict the distribution or use of the product.

Section 505(b)(2) New Drug Applications

We submit applications for certain product candidates via the 505(b)(2) regulatory pathway. As an alternate path for FDA approval of new indications or new formulations of previously approved products, a company may submit a Section 505(b)(2) NDA, instead of a "stand-alone" or "full" NDA. Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("FDCA") was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Amendments. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Some examples of products that may be allowed to follow a 505(b)(2) path to approval are drugs that have a new dosage form, strength, route of administration, formulation, or indication.

The Hatch-Waxman Amendments permit applicants to rely upon certain published nonclinical or clinical studies conducted for an approved product or the FDA's conclusions from prior review of such studies. The FDA may require companies to perform additional studies or measurements to support any changes from the approved product. The FDA may then approve the new product for all or some of the labeled indications for which the reference product has been approved, as well as for any new indication supported by the Section 505(b)(2) application. While references to nonclinical and clinical data not generated by the applicant or for which the applicant does not have a right of reference are allowed, all development, process, stability, qualification, and validation data related to the manufacturing and quality of the new product must be included in an NDA submitted under Section 505(b)(2).

To the extent that the Section 505(b)(2) applicant is relying on the FDA's conclusions regarding studies conducted for an already approved product, the applicant must provide the patent number and certify to the FDA in its opinion and to the best of its knowledge, one of the following circumstances: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The Section 505(b)(2) application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the reference product has expired. If the Orange Book certifications outlined above are not accomplished, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized.

Section 505(j) Abbreviated New Drug Applications

The 505(j) pathway is used for product candidates that are therapeutically equivalent to an approved product. The underlying premise of the 505(j) pathway is that a product candidate classified as therapeutically equivalent can be substituted for the approved product with the full expectation that the substituted product will produce the same clinical effect and safety profile as the approved product when administered under the same conditions. A product candidate utilizing the 505(j) pathway requires an abbreviated new drug application, ("ANDA"), which relies on the FDA's finding that the previously approved drug candidate is safe and effective. An ANDA generally must contain information to show that the product candidate is the same as the approved product with respect to API, conditions of use, route of administration, dosage form, strength, and labeling, with certain permissible differences, and is the bioequivalent of the approved drug. The 505(j) pathway typically requires no clinical testing other than a bioequivalence trial. While the 505(j) pathway is typically shorter and less expensive than the 505(b)(2) pathway, the 505(b)(2) pathway allows greater flexibility as to the characteristics of the product candidate.

Other U.S. Healthcare Laws and Compliance Requirements

Products distributed in the United States are also subject to additional healthcare regulation and enforcement by the federal government and the states in which we conduct our business. Applicable federal and state healthcare laws and regulations include the following:

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

- The federal civil and criminal false claims laws, including the U.S. False Claims Act, can be enforced by individuals, on behalf of the government, through civil whistleblower or qui tam actions, and the civil monetary penalties law, prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government;

- The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which prohibits, among other things, executing a scheme to defraud any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and

- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require the reporting of information related to drug pricing; state and local laws requiring the registration of pharmaceutical sales and medical representatives; and state and foreign laws, such as the General Data Protection Regulation (EU) 2016/679, governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal or state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including significant criminal, civil, and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, integrity oversight and reporting obligations to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

Reimbursement

Sales of our products in the United States may depend, in part, on the extent to which the costs of the products will be covered and reimbursed by third-party payors, such as government health programs, commercial insurance and managed health care organizations. These third-party payors are increasingly challenging the prices charged for medical products and services. Additionally, the containment of health care costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The United States government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, (the "MMA"), imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries and included a major expansion of the prescription drug benefit under Medicare Part D. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Parts A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the

MMA applies only to drug benefits for Medicare beneficiaries, private third-party payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

Decreases in third-party reimbursement for our products or a decision by a third-party payor to not cover our products could reduce physician usage of the products and have a material adverse effect on our sales, results of operations and financial condition.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the health-care system that could prevent or delay marketing approval of pharmaceutical products, restrict or regulate post-approval activities and affect our ability to profitably sell our product candidates. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

In March 2010, then President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "Health Care Reform Law"), which, among other things, imposed reporting requirements on manufacturers related to drug samples and financial relationships with physicians and teaching hospitals, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees on manufacturers of certain branded prescription drugs, and established a Medicare Part D coverage gap discount program.

Some of the provisions of the Health Care Reform Law have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the Health Care Reform Law. In addition, Congress has considered legislation that would repeal or repeal and replace all or part of the Health Care Reform Law. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Health Care Reform Law have been signed into law and became effective in January 2019. The Tax Cuts and Jobs Act of 2017 (the "Tax Act") included a provision which repealed the tax-based shared responsibility payment imposed by the Health Care Reform Law on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." The Bipartisan Budget Act of 2018, among other things, amended the Health Care Reform Law to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole".

In addition, other legislative changes have been proposed and adopted in the United States since the Health Care Reform Law was enacted, including:

- In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for deficit reduction of at least $1.2 trillion for the years 2013 through 2021. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, up to 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect through 2030 unless Congress takes additional action. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional action is taken by Congress.

- On April 13, 2017, the Centers for Medicare and Medicaid Services ("CMS") published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the Health Care Reform Law for plans sold through such marketplaces.

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

- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent U.S. Congressional Inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer and patient programs, and reform government program reimbursement methodologies for products. In July 2021, President Biden signed an Executive Order affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drugs and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs the U.S. Department of Health & Human Services ("HHS") to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. The FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. On September 25, 2020, CMS stated drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. Additionally, on November 30, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2032. Although a number of these and other proposed measures

may require authorization through additional legislation to become effective, and the Trump administration may reverse or otherwise change these measures.

In August 2022, President Biden signed the Inflation Reduction Act ("IRA") which provides for (i) the government to set or negotiate prices for select high-cost Medicare Part D (beginning in 2026) and Medicare Part B drugs (beginning in 2028) that are more than nine years (for small-molecule drugs) or 13 years (for biological products) from their FDA approval, (ii) manufacturers to pay a rebate for Medicare Part B and Part D drugs when prices increase faster than inflation beginning in 2022 for Medicare Part D and 2023 for Medicare Part B drugs, and (iii) Medicare Part D redesign which replaces the current coverage gap provisions and establishes a $2,000 cap for out-of-pocket limits costs for Medicare beneficiaries beginning in 2025, with manufacturers being responsible for 10% of costs up to the $2,000 cap and 20% after that cap is reached. Implementation of the IRA is expected to be carried out through actions by regulatory authorities, the outcome of which is uncertain.

In August 2023, the Biden Administration published the first ten medicines subject to the Medicare Drug Price Negotiation program. Eton signed a program agreement in February 2024 with an effective date of January 1, 2025 that could change our discounting obligations for all medicines in Medicare, however the impact to our business is minimal since Eton products are prescribed to very few Medicare patients. Should the program change such that it significantly increases our discounting obligations, or should the number of our products prescribed to Medicare patients increase substantially, it could have a material adverse effect on our net revenues, financial condition, results of operations or prospects.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that states will continue to seek cost cutting, which may focus on managed care capitation payments, supplemental rebates, and/or formulary management.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private third-party payors.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal, and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Employees

At December 31, 2025, we had 44 full-time employees, twelve of whom are engaged in research and development activities, twenty-four are engaged in sales and marketing operations and eight of whom are engaged in general corporate and strategy roles. We periodically utilize outside consultants on an as-needed basis, including medical consultants.

Corporate and Other Information

We were incorporated under the laws of the state of Delaware in April 2017. Our principal executive offices are located at 21925 W. Field Parkway, Suite 235, Deer Park, Illinois, 60010, and our telephone number is (847) 787-7361. Our corporate website address is www.etonpharma.com, to which we regularly post copies of our press releases as well as links to reports we have filed with the SEC, which are available free of charge as soon as reasonably practicable after being electronically filed with or furnished to the SEC. Interested persons can subscribe on our website to email alerts that are sent automatically when we issue press releases, file reports with the SEC or post certain other information to our website. Information contained on or accessible through our website is not a part of this Annual Report on Form 10-K or our other filings with the SEC.

We own two U.S. federal trademark applications and unregistered trademarks, including our company name. All other trademarks or trade names referred to in this Annual Report are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Annual Report are referred to without the symbols ® and ™, but such references should not be construed as any indication that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

Risk Factors Summary

You should carefully consider the risks set forth in the section of this Annual Report of Form 10-K entitled "Risk Factors" beginning on page 10 of this Annual Report, including, but not limited to, the following:

- The Inflation Reduction Act and related Medicare reforms may adversely affect the prices we realize and the demand for our products.
- Our participation in U.S. government price reporting and discount programs (including the Medicaid Drug Rebate Program, 340B, VA/FSS and TRICARE) could adversely affect the net prices we realize and expose us to significant liabilities.
- Third-party coverage and reimbursement and health care cost containment initiatives, including PBM practices, formulary controls and utilization management may constrain our future revenues.
- We may operate or support patient services and assistance programs, and government scrutiny of these activities could require us to curtail such programs, reducing patient access and adversely affecting demand for our products.
- If we obtain or seek marketing authorizations and commercialization outside the United States, we may be subject to pricing controls and health technology assessment processes that could delay commercialization and reduce net prices.
- We may need to grow the size of our organization, and we may experience difficulties in managing this growth.
- If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.
- We may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.
- We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.
- Use of artificial intelligence-based software by us or third parties with which we contract, may lead to the release of confidential information which may impact our ability to realize the benefits of our intellectual property.
- Sales of counterfeits of any of our product candidates, as well as unauthorized sales of any of our product candidates, may have adverse effects on our revenues, business and results of operations and damage our brand and reputation.
- We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.
- Our competitors may obtain FDA or other regulatory approval for comparable products more rapidly than we may obtain approval for ours, and the risk of our competitors doing so may lead us to develop drug candidates without disclosing certain information with regard to such candidates.
- If we are not able to obtain regulatory approvals for our product candidates, we will not be able to commercialize our product candidate and our ability to generate revenue will be limited.
- If the FDA concludes that our product candidates do not satisfy the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of any of our product candidates under Section 505(b)(2) are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.
- An NDA submitted under Section 505(b)(2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of our product candidate.
- Even if we receive regulatory approval for any of our product candidates, we may not be able to successfully commercialize the product, and the revenue that we generate from its sales, if any, may be limited.
- We are subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates could be subject to labeling and other restrictions and 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 product candidates.
- Significant additional labeling or warning requirements or limitations on the availability of our products may inhibit sales of affected products.
- We are subject to Drug Supply Chain Security Act requirements, and failure to comply could disrupt our distribution and result in enforcement action.
- Changes in U.S. trade policy, threats of international tariffs, and changes to the U.S. political landscape may adversely affect our business, results of operations, financial condition, and prospects.
- If we market any of our products or product candidates in a manner that violates health care fraud and abuse laws, we may be subject to civil or criminal penalties.
- We may not be able to establish agreements with third parties with whom we wish to collaborate and, if we are able to establish them, we may not be able to establish them on commercially reasonable terms, which could result in alterations or delays of our development and commercialization plans.
- We expect to rely on third parties to conduct clinical trials for our product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize any of our product candidates and our business would be substantially harmed.
- We enter into various contracts in the normal course of our business, some or all of which may require us to indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have an adverse effect on our business, financial condition and results of operations.
- Any termination or suspension of, or delays in the commencement or completion of, any necessary studies of any of our product candidates for any indications could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.
- We are subject to extensive laws and regulations related to data privacy, and our failure to comply with these laws and regulations could harm our business.
- We will depend on rights to certain pharmaceutical compounds that have been acquired by us. We do not have complete control over these pharmaceutical compounds and any loss of our rights to them could prevent us from selling our products.
- It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights.
- Changes in either U.S. or foreign patent law or interpretation of such laws could diminish the value of patents in general, thereby impairing our ability to protect our products.
- Our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts.
- Others may claim an ownership interest in our intellectual property, which could expose us to litigation and have an adverse effect on our prospects.
- We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

Item 1A. Risk Factors

We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Annual Report on Form 10-K and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our results of operations and financial condition.

Risks Relating to Pricing, Reimbursement and Market Access

The Inflation Reduction Act and related Medicare reforms may adversely affect the prices we realize and the demand for our products.

The Inflation Reduction Act of 2022 (the "IRA"), and related federal and state healthcare reforms, have introduced new and evolving mechanisms that may affect the prices we realize for our products and the demand for our products over time. These mechanisms include, among others, inflation-based rebates under Medicare Parts B and D that can require payments when certain reported prices increase faster than inflation; changes to the Medicare Part D benefit beginning in 2025 that redistribute financial liability among manufacturers, plans and the government while capping patient out-of-pocket costs; and a program under which certain drugs may become subject to price negotiation on a defined timetable. The applicability and impact of these mechanisms will evolve over time based on our portfolio mix and the characteristics of individual products. For example, whether and when a product becomes subject to the Medicare drug price negotiation program depends, among other factors, on the time elapsed since FDA approval and other selection criteria, and inflation-based rebates in Medicare Parts B and D apply when prices increase faster than inflation. Changes in our portfolio, utilization and payer mix could therefore alter our exposure to negotiation, inflation-based rebates, and the redesigned Medicare Part D benefit, including our financial responsibility under the new benefit structure. Implementation will occur through ongoing regulatory actions, the outcomes of which remain uncertain. Even where our current products are not immediately selected for negotiation or have limited Medicare utilization, these changes may alter channel economics, increase our obligations, reduce the net prices we realize, and adversely affect patient access and demand. Certain statutory exemptions may apply to particular products based on their indications, approval history or other factors; however, exemptions are narrow and can change with future legislation, guidance or changes in our product portfolio. The IRA, its implementing regulations and related guidance continue to evolve, and the scope and timing of their impact on our business remains uncertain.

Our participation in U.S. government price reporting and discount programs imposes complex and evolving obligations that could adversely affect the net prices we realize and expose us to significant liabilities.

Our participation in U.S. government price reporting and discount programs materially affects the net prices we realize and requires us to comply with complex and evolving legal and reporting obligations. For example, under the Medicaid Drug Rebate Program, we must calculate and report Average Manufacturer Price ("AMP") and, where applicable, Best Price, and pay rebates to states. Recalculations or restatements—whether due to errors, new interpretations, government audits or other factors—can be retroactive and may require us to pay additional rebates. These obligations can also affect pricing and refund requirements under the 340B Drug Pricing Program, including through recalculation of ceiling prices and controls intended to prevent duplicate discounts. In addition, our products may be subject to pricing and discount requirements under the U.S. Department of Veterans Affairs and Federal Supply Schedule programs, including obligations tied to Non-Federal Average Manufacturer Price ("Non-FAMP"), Federal Ceiling Price ("FCP") and related certifications, as well as TRICARE rebate requirements. Government authorities continue to increase scrutiny of these programs, and noncompliance (including inaccurate reporting, failure to timely report changes, or failure to implement required controls) may result in significant refunds, civil monetary penalties, contractual damages, suspension or termination from participation in government programs, reputational harm, and potential liability under the False Claims Act.

Third-party coverage and reimbursement and healthcare cost containment initiatives, including formulary controls and utilization management, may constrain our future revenues.

Our ability to successfully commercialize our products and product candidates depends in significant part on the extent to which governmental authorities, commercial insurers and other third-party payors provide coverage for, and establish adequate reimbursement levels for, our products. Even if a product is approved, payors may limit or exclude coverage, place the product at a disadvantageous formulary tier, require prior authorization, impose step-therapy or other utilization management restrictions, or require patients to pay higher out-of-pocket costs. Pharmacy benefit managers ("PBMs") and payors may also increase their leverage through formulary exclusions, restrictive network arrangements, and demands for greater rebates, discounts or other price concessions, which can increase our gross-to-net reductions and reduce realized prices. In addition, treatment guidelines, clinical pathways, and health technology assessment frameworks may influence prescribing behavior and coverage determinations. If coverage and reimbursement are inadequate, delayed or more restrictive than we anticipate, or if our gross-to-net reductions increase, our sales, profitability and results of operations could be adversely affected.

We may operate or support patient services and assistance programs, and government scrutiny of these activities could require us to curtail such programs, reducing patient access and adversely affecting demand for our products.

We may operate or support patient services, including product access hubs, patient assistance programs, or programs that help patients address out-of-pocket costs. Government authorities have increased scrutiny of these activities, including our interactions with third-party service providers and independent charitable foundations, and the application of fraud and abuse laws to certain patient support arrangements. Evolving guidance, audits, investigations or enforcement actions could require us to modify, curtail or discontinue some of these programs or arrangements. If patient services or assistance programs are reduced or not available on terms that support patient access, patients may be unable to afford our products, prescription abandonment may increase, and demand and net sales could decline. Investigations or enforcement actions could also result in significant costs, penalties, settlements, or reputational harm.

If we obtain or seek marketing authorizations and commercialization outside the United States, we may be subject to pricing controls and health technology assessment processes that could delay commercialization and reduce net prices.

If we obtain or seek marketing authorizations and commercialization in jurisdictions outside the United States, we may be subject to national price controls, reimbursement reviews, reference pricing, and health technology assessment ("HTA") processes that can delay launch timing, require additional comparative effectiveness or other evidence, and reduce the net prices we realize. For example, in the European Union, HTA reforms are being implemented on a phased basis and may include Joint Clinical Assessments for certain products, which could increase evidentiary requirements and affect

timing and pricing negotiations. Any delay or reduction in reimbursement or pricing in non-U.S. markets could adversely affect our revenues and profitability.

Risks Relating to Our Business

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

As our development and commercialization plans and strategies develop, we may need to expand the size of our employee and consultant/contractor base. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize our product candidates and any other future product candidates and our ability to compete effectively will depend, in part, on our ability to effectively manage our future growth.

We focus on rare diseases, which may create additional risks and challenges, including that the target patient populations of our products and product candidates may be small.

Because we focus on developing drugs as treatments for rare diseases, we may seek orphan drug, breakthrough therapy or fast track designations for our product candidates. Often, regulatory authorities have broad discretion in determining whether or not to grant such designations. We cannot guarantee that our product candidates will receive orphan drug status from the FDA or equivalent designations from other regulatory authorities. Even with an orphan drug designation for our current and potential future product candidates, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for an existing or future product candidate, that exclusivity may not effectively protect the product from competition.

We also cannot guarantee that we will receive breakthrough therapy, fast track, or equivalent designations, which provide certain potential benefits such as more frequent meetings with the applicable regulatory authorities to discuss development plans, intensive guidance on efficient drug development programs, and potential eligibility for rolling review or priority review. Even if we are successful in obtaining any such designations for our product candidates, such designations may not lead to faster development or regulatory review or approval and do not increase the likelihood that our product candidates will receive marketing approval. We may not be able to obtain or maintain these designations for our product candidates that receive them, and our competitors may obtain these designations for their product candidates, which could impact our ability to develop and commercialize our products and product candidates or compete with such competitors, which may adversely impact our business, financial condition or results of operations.

Given the small number of patients who have the diseases that we are targeting, it is critical to our ability to grow and become profitable that we continue to successfully identify patients with these rare diseases. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our products and product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for each of our products and product candidates may be limited or may not be amenable to treatment with our products and product candidates, and new patients may become increasingly difficult to identify or access. Further, even if we obtain significant market share for our products and product candidates, because the potential target populations are small, we may struggle to remain profitable or generate sufficient revenue growth to sustain our business.

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

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

- decreased demand for our current products or any of our product candidates or any future products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;

- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- the inability to commercialize some or all of our product candidates; and
- a decline in the value of our stock.

We carry product liability insurance we consider adequate for our current level of expected product sales, clinical testing and product development. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our approved products or additional products we develop. Although we will endeavor to obtain and maintain such insurance in coverage amounts which we deem adequate, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

We may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

Significant disruptions of IT systems or breaches of information security could adversely affect our business. Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. We rely on technology developed, supplied, and/or maintained by third parties that may make us vulnerable to "supply chain" style cyber-attacks. System failures, accidents or security breaches could cause interruptions in our operations, and result in a material disruption of our product development and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. Cybersecurity attacks in particular are evolving and include, but are not limited to, malicious software, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in systems, misappropriation of our confidential or otherwise protected information and corruption of data. The loss, theft or sabotage of product development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs and the development of our product candidates could be delayed. Any technology service interruption or breach of our systems could adversely affect our business operations and/or result in the loss of personal data, confidential information or intellectual property. Such incidents require disclosure to government authorities and/or regulators and any incident could result in financial, legal, business and reputational harm to us. We are also subject to evolving cybersecurity disclosure and reporting requirements, included those adopted by the SEC, and any cybersecurity incident could require us to make public disclosures and could result in regulatory scrutiny or litigation, increase our costs, and harm our reputation. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems. For additional information regarding our cybersecurity risk management, third-party oversight, incident response processes, and board and committee oversight, see Item 1C, "Cybersecurity—Risk Management and Strategy."

Use of artificial intelligence-based software by us or third parties with which we contract, may lead to the release of confidential information which may impact our ability to realize the benefits of our intellectual property.

Artificial intelligence-based software is increasingly being used in the biopharmaceutical and healthcare industries. As with many developing technologies, artificial intelligence-based software presents risks and challenges. For example, algorithms may be flawed, data sets may be insufficient, of poor quality, or contain biased information; and inappropriate or controversial data practices by data scientists, engineers, and end-users could impair results. If the analyses that artificial intelligence-based applications assist in producing are deficient or inaccurate, we could be subjected to competitive harm, potential legal liability and brand or reputational harm. Furthermore, use of artificial intelligence-based software by us or third parties with which we contract, may lead to the release of confidential information which may impact our ability to realize the benefits of our intellectual property and could negatively impact our competitive position, financial condition, results of operations and prospects.

Sales of counterfeits of any of our product candidates, as well as unauthorized sales of any of our product candidates, may have adverse effects on our revenues, business and results of operations and damage our brand and reputation.

Our current approved products or our new product candidates may become subject to competition from counterfeit pharmaceutical products, which are pharmaceutical products sold under the same or very similar brand names and/or having a similar appearance to genuine products, but which are sold without proper licenses or approvals. Such products divert sales from genuine products, often are of lower cost, often are of lower quality (having different ingredients or formulations, for example), and have the potential to damage the reputation for quality and effectiveness of the genuine product. Obtaining regulatory approval for our product candidates is a complex and lengthy process. If during the period while the regulatory approval is pending, illegal sales of counterfeit products begin, consumers may buy such counterfeit products, which could have an adverse impact on our revenues, business and results of operations. In addition, if illegal sales of counterfeits result in adverse side effects to consumers, we may be associated with any negative publicity resulting from such incidents. Although pharmaceutical regulation, control and enforcement systems throughout the world have been increasingly active in policing counterfeit pharmaceuticals, we may not be able to prevent third parties from manufacturing, selling or purporting to sell counterfeit products competing with our current products or our new product candidates. Such sales may also be occurring without our knowledge. The existence and any increase in production or sales of counterfeit products or unauthorized sales could negatively impact our revenues, brand reputation, business and results of operations.

Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization

We depend entirely on the success of current approved products and our new product candidates. If we are unable to generate revenues from our approved products and new product candidates, our ability to create stockholder value will be limited.

We may not be successful in obtaining acceptance from the FDA or comparable foreign regulatory authorities to start our clinical trials. If we do not obtain such acceptance, the time in which we expect to commence clinical programs for any product candidate will be extended and such extension will increase our expenses and increase our need for additional capital. Moreover, there is no guarantee that our clinical trials will be successful or that we will continue clinical development in support of additional product approvals from the FDA or comparable foreign regulatory authorities for any indication. We note that most product candidates never reach the clinical development stage and even those that do commence clinical development have only a small chance of successfully completing clinical development and gaining regulatory approval. Therefore, our business depends entirely on the successful development, regulatory approval and commercialization of our product candidates, which may never occur.

We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have existing competitors and potential new competitors in a number of jurisdictions, many of which have or will have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have. Established competitors may invest heavily to quickly discover and develop novel compounds that could make any of our product candidates obsolete or uneconomical. In addition, mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors, potentially reducing or eliminating our commercial opportunity. Furthermore, such potential competitors may enter the market before us, and their products may be designed to circumvent our pending patent applications and any patents we may receive. They may also challenge, narrow or invalidate any granted patents or our patent applications, and such patents and patent applications may fail to provide adequate protection for our product candidates. Any new product that competes with an approved product may need to demonstrate compelling advantages in efficacy, cost, convenience, tolerability and safety to be commercially successful. Other competitive factors, including generic competition, could force us to lower prices or could result in reduced sales. In addition, new products developed by others could emerge as competitors to our product candidates. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

We face substantial competition, which may result in others discovering, developing and commercializing products before or more successfully than our product candidates.

The development and commercialization of new drugs is highly competitive. We face competition (from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide) 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. We compete directly with companies that focus on 505(b)(2) and generic drugs, and companies dedicating their resources to novel forms of therapies for these indications. Many of these competitors are attempting to develop products for our target indications. We face the risk that our competitors will develop a competing product using the same 505(b)(2) pathway that we intend to pursue. Our business model is to focus on product candidates that we consider to have a shorter timeline to, and lower cost of, regulatory approval. These attributes can also be taken advantage of by our competitors to develop and obtain marketing approval for a competing product. In addition, following FDA approval of our product candidates for which we have no patent protection, our competitors may seek to develop a competing product pursuant to the 505(j) pathway, which is an abbreviated pathway used for the regulatory approval of generic product candidates. As a result of the foregoing, we may find that the market opportunity for our product candidates for which we have no patent protection is relatively small due to the fact that barriers to entry are low and generic competition may follow within relatively short time periods after our product is approved. With the proliferation of new drugs and therapies in these areas, we expect to face increasingly intense competition as new technologies become available. Any product candidates that we successfully develop and commercialize will compete with existing products and new products that may become available in the future.

There are products already approved for all of the indications we are targeting. Many of these approved products are well established therapies and are widely accepted by physicians, patients and third-party payors. This may make it difficult for us to achieve our business strategy of replacing existing products with our product candidates. In addition, where we are able to offer benefits over existing products offered by our competitors, those competitors may reformulate their drugs in a manner that mimics the benefits offered by our product candidates. As noted below, many of our product candidates are not eligible for patent protection or the market and data exclusivity provisions under the FDCA. Consequently, our commercial operations face significant direct competition and our competitors may develop products that are similar to ours and perhaps safer, more effective, more convenient or less costly than any that we are developing or that would render our product candidates obsolete or non-competitive. Our inability to successfully compete could negatively impact our business, results of operations and stock price.

Our competitors may obtain FDA or other regulatory approval for comparable products more rapidly than we may obtain approval for ours, and the risk of our competitors doing so may lead us to develop drug candidates without disclosing certain information with regard to such candidates.

The FDCA provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA, or supplement to an existing NDA or 505(b)(2) NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, (e.g., for new indications, dosages, strengths or dosage forms of an existing drug). Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. As a result, many of our competitors have the ability to bring a product candidate to market more rapidly than we can and depending on the nature of their product candidate they could substantially delay the introduction of our product candidate into the market if their product qualifies for the market and data exclusivity provisions under the FDCA. In order to preserve any competitive advantage, we will, at times, make the decision to pursue a product candidate for which we will not disclose the API, dosage or reference drug until such time as we believe that any competitive advantage would not be materially compromised by public disclosure of such information, which in some cases may be as late as our receipt of marketing approval from the FDA. Our business currently depends on our ability to bring our product candidates to market in a manner that preserves our perceived competitive advantage, and any loss of that competitive advantage could negatively impact our business, results of operations and stock price.

If we are not able to obtain any required regulatory approvals for our product candidates, we will not be able to commercialize our product candidate and our ability to generate revenue will be limited.

We may be required to successfully complete clinical trials for our product candidates before we can apply for marketing approval. Even if we complete any such clinical trials, it does not assure marketing approval. Any such clinical trials may be unsuccessful, which would materially harm our business. Even if such initial clinical trials are successful, we may be required to conduct additional clinical trials to establish our product candidates' safety and efficacy before an NDA or foreign equivalents can be submitted to the FDA or comparable foreign regulatory authorities for marketing approval of our product candidates.

Our success depends on the receipt of regulatory approval and the issuance of such regulatory approvals is uncertain and subject to a number of risks, including the following:

- the results of any required toxicology studies may not support the submission of an IND for our product candidates;
- the FDA or comparable foreign regulatory authorities or Institutional Review Boards ("IRB"), may disagree with the design or implementation of our clinical trials;
- we may not be able to provide acceptable evidence of our product candidates' safety and efficacy;
- the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA or other regulatory agencies for marketing approval;
- the dosing of our product candidates in any required clinical trial may not be at an optimal level;
- the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA or other regulatory agencies for marketing approval;
- the dosing of our product candidates in any required clinical trial may not be at an optimal level;
- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to our product candidates;
- the data collected from clinical trials may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for approval.

Failure to obtain regulatory approval for our product candidates for the foregoing, or any other reasons, will prevent us from commercializing our product candidates, and our ability to generate sufficient revenue will be materially impaired. We cannot guarantee that regulators will agree with our assessment of the results of the clinical trials we intend to conduct in the future or that such trials will be successful. The FDA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional clinical trials, or pre-clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of our product candidates.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the product candidates involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of the regulatory authorities. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application may cause delays in the approval or rejection of an application. Regulatory approval obtained in one jurisdiction does not necessarily mean that a product candidate will receive regulatory approval in all jurisdictions in which we may seek approval, but the failure to obtain approval in one jurisdiction may negatively impact our ability to seek approval in a different jurisdiction. Failure to obtain regulatory marketing approval for our product candidates will prevent us from commercializing the product candidate, and our ability to generate sufficient revenue will be materially impaired.

If the FDA does not conclude that our product candidates satisfy the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of any of our product candidates under Section 505(b)(2) are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.

We intend to seek FDA approval through the 505(b)(2) regulatory pathway for the majority of our product candidates. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant. If the FDA does not allow us to pursue the 505(b)(2) regulatory pathway for our product candidates as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates would likely substantially increase. Moreover, the inability to pursue the 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than our product candidates, which could materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the 505(b)(2) regulatory pathway for a product candidate, we cannot assure you that we will receive the requisite or timely approvals for commercialization of such product candidate. For example, we had under development a patented injectable pentoxifylline therapeutic candidate, which we believed would satisfy the requirements of the 505(b)(2) regulatory pathway. However, based on a pre-IND meeting with the FDA in March 2018 to discuss the clinical and regulatory pathway for the product, we decided to suspend all further development activities for this candidate indefinitely due to extraordinarily high costs of the clinical trials that would be required by the FDA.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2) to allow reliance on the FDA's prior findings of safety and effectiveness. If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) application that we submit. In addition, we expect that our competitors will file citizens' petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

Moreover, the FDA recently adopted an interpretation of the three-year exclusivity provisions whereby a 505(b)(2) application can be blocked by exclusivity even if does not rely on the previously approved drug that has exclusivity (or any safety or effectiveness information regarding that drug). Under the FDA's new interpretation, approval may be blocked by exclusivity awarded to a previously-approved drug product that shares certain innovative features with our product, even if our 505(b)(2) application does not identify the previously-approved drug product as a listed drug or rely upon any of its safety or efficacy data. Any failure to obtain regulatory approval of our product candidates would significantly limit our ability to generate sufficient revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

An NDA submitted under Section 505(b)(2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of our product candidate.

The 505(b)(2) application would enable us to reference published literature or the FDA's previous findings of safety and effectiveness for the branded reference drug. For NDAs submitted under Section 505(b)(2) of the FDCA, the patent certification and related provisions of the Hatch-Waxman Act apply. In accordance with Hatch-Waxman Act, in seeking approval for a drug through such an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct or submit results of pre-clinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that either: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

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 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. Under the Hatch-Waxman Act, the holder of patents that the 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the Paragraph IV certification. Filing of a patent infringement lawsuit against the filer of the 505(b)(2) applicant within 45 days of the patent owner's receipt of notice triggers a one-time, automatic, 30-month stay of the FDA's ability to approve the 505(b)(2) NDA, unless patent litigation is resolved in favor of the Paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all.

In addition, a 505(b)(2) application will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity listed in the Orange Book for the referenced product has expired. The FDA may also require us to perform one or more additional clinical studies or measurements to support the change from the branded reference drug, which could be time-consuming and could substantially delay our achievement of regulatory approvals for such product candidates. The FDA may also reject our future 505(b)(2) submissions and require us to file such submissions under Section 505(b)(1) of the FDCA, which would require us to provide extensive data to establish safety and effectiveness of the drug for the proposed use and could cause delay and be considerably more expensive and time-consuming. These factors, among others, may limit our ability to successfully commercialize our product candidates.

Companies that produce branded reference drugs routinely bring litigation against ANDA or 505(b)(2) applicants that seek regulatory approval to manufacture and market generic and reformulated forms of their branded products. These companies often allege patent infringement or other violations of intellectual property rights as the basis for filing suit against an ANDA or 505(b)(2) applicant. Likewise, patent holders may bring patent infringement suits against companies that are currently marketing and selling their approved generic or reformulated products. Litigation to enforce or defend intellectual property rights is often complex and often involves significant expense and can delay or prevent introduction or sale of our product candidates. If patents are held to be valid and infringed by our product candidates in a particular jurisdiction, we would, unless we could obtain a license from the patent holder, be required to cease selling in that jurisdiction and may need to relinquish or destroy existing stock in that jurisdiction. There may also be situations where we use our business judgment and decide to market and sell our approved products, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts, which is known as an "at-risk launch." The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement may include, among other things, damages measured by the profits lost by the patent owner and not necessarily by the profits earned by the infringer. In the case of a willful infringement, the definition of which is subjective, such damages may be increased up to three times. Moreover, because of the discount pricing typically involved with bioequivalent and, to a lesser extent, 505(b)(2) products, patented branded products generally realize a substantially higher profit margin than bioequivalent and, to a lesser extent, 505(b)(2) products, resulting in disproportionate damages compared to any profits earned by the infringer. An adverse decision in patent litigation could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Even if we receive regulatory approval for our additional product candidates, we may not be able to successfully commercialize these products, and the revenue that we generate from those sales, if any, may be limited.

If approved for marketing, the commercial success of our product candidates will depend upon each product's acceptance by the medical community, including physicians, patients and health-care payors. The degree of market acceptance for any of our product candidates will depend on a number of factors, including:

- demonstration of clinical safety and efficacy;
- relative convenience, dosing burden and ease of administration;
- the willingness of physicians to prescribe our product candidates, and the target patient population to try new therapies;
- efficacy of our product candidates compared to competing products;
- the introduction of any new products that may in the future become available targeting indications for which our product candidates may be approved;
- new procedures or therapies that may reduce the incidences of any of the indications in which our product candidates may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of our product candidates in applicable therapeutic and vaccine guidelines;
- the effectiveness of our own or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in approved labeling from regulatory authorities;
- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors or to receive the necessary pricing approvals from government bodies regulating the pricing and usage of therapeutics; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or adequate reimbursement or government pricing approvals.

If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, health care payors, and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

In addition, even if we obtain regulatory approvals for our product candidates, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our product candidates successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our product candidates not commercially viable. For example, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for any of our product candidates, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve any of our product candidates with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that indication. Further, the FDA or comparable foreign regulatory authorities may place conditions on approvals or require risk management plans or a REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA may also require a REMS for an approved product when new safety information emerges. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of our product candidates. Moreover, product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of our product candidates.

We are subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates could be subject to labeling and other restrictions and 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 product candidates.

The FDA or foreign equivalent may still impose significant restrictions on our products indicated uses or the conditions of approval, or impose ongoing requirements for potentially costly and time-consuming post-approval studies, including Phase 4 clinical trials, and post-market surveillance to monitor safety and efficacy. Our product candidates will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post-market information. These requirements include registration with the FDA, as well as continued compliance with current GCP regulations for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with GMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents.

The FDA has the authority to require a REMS as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring patient testing, monitoring and/or enrollment in a registry.

With respect to sales and marketing activities by us or any future partner, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state and local laws in the United States and similar legal requirements in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

In addition, if any of our product candidates are approved for a particular indication, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with the product's approved FDA labeling. If we receive marketing approval for our product candidates, physicians may nevertheless legally prescribe our products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. 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 sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed.

If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, problems with the facility where the product is manufactured, or we or our manufacturers fail to comply with applicable regulatory requirements, we may be subject to the following administrative or judicial sanctions:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- issuance of warning letters or untitled letters;
- clinical holds;
- injunctions or the imposition of civil or criminal penalties or monetary fines;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical trials;

- refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;

- suspension or imposition of restrictions on operations, including costly new manufacturing requirements; or

- product seizure or detention or refusal to permit the import or export of product.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure.

We are subject to Drug Supply Chain Security Act requirements, and failure to comply could disrupt our distribution and result in enforcement action.

We are subject to requirements under the Drug Supply Chain Security Act ("DSCSA") and related state and federal laws governing the pharmaceutical distribution supply chain. These requirements include, among other things, product identification and serialization, interoperable product tracing, verification of certain products, and prompt investigation and disposition of suspect or illegitimate product. Compliance with DSCSA requires coordination with our third-party manufacturers, wholesalers, distributors and other trading partners and may require changes to our systems, processes and contractual arrangements, as well as ongoing investment. If we or our trading partners fail to maintain DSCSA-compliant systems and processes, or if we do not identify and respond appropriately to suspect or illegitimate product, our distribution could be disrupted, we could face product holds, recalls or shortages, and we could be subject to enforcement action, fines, penalties or reputational harm, any of which could adversely affect our business and results of operations.

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

Significant additional labeling or warning requirements or limitations on the availability of our products may inhibit sales of affected products.

Various jurisdictions may seek to adopt significant additional product labeling or warning requirements or limitations on the availability of our products relating to the content or perceived adverse health consequences of our products. Federal laws may preempt some or all of these attempts by state or localities to impose additional labeling or warning requirements. If these types of requirements become applicable to our products under current or future environmental or health laws or regulations, they may inhibit sales of our products. Moreover, if we fail to meet compliance deadlines for any such new requirements, our products may be deemed misbranded or mislabeled and could be subject to enforcement action, or we could be exposed to private lawsuits alleging misleading labels or product promotion.

Changes in U.S. trade policy, threats of international tariffs, and changes to the U.S. political landscape may adversely affect our business, results of operations, financial condition, and prospects.

Rising threats of international tariffs, including tariffs applied to goods traded between the U.S. and Canada, Mexico, Europe and other international markets, could materially and adversely affect our business, results of operations, financial condition, and prospects. Over the past several years, legislative and executive action from U.S. and foreign leaders has led to both threats of and the imposition of tariffs on certain materials and products, including pharmaceutical products. Changes in U.S. relations with these international trading partners, including the current trade tensions, are difficult to predict and could adversely affect our operations or financial condition. We cannot predict the extent to which the U.S. or other countries will impose quotas, duties, tariffs, taxes or other similar restrictions upon the import or export of our products in the future, nor can we predict future trade policy or the terms of any renegotiated trade agreements and their impact on our business. The adoption and expansion of trade restrictions, the occurrence of a trade war, or other governmental action related to tariffs or trade agreements or policies has the potential to adversely impact demand for our products, our costs, our customers, our suppliers, and the U.S. economy, which in turn could have a material adverse effect on our business, results of operations, financial condition, and prospects.

If we market our existing approved products or any of our new product candidates in a manner that violates health care fraud and abuse laws, we may be subject to civil or criminal penalties.

The FDA enforces laws and regulations, which require that the promotion of pharmaceutical products be consistent with the approved prescribing information. While physicians may prescribe an approved product for a so-called "off label" use, it is unlawful for a pharmaceutical company to promote its products in a manner that is inconsistent with its approved label and any company which engages in such conduct can be subject to significant liability. Similarly, industry codes in the EU and other foreign jurisdictions prohibit companies from engaging in off-label promotion and regulatory agencies in various countries enforce violations of the code with civil penalties. While we intend to ensure that our promotional materials are consistent with our label, regulatory agencies may disagree with our assessment and may issue untitled letters, warning letters or may institute other civil or criminal enforcement proceedings. In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal health care fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include, among others, the U.S. Anti-Kickback Statute, U.S. False Claims Act and similar state laws. Because of the breadth of these laws and the narrowness of their exceptions and safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

The U.S. Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid or other federally financed health care programs. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, formulary managers, and others on the other hand. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not, in all cases, meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, recent health care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amended the intent requirement of the U.S. Anti-Kickback Statute and other criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of the statutes or specific intent to violate them in order to have committed a violation. In addition, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the U.S. Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the U.S. False Claims Act. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid.

Over the past few years, several pharmaceutical and other health care companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly 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 that caused claims to be submitted to Medicare or Medicaid for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the U.S. Anti-Kickback Statute and the U.S. False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include significant administrative, criminal, and civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, fines and imprisonment. Due to the breadth of these federal and state anti-kickback laws, and the potential for additional legal or regulatory change in this area, it is possible that our future business activities, including our sales and marketing practices and/or our future relationships with physicians and the medical community might be challenged under anti-kickback laws, which could harm us.

We are completely dependent on third parties to manufacture our approved products and new product candidates, and our commercialization of our product candidates could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture the API in our product candidates for use in our clinical trials or for commercial product, if any. In addition, we do not have the capability to encapsulate any of our product candidates as a finished drug product for commercial distribution. As a result, we will be obligated to rely on contract manufacturers, if and when any of our product candidates are approved for commercialization. While we have entered into certain agreements with contract manufacturers for clinical and commercial supply, there can be no assurance we will be able to maintain those relationships or engage additional contract manufacturers for clinical or commercial supply of any of our product candidates on favorable terms to us, or at all.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or comparable foreign regulatory authorities pursuant to inspections that will be conducted after we submit an NDA to the FDA or their equivalents to other relevant regulatory authorities. We will not control the manufacturing process of, and will be completely dependent on, our contract manufacturing partners for compliance with GMPs for manufacture of both active drug substances and finished drug products. These GMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to our product candidates. If our contract manufacturers do not successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with GMPs and similar regulatory requirements. We will not have control over our contract manufacturers' compliance with these regulations and standards. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market any of our product candidates, delays, suspensions or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we will not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to develop, obtain regulatory approval for or market any of our product candidates.

If, for any reason, these third parties are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our API or finished products or should cease doing business with us, we could experience significant interruptions in the supply of any of our product candidates or may not be able to create a supply of our product candidates at all. Were we to encounter manufacturing issues, our ability to produce a sufficient supply of any of our product candidates might be negatively affected. Our inability to coordinate the efforts of our third-party manufacturing partners, or the lack of capacity available at our third-party manufacturing partners, could impair our ability to supply any of our product candidates at required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk or finished product manufacturer, if we face these or other difficulties with our current manufacturing partners, we could experience significant interruptions in the supply of any of our product candidates if we decided to transfer the manufacture of any of our product candidates to one or more alternative manufacturers in an effort to deal with the difficulties.

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to a contract manufacturer caused by problems at suppliers could delay shipment of any of our approved products or product candidates in development, increase our cost of goods sold and result in lost sales.

We cannot guarantee that our future manufacturing and supply partners will be able to reduce the costs of commercial-scale manufacturing of any of our product candidates over time. If the commercial-scale manufacturing costs of any of our product candidates are higher than expected, these costs may significantly impact our operating results. In order to reduce costs, we may need to develop and implement process improvements. However, in order to do so, we will need, from time to time, to notify or make submissions with regulatory authorities, and the improvements may be subject to approval by such regulatory authorities. We cannot be sure that we will receive these necessary approvals or that these approvals will be granted in a timely fashion. We also cannot guarantee that we will be able to enhance and optimize output in our commercial manufacturing process. If we cannot enhance and optimize output, we may not be able to reduce our costs over time.

We may also rely on single-source or limited-source suppliers and contract manufacturers for certain products, and certain raw materials, intermediates or finished products may be sourced from or manufactured in locations outside the United States. Supply-chain disruptions, capacity constraints, quality issues, natural disasters, cyber incidents, labor disruptions, geopolitical developments, export controls, sanctions, trade restrictions or other government actions (including actions that could restrict the ability of U.S. companies to use certain foreign contract manufacturers or suppliers) could limit our ability to obtain materials or manufacture and distribute our products and product candidates. Although we seek to identify and qualify alternative suppliers and manufacturing sites where feasible, qualifying and transferring manufacturing to a new supplier or site can be time-consuming and costly, may require regulatory submissions and approval, and may not be successful on our anticipated timelines or at all.

We have concentration risk within our supply chain, including reliance on single- or sole-source suppliers and contract manufacturers, and certain raw materials, intermediates, components or finished products may be sourced from, processed in, or otherwise dependent on suppliers located in the People's Republic of China or other higher-risk geographies. Legislative or executive actions, export controls, sanctions, or other government measures, including measures that could be adopted in the United States restricting the use of certain foreign contract manufacturers or suppliers, could materially impair our ability to qualify, audit, access or continue to use affected suppliers, increase our costs and timelines, or require us to identify and qualify second-site manufacturing. Qualifying and transferring to an alternative supplier or site can be time-consuming and costly, may require regulatory submissions and approvals, entail technology transfer and validation activities, and may not be successful on our anticipated timelines or at all. If we are required to identify and qualify an alternative supplier or manufacturing site, or to implement redundant supply, we could experience delays, increased cost of goods, supply interruptions or shortages, and adverse impacts on our development and commercialization plans.

We may not be able to establish agreements with third parties with whom we wish to collaborate and, if we are able to establish them, we may not be able to establish them on commercially reasonable terms, which could result in alterations or delays of our development and commercialization plans.

We face significant competition in seeking appropriate third parties to assist us in our business operations. Whether we reach a definitive agreement will depend, among other things, upon our assessment of the third parties' resources and expertise, the terms and conditions of the proposed agreement, and the proposed parties' evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. Potential third parties may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. The terms of any arrangements that we may establish may also not be favorable to us.

Agreements with third parties are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future third parties to assist us in our business operations. We may not be able to negotiate agreements on a timely basis, on acceptable terms or at all. If we are unable to do so, we may have to curtail the development of the product candidate, reduce or delay its development program, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidate or bring it to market and generate product revenue.

In addition, any future agreements that we enter into may not be successful. The success of our arrangements will depend heavily on the efforts and activities of our third-party collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to an agreement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the agreement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

We may need to rely on third parties to conduct clinical trials for our future product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize any of our product candidates and our business would be substantially harmed.

We have entered into agreements with third-party CROs to conduct and manage our clinical programs including contracting with clinical sites to perform our clinical studies. We plan to rely heavily on these parties for execution of clinical studies for our product candidates and will control only certain aspects of their activities. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs and clinical sites will not relieve us of our regulatory responsibilities. We and our CROs will be required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for any products in clinical development. The FDA and its foreign equivalents enforce these GCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA or other regulatory authorities will determine that any of our clinical trials comply with GCPs. In addition, our clinical trials must be conducted with products produced under GMP regulations and will require a large number of test subjects. Our failure or the failure of our CROs or clinical sites to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

Although we intend to design the clinical trials for our product candidates in consultation with CROs, we expect that the CROs will manage all of the clinical trials conducted at contracted clinical sites. As a result, many important aspects of our drug development programs would be outside of our direct control. In addition, the CROs and clinical sites may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements. If the CROs or clinical sites do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of any of our product candidates for the subject indication may be delayed or our development program materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs and clinical sites will devote to our program or any of our product candidates. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of our clinical trials, which could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs or clinical sites terminate, we may not be able to enter into arrangements with alternative CROs or clinical sites. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any such clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for any of our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

We enter into various contracts in the normal course of our business, some or all of which may require us to indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have an adverse effect on our business, financial condition and results of operations.

In the normal course of business, we periodically may enter into commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our commercial agreements, vendors typically ask for indemnification from any third-party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party. Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a third party to indemnify us and the party is denied insurance coverage, or the indemnification obligation exceeds the applicable insurance coverage and does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

Any termination or suspension of, or delays in the commencement or completion of, any necessary studies of any of our product candidates for any indications could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

The commencement and completion of clinical studies can be delayed for a number of reasons, including delays related to:

- the FDA or a comparable foreign regulatory authority failing to grant permission to proceed and placing the clinical study on hold;
- subjects for clinical testing failing to enroll or remain in our trials at the rate we expect;
- a facility manufacturing any of our product candidates being ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of GMP requirements or other applicable requirements, or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- subjects choosing an alternative treatment for the indications for which we are developing our product candidates, or participating in competing clinical studies;
- subjects experiencing severe or unexpected drug-related adverse effects;
- reports from clinical testing on similar technologies and products raising safety and/or efficacy concerns;
- third-party clinical investigators losing their license or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or employing methods consistent with the clinical trial protocol, GMP requirements, or other third parties not performing data collection and analysis in a timely or accurate manner;
- inspections of clinical study sites by the FDA, comparable foreign regulatory authorities, or IRBs finding regulatory violations that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study, or that prohibit us from using some or all of the data in support of our marketing applications;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications;
- one or more IRBs refusing to approve, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- deviations of the clinical sites from trial protocols or dropping out of a trial;
- adding new clinical trial sites;
- the inability of the CRO to execute any clinical trials for any reason; and
- government or regulatory delays or “clinical holds” requiring suspension or termination of a trial.

Product development costs for any of our product candidates will increase if we have delays in testing or approval or if we need to perform more or larger clinical studies than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit our study protocols to the FDA, comparable foreign regulatory authorities, and IRBs for reexamination, which may impact the costs, timing or successful completion of that study. If we experience delays in completion of, or if we, the FDA or other regulatory authorities, the IRB, or other reviewing entities, or any of our clinical study sites suspend or terminate any of our clinical studies of any of our product candidates, its commercial prospects may be materially harmed and our ability to generate sufficient product revenues will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to generate sufficient revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical studies may also ultimately lead to the denial of regulatory approval of our product candidates. In addition, if one or more clinical studies are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of any of our product candidates could be significantly reduced.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing of drug product candidates is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical studies and early clinical trials may not be predictive of the results of later-stage clinical trials. We cannot assure you that the FDA or comparable foreign regulatory authorities will view the results as we do or that any future trials of any of our product candidates will achieve positive results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Any future clinical trial results for our product candidates may not be successful.

In addition, a number of factors could contribute to a lack of favorable safety and efficacy results for any of our product candidates. For example, such trials could result in increased variability due to varying site characteristics, such as local standards of care, differences in evaluation period and surgical technique, and due to varying patient characteristics including demographic factors and health status.

We may need to conduct clinical trials for our new product candidates and we may be delayed in commercializing or fail to find success in these trials. Further, the results of any clinical trial may not be predictive of future trial results. Positive results in preclinical testing and early clinical trials do not ensure that later clinical trials will be successful. A number of pharmaceutical companies have suffered significant setbacks in clinical trials, including in Phase 3, after promising results in preclinical testing and early clinical trials. These setbacks have included negative safety and efficacy observations in later clinical trials, including previously unreported adverse events.

Phase 3 clinical trials often produce unsatisfactory results even though prior clinical trials were successful. Moreover, the results of clinical trials may be unsatisfactory to the FDA or foreign regulatory authorities even if we believe those clinical trials to be successful. The FDA or applicable foreign regulatory agencies may suspend one or all of our clinical trials or require that we conduct additional clinical, nonclinical, manufacturing, validation or drug product quality studies and submit that data before considering or reconsidering any NDA or similar foreign regulatory application we may submit. Depending on the extent of these additional studies, approval of any applications that we submit may be significantly delayed or may require us to expend more resources than we have available. It is also possible that additional studies we conduct may not be considered sufficient by the FDA or applicable foreign regulatory agencies to provide regulatory approval.

If any of these outcomes occur, we may not receive approval for our product candidates, which could negatively impact our business, financial condition, or results of operations.

We are subject to extensive laws and regulations related to data privacy, and our failure to comply with these laws and regulations could harm our business.

We are subject to data privacy and security laws and regulations by both the federal government and the states in which we conduct our business. HIPAA and their respective implementing regulations, including the Final Omnibus Rule published on January 25, 2013, govern our processing of personal data, including the collection, access, use, analysis, modification, storage, transfer, security breach notification, destruction and disposal of personal data. There are foreign and state law versions of these laws and regulations to which we are currently and/or may in the future, be subject. For example, the collection and use of personal health data in the European Union is governed by the GDPR. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States, provides an enforcement authority and imposes large monetary penalties for noncompliance. The GDPR requirements apply not only to third-party transactions, but also to transfers of information within our company, including employee information.

In the United States, there are numerous privacy laws that may be applicable to our activities, and a range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. New laws also are being considered or have been implemented at both the state and federal levels. For example, the California Consumer Privacy Act of 2018 (effective on January 1, 2020), as amended by the California Privacy Rights and Enforcement Act of 2020 (effective on January 1, 2023) ("CCPA"), requires companies that process information of California residents ("consumers," as defined under the CCPA) to make specific disclosures about their data collection, use and disclosure practices, provides consumers with individual data privacy rights, including enabling consumers to limit the use of their sensitive personal information, imposes new operational requirements for covered businesses, imposes data retention limitations, provides a private right of action for data breaches, creates a statutory damages framework and creates a new state agency, the California Privacy Protection Agency, that is vested with the authority to implement and enforce the CCPA. Although there are limited exemptions for clinical trial data under the CCPA, the CCPA and other similar laws could impact our business activities in the future depending on our revenue growth, how much consumer data we process, and how such laws are interpreted. Additionally, four additional states have enacted privacy laws, which could increase our potential liability and adversely affect our business in the future. In particular, the Virginia Consumer Data Protection Act ("VCDPA") became effective on January 1, 2023; the Colorado Privacy Act ("CPA") and the Connecticut Data Privacy Act ("CTDPA") became effective on July 1, 2023; and the Utah Consumer Privacy Act ("UCPA") became effective on December 31, 2023. While these regulations incorporate many similar concepts to the CCPA, there are also several key differences in their scope, application, and enforcement that will, among other things, impact how regulated businesses collect and process personal sensitive data, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests. Other states are considering similar legislation and a broad range of legislative measures also have been introduced at the federal level. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country makes our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

Further, regulations promulgated pursuant to HIPAA impose privacy, security and breach notification obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities, and their covered subcontractors. HIPAA establishes privacy and security standards that limit the use and disclosure of individually identifiable health information and protected health information, or PHI, and requires the implementation of administrative, physical, and technological safeguards to protect the privacy of PHI and ensure the confidentiality, integrity, and availability of electronic PHI. Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA. We do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

The global legislative and regulatory landscape for privacy and data protection continues to evolve, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to continue to increase in the future.

It is possible that privacy laws may be interpreted and applied in a manner that is inconsistent with our practices. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems. Further, any failure by our third-party collaborators, service providers, contractors or consultants to comply with applicable law, regulations or contractual obligations related to data privacy or security could result in proceedings against us by governmental entities or others.

We may also publish privacy policies and other documentation regarding our collection, processing, use and disclosure of personal information and/or other confidential information. Although we endeavor to comply with applicable regulations, our published policies and other documentation, we may at times fail to do so or may be perceived to have failed to do so. Despite our efforts, we may not be successful in achieving compliance if our employees or vendors fail to comply with our published policies and documentation. Such failures can subject us to potential international, local, state and federal action if they are found to be deceptive, unfair, or misrepresentative of our actual practices. Claims that we have violated individuals' privacy rights or failed to comply with data protection laws or applicable privacy notices, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. We also face a threat of consumer class actions related to these laws and the overall protection of personal information. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business, financial condition, results of operations or prospects.

Risks Relating to Our Intellectual Property Rights

We will depend on rights to certain pharmaceutical compounds that have been acquired by us. We do not have complete control over these pharmaceutical compounds and any loss of our rights to them could prevent us from selling our products.

We are dependent on the assignment and licensing from third parties for certain of our pharmaceutical compounds and potential product candidates. Our rights to use the pharmaceutical compounds we were assigned are subject to the negotiation of, continuation of and compliance with the terms of those assignments and licenses. Moreover, under these agreements, any related patents may remain under the control of the assignor or licensor. Our rights to develop and commercialize the product candidates are subject to the validity of the intellectual property rights. Enforcement of any assigned or licensed patents or defense or any claims asserting the invalidity of these patents is often subject to the control or cooperation of the assignor or licensor. Legal action could be initiated against the original owners of the intellectual property that we acquired and an adverse outcome in such legal action could harm our business because it might prevent such companies or institutions from continuing to assign intellectual property that we may need to operate our business.

In addition, our rights to practice the inventions claimed in any patents and patent applications are subject to our assignors and licensors abiding by the terms of those agreements and not terminating them. These agreements may be terminated by the assignor or licensor if we are in material breach of certain terms or conditions of the agreement or in certain other circumstances. Our rights under these agreements are subject to our continued compliance with the terms of the agreements, including the payment of royalties and other payment due under the agreements. Termination of these agreements could prevent us from marketing some or all of our products. Because of the complexity of our products and the patents, determining the scope of the assignment or license and related royalty obligations can be difficult and can lead to disputes between us and the assignor or licensor. An unfavorable resolution of such a dispute could lead to an increase in the royalties payable pursuant to the agreement. If the assignor or licensor believed we were not paying the royalties due under the agreement or were otherwise not in compliance with the terms of the agreement, the assignor or licensor might attempt to revoke the agreement. If such an attempt were successful, we might be barred from producing and selling some or all of our products.

It may be difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights.

Our commercial success depends, in part, on obtaining and maintaining patent protection for our technologies, products and processes, successfully defending these patents against third-party challenges and successfully enforcing these patents against third-party competitors. Proprietary rights relating to our current and potential products will be protected from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents or are effectively maintained as trade secrets. Patents owned by or licensed to us may not afford protection against competitors, and our pending patent applications now or hereafter filed by or licensed to us may not result in patents being issued.

Our patents or patent applications, or those licensed to us, if issued, may be challenged, invalidated or circumvented, and the rights granted thereunder may not provide proprietary protection or competitive advantages to us against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent, which could adversely affect our ability to protect future product development and, consequently, our operating results and financial position.

If we cannot maintain the confidentiality of our proprietary technology and other confidential information, our ability to receive patent protection and our ability to protect valuable information owned by us may be imperiled. Litigation may be necessary to assert claims of infringement, to enforce patents issued to us, to protect trade secrets or know-how owned by us, or to determine the scope and validity of the proprietary rights of others. In addition, interference, derivation, post-grant oppositions, and similar proceedings may be necessary to determine rights to inventions in our patents and patent applications. Litigation or similar proceedings could result in substantial costs to and diversion of effort by us and could have a material adverse effect on our business, financial condition and results of operations. These efforts by us may not be successful.

Additionally, if we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering any product candidate, the defendant could counterclaim that the patent covering any other product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions, e.g., opposition proceedings. Such proceedings could result in revocation or amendment of our patents or our licensors' patents in such a way that they no longer cover product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on any product candidate. Such a loss of patent protection would have a material adverse impact on our business.

We also rely on our know-how, trade secrets, and continuing technological innovation to develop and maintain our proprietary position. However, know-how and trade secrets are difficult to protect. While we require and continue to intend to require employees, academic collaborators, consultants and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary or licensed information. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may also arise as to the rights in related or resulting know-how and inventions.

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

Filing, prosecuting and defending patents on product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those offered in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

Competitors may use our technologies in jurisdictions where we do not have, or where we do not pursue and obtain, patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing.

Further, the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biotechnology. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Moreover, proceedings to enforce our patent rights, or those of our licensors or partners, in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our in-licensed patents, or any patents that we may own in the future, at risk of being invalidated or interpreted narrowly, could put our owned or in-licensed patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

If we fail to obtain or maintain patent protection or trade secret protection for our product candidates or our technologies, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and attain profitability.

We may also rely on the trademarks we may develop to distinguish our products from the products of our competitors. We cannot guarantee that any trademark applications filed by us or our business partners will be approved. Third parties may also oppose such trademark applications, or otherwise challenge our use of the trademarks. In the event that the trademarks we use are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, we cannot provide assurance that competitors will not infringe the trademarks we use, or that we will have adequate resources to enforce these trademarks.

Changes in either U.S. patent law or interpretation of such laws could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and it therefore is costly, time-consuming and inherently uncertain. In addition, on September 16, 2011, the Leahy-Smith America Invents Act ("AIA"), was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the U.S. PTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard necessary to invalidate a patent claim in the USPTO proceedings compared to the evidentiary standard in U.S. federal court, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Depending on decisions by the U.S. Congress, the federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing in-licensed patents and patents that we might obtain in the future.

Our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts.

Our success depends in part on avoiding infringement of the proprietary technologies of others. The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Identification of third-party patent rights that may be relevant to our proprietary technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Additionally, because patent applications are maintained in secrecy until the application is published, we cannot be certain that we were the first to make inventions or file for protection of inventions set forth in our patents or patent applications. There may also be issued patents and patent applications claiming subject matter that we may be required to license in order to research, develop or commercialize any of our product candidates, and we do not know if such patents and patent applications would be available to license on commercially reasonable terms, or at all. Any claims of patent infringement asserted by third parties would be time-consuming and may:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- prevent us from commercializing a product until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to cease or modify our use of the technology and/or develop non-infringing technology; or
- require us to enter into royalty or licensing agreements.

Third parties may hold proprietary rights that could prevent any of our product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to any of our product candidates or our processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market any of our product candidates or any future product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign our product candidates or any future product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing any of our product candidates or a future product candidate, which could harm our business, financial condition and operating results.

We expect that there are other companies, including major pharmaceutical companies, working in the areas competitive to our proposed product candidates which either has resulted, or may result, in the filing of patent applications that may be deemed related to our activities. If we were to challenge the validity of these or any issued U.S. patent in court, we would need to overcome a statutory presumption of validity that attaches to every issued U.S. patent. This means that, in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. If we were to challenge the validity of these or any issued U.S. patent in an administrative trial before the Patent Trial and Appeal Board in the USPTO, we would have to prove that the claims are unpatentable by a preponderance of the evidence. There is no assurance that a jury and/or court would find in our favor on questions of infringement, validity or enforceability.

Others may claim an ownership interest in our intellectual property, which could expose us to litigation and have an adverse effect on our prospects.

A third party may claim an ownership interest in one or more of our or our licensors' patents or other proprietary or intellectual property rights. A third party could bring legal actions against us and seek monetary damages and/or enjoin clinical testing, manufacturing and marketing of the affected product or products. We cannot guarantee that a third party will not assert a claim or an interest in any of such patents or intellectual property. If we become involved in any litigation, it could consume a substantial portion of our resources, and cause a significant diversion of effort by our technical and management personnel. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product, in which case we may be required to pay substantial royalties or grant cross-licenses to our patents. We cannot, however, assure you that any such license will be available on acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product candidate, or be forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is commonplace in our industry, we will employ individuals who were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject in the future to claims that our employees or prospective employees are subject to a continuing obligation to their former employers (such as non-competition or non-solicitation obligations) or claims that our employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Owning Our Common Stock

An active, liquid and orderly trading market for our shares may not continue to be developed or sustained.

Our common stock is listed on the Nasdaq Global Market. However, trading volume has been limited and a more active public market for our common stock may not develop or be sustained over time. The market price of our common stock could be subject to significant fluctuations. The price of our stock may change in response to variations in our operating results and also may change in response to other factors, including factors specific to companies in our industry many of which are beyond our control. Our shares may be less liquid than the shares of other public companies and there may be imbalances between supply and demand for our shares. As a result, our share price may experience significant volatility and may not necessarily reflect the value of our expected performance. Moreover, sales of our common stock in the public market, or the perception that such sales could occur, could negatively impact the price of our common stock. As a result, you may not be able to sell your shares of our common stock in short time periods, or possibly at all, and the price per share of our common stock may fluctuate significantly.

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

The trading price of our common stock has fluctuated significantly in the past and is likely to be volatile. The stock market in general, and early stage public companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of such companies. The stock market in general has been, and the market price of our shares in particular will likely be, subject to fluctuation, whether due to, or irrespective of, our operating results and financial condition. The market price of our shares on the Nasdaq Global Market may fluctuate as a result of a number of factors, some of which are beyond our control, including, but not limited to:

- actual or anticipated variations in our and our competitors' results of operations and financial condition;
- market acceptance of our products;
- the mix of products that we sell and related services that we provide;
- changes in earnings estimates or recommendations by securities analysts, if our shares are covered by analysts;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley Act");
- changes in earnings estimates or recommendations by securities analysts, if our shares are covered by analysts;
- development of technological innovations or new competitive products by others;
- announcements of technological innovations or new products by us;
- publication of the results of preclinical or clinical trials for our other product candidates;
- failure by us to achieve a publicly announced milestone;
- delays between our expenditures to develop and market new or enhanced products and the generation of sales from those products;
- developments concerning intellectual property rights, including our involvement in litigation brought by or against us;
- regulatory developments and the decisions of regulatory authorities as to the approval or rejection of new or modified products;
- changes in the structure of healthcare payment systems;
- changes in the amounts that we spend to develop, acquire or license new products, technologies or businesses;
- changes in our expenditures to promote our products;
- our sale or proposed sale, or the sale by our significant stockholders, of our shares or other securities in the future;
- changes in key personnel;
- success or failure of our research and development projects or those of our competitors;
- the trading volume of our shares; and
- general economic and market conditions and other factors, including factors unrelated to our operating performance.

These factors and any corresponding price fluctuations may materially and adversely affect the market price of our shares and result in substantial losses being incurred by our investors. In the past, following periods of market volatility, public company stockholders have often instituted securities class action litigation. If we were involved in securities litigation, it could impose a substantial cost upon us and divert the resources and attention of our management from our business.

We are a "smaller reporting company" and we cannot be certain if the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are a "smaller reporting company" pursuant to the Securities Exchange Act of 1934. As a smaller reporting company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not smaller reporting companies. These exemptions include, but are not limited to, presenting only two years of audited financial statements in our registration statement and annual reports on Form 10-K, selected financial data in such registration statements and annual reports, and reduced disclosure obligations on executive compensation. As a result of our reduced disclosure requirements, the information we provide stockholders will be different than the information that is available with respect to other public companies. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common shares.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm when required, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retrospective changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common shares. There is also a risk that neither we nor our independent registered public accounting firm (when applicable in the future) will be able to conclude within the prescribed timeframe that internal controls over financial reporting are effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

We have not paid dividends in the past and have no immediate plans to pay dividends, so any returns will be limited to the value of our stock.

We plan to reinvest all of our earnings, to the extent we have earnings, to cover operating costs and otherwise become and remain competitive. We do not plan to pay any cash dividends with respect to our securities in the foreseeable future. We cannot assure you that we would, at any time, generate sufficient surplus cash that would be available for distribution to the holders of our common stock as a dividend. Therefore, you should not expect to receive cash dividends on our common stock, and any return to stockholders will therefore be limited to the appreciation of their stock.

If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our shares, the price of our shares could decline.

The trading market for our shares will rely in part on the research and reports that equity research analysts publish about us and our business, if at all. We do not have control over these analysts, and we do not have commitments from them to write research reports about us. The price of our shares could decline if no research reports are published about us or our business, or if one or more equity research analysts downgrades our shares or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business.

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

Under the Tax Act, federal Net Operating Losses ("NOLs") incurred in taxable years ending after December 31, 2017, may be carried forward indefinitely, but can only be applied to 80% of taxable income for the year. As of December 31, 2025, our remaining federal NOLs were generated after the 2017 tax year. Our significant state NOLs as of December 31, 2025, were generated in IL and TN, which begin to expire in 2037 and 2035, respectively. Neither IL nor TN conform to the federal 80% utilization limitation, but IL has suspended annual NOL utilization above $0.5 million of IL taxable income until the 2027 tax year. IL NOLs that would have been utilized if not for this suspension are granted an additional carryforward year. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. We do not currently expect IRC Sections 382 and 383 to significantly impact our ability to utilize our tax attributes based on ownership changes through December 31, 2025. However, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership some of which may be outside of our control. As a result, if we earn net taxable income, our ability to use our pre-ownership change NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Assuming a market for our common stock continues to develop, sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to fall.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock.

As of March 17, 2026, we had 27,284,491 shares of common stock outstanding, all of which, other than shares held by our directors and certain officers, are eligible for sale in the public market, subject in some cases to compliance with the requirements of Rule 144, including volume limitations and manner of sale requirements.

Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended (the "Securities Act"). Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and applicable provisions of Delaware law may delay or discourage transactions involving an actual or potential change in control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. The provisions in our amended and restated certificate of incorporation and amended and restated bylaws:

- authorize our board of directors to issue, without further action by the stockholders, shares of undesignated preferred stock with terms, rights and preferences determined by our board of directors that may be senior to our common stock;
- establish an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors;
- establish that our board of directors is divided into three classes, with each class serving three-year staggered terms;
- require the approval of our board of directors or the holders of at least seventy-five percent (75%) of our outstanding shares of capital stock to amend our bylaws and certain provisions of our certificate of incorporation;
- limit who may call stockholder meetings;
- do not provide for cumulative voting rights; and
- provide that all vacancies may be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum.

In addition, Section 203 of the Delaware General Corporation Law may limit our ability to engage in any business combination with a person who beneficially owns 15% or more of our outstanding voting stock unless certain conditions are satisfied. This restriction lasts for a period of three years following the share acquisition. These provisions may have the effect of entrenching our management team and may deprive our stockholders of the opportunity to sell their shares to potential acquirers at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock.

Our amended and restated certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or stockholders.

Provisions in our amended and restated certificate of incorporation provide that the Court of Chancery of the State of Delaware will, to the fullest extent permitted by law, be the sole and exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed to us or our stockholders by any of our directors, officers or other employees;
- any action asserting a claim against us or any of our directors, officers or other employees arising pursuant to any provision of Delaware law or our charter documents; or
- any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine, but excluding actions to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

In addition, unless we consent in writing to the selection of an alternative forum, the Federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. However, a court may determine that this provision is unenforceable.

Ownership portions held by our executives and directors may limit our stockholders' ability to influence corporate matters.

As of December 31, 2025, our directors and executive officers beneficially own approximately 18.8% of our common stock. Accordingly, these parties, together, can significantly influence, though not independently determine, the outcome of matters required to be submitted to our stockholders for approval, including decisions relating to the election of our board of directors and the outcome of any proposed merger or consolidation of our company. These interests may not be consistent with those of our other stockholders. In addition, the significant interest held by these parties may discourage third parties from seeking to acquire control of us, which may adversely affect the market price of our shares.

As stockholders in our company, you will be deemed to have notice of and have consented to the provisions of our amended and restated certificate of incorporation related to choice of forum, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. The choice of forum provisions in our amended and restated certificate of incorporation may limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or any of our directors, officers or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provision contained in our restated charter to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

Managing cybersecurity risk is critical to supporting our vision, enabling our strategy, and safely operating our business. We recognize the importance of assessing, identifying, and managing material risks associated with cybersecurity threats. Our process for identifying and assessing material risks from cybersecurity threats operates alongside our broader overall risk assessment process which covers all Company risks. As part of this process, appropriate personnel collaborate with third-party subject matter experts to gather insights for identifying and assessing material risks associated with cybersecurity threats, their severity, and potential mitigations. Further, we provide periodic training for all personnel regarding cybersecurity threats, with such training appropriate to the roles, responsibilities and access of the relevant Company personnel. Our policies require all workers to report any real or suspected cybersecurity event.

We have a cybersecurity risk assessment process that involves the activities listed below, among others:

- Compare our processes to benchmark standards, such as those set by the National Institute of Standards and Technology ("NIST").
- Closely monitor emerging data protection laws and implement changes to our processes as needed.
- Conduct annual cybersecurity management and incident training for employees involved in our systems that contain sensitive data.
- Run tabletop exercises to simulate a response to a cybersecurity incident and use the findings to improve our processes and technologies as needed.
- Carry cybersecurity risk insurance that provides protection against potential losses arising from a cybersecurity incident.

As part of the above process, we engage third-party services to provide 24-hour, 365-day monitoring, escalation, and response to cyber events. In addition to consulting on best practices, we leverage a third-party expert security firm for independent evaluations of our security controls through penetration testing. These evaluations test both the design and the operational effectives of security controls.

Our process also addresses material risks from cybersecurity threats associated with our use of third-party service providers, including those in our supply chain, our product development partners, or those who have access to sensitive data or our systems. Third-party risks are included within our broader overall risk assessment process, and cybersecurity considerations are considered during the selection and oversight of our third-party service providers.

Governance

Our board of directors, in coordination with the Audit Committee, oversees our risk management program, including the management of risks associated with cybersecurity threats. Our board of directors and Audit Committee receive periodic updates on developments in our cybersecurity risk management practices, evolving standards, third-party vulnerability assessments, and information security issues. On an annual basis, our board of directors and the Audit Committee discuss our approach to overseeing cybersecurity threats with senior management, including our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO").

Senior management works collaboratively across the organization to implement a program designed to protect our information systems from cybersecurity threats and to respond to any cybersecurity incidents in accordance with our incident response and recovery plans. A cross-functional team addresses cybersecurity threats and responds to cybersecurity incidents through communications within the team and with third-party experts to stay informed about and monitor the prevention, detection, mitigation, and remediation of cybersecurity threats and incidents and report such incidents to the board of directors and the Audit Committee when appropriate.

As of the date of this Form 10-K, we are not aware of cybersecurity incidents that have materially affected or are reasonably likely to materially affect the Company, including our business, strategy, results of operations, or financial condition at this time. For further discussion of the risks associated with cybersecurity incidents, see Part I, Item 1A of this Form 10-K under the risk factor entitled "*We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.*"

Item 2. Properties

We conduct all of our administrative activities for Eton Pharmaceuticals, Inc. at our 8,079 square foot leased office space located at 21925 W. Field Parkway, Suite 235, Deer Park, Illinois 60010. The lease for this facility expires in January 2031.

We consider our current facilities suitable and adequate to meet our current needs.

Item 3. Legal Proceedings

None.

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 listed on the Nasdaq Global Market under the symbol "ETON." The closing price of our common stock on the Nasdaq Global Market on December 31, 2025, the last trading date in 2025, was $16.91 per share.

Record Holders

As of March 17, 2026, we had four holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities. The closing price per share of our common stock on March 17, 2026 was $18.92.

Dividends

We have never declared or paid a cash dividend on our common stock. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. Any future determinations to pay cash dividends will be made at the discretion of our board of directors, subject to applicable laws, and will depend on a number of factors, including our financial condition, results of operations, capital requirements, contractual restrictions, general business conditions, and any other factors that our board of directors may deem relevant.

Item 6. Reserved

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

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

Overview

Eton is an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases. We currently have eight commercial rare disease products: INCRELEX®, ALKINDI SPRINKLE®, KHINDIVI™, GALZIN®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous and Nitisinone. We have five additional product candidates in late-stage development: ET-600, Amglidia®, ET-700, ET-800 and ZENEO® hydrocortisone autoinjector.

Results of Operations

Year Ended December 31, 2025 Compared to Year Ended December 31, 2024

During the twelve months ended December 31, 2025, we had $80.0 million in total revenues that generated a gross profit of $42.7 million, compared to total revenues of $39.0 million during the twelve-months ended December 31, 2024 that generated a gross profit of $23.4 million during the period. During the twelve-months ended December 31, 2025, we had product sales and royalties, net of $76.7 million, compared to product sales and royalties, net of $38.5 million during the twelve-months ended December 31, 2024, an increase of $38.2 million. The increase in product sales and royalties, net was the result of increased sales volume of our INCRELEX®, ALKINDI SPRINKLE® and GALZIN® products in the current year.

Licensing revenue during the twelve-months ended December 31, 2025 was $3.3 million, compared to $0.5 million in licensing revenue during the twelve-months ended December 31, 2024. The increase in licensing revenue during the twelve-months December 31, 2025 was due to $1.8 million from our out-licensing of INCRELEX® rights outside of the U.S. and $1.5 million from the recognition of a development milestone event associated with our divestiture of DS-200. During the twelve-months ended December 31, 2024, we recognized $0.5 million in licensing revenue associated with the sale of our DS-200 product candidate in September 2024.

Cost of Sales

During the twelve-months ended December 31, 2025, total costs of sales was $37.2 million, compared to $15.6 million in total costs of sales during the twelve-months ended December 31, 2024. The increase in total costs of sales during the twelve-months December 31, 2025, was due to increases in INCRELEX® and ALKINDI SPRINKLE® product sales and higher commissions with respect to our out-licensing of INCRELEX® rights outside of the U.S. Gross profit during the twelve-months ended December 31, 2025 was $42.7 million or 53.5% as a percentage of total net revenues, compared to gross profit of $23.4 million or 60.0% as a percentage of total net revenues during the twelve-months ended December 31, 2024. The decrease in gross profit during the twelve-months ended December 31, 2025 was primarily attributable to higher commission with respect to our out-licensing of INCRELEX® rights outside of the U.S.

Research and Development Expenses

We currently have twelve employees that support our overall product development function. The majority of our spend in research and development ("R&D") expenses is to third parties we contract with to develop, test our products and the development of partner milestone payments. During the twelve-months ended December 31, 2025, we incurred $7.8 million of R&D expenses, compared to $3.3 million during the twelve-months ended December 31, 2024. The increase in R&D expenses was primarily due to a $2.2 million NDA filing fee for ET-600 and increased expenses associated with our ET-700 and ET-800 project development activities.

General and Administrative Expenses

General and administrative expenses ("G&A") expenses consist primarily of employee compensation expenses, selling and advertising/promotional expenses, legal and professional fees, business insurance and FDA fees associated with approved products. We anticipate that our G&A expenses will increase to support our business growth, particularly with respect to sales and marketing activities and additional personnel. During the twelve-months ended December 31, 2025 and 2024, we incurred $35.8 million and $22.8 million, respectively, of G&A expenses. The increase in G&A expenses during the twelve-months ended December 31, 2025 was primarily attributable to an increase in product advertising and promotional expenses, higher stock-based compensation expense and an increase in compensation and benefit expenses due to an increase in general and administrative headcount during the current year.

Year Ended December 31, 2024 Compared to Year Ended December 31, 2023

Net revenues of $39.0 million in 2024 included $0.5 million of licensing revenue from the sale of our DS-200 product candidate in September 2024. Net revenue of $31.6 million in 2023 included $5.5 million of licensing revenue from the sale of our neurology product royalty streams to Azurity in June 2023. Net product revenue of $38.5 million in 2024 increased by $12.4 million from $26.1 million in 2023 primarily as a result of higher product sales for ALKINDI SPRINKLE® and Carglumic Acid.

Our 2024 gross profit of $23.4 million was up from $21.1 million in 2023 primarily as a result of higher product sales for ALKINDI SPRINKLE® and Carglumic Acid.

For the years ended December 31, 2024 and 2023, we incurred $3.3 million and $3.3 million in R&D expenses, respectively, and $22.8 million and $18.9 million of G&A expenses, respectively. The $3.8 million increase in G&A expenses was primarily due to personnel additions to support our growing business as well as marketing spend on new products. We incurred a net loss of $3.8 million and $0.9 million for the years ended December 31, 2024 and 2023, respectively.

Liquidity and Capital Resources

As of December 31, 2025, we had total assets of $92.1 million, cash and cash equivalents of $25.9 million and working capital of $22.1 million. We believe that our revenues and cash flows from our product portfolio will be sufficient for at least the next twelve months of our operations. However, our projected estimates for our product development spending, administrative expenses and our working capital requirements could change significantly, or we may experience growth more quickly or on a larger scale than we expect, any of which could result in the depletion of capital resources more rapidly than anticipated and could require us to seek additional financing earlier than we would expect to support our operations.

Cash Flows

The following table sets forth a summary of our cash flows for the years ended December 31, 2025, 2024 and 2023 (in thousands):

	Year ended December 31, 2025	Year ended December 31, 2024	Year ended December 31, 2023
Net cash from (used in) operating activities	$ 10,524	$ 969	$ 6,815
Net cash from (used in) investing activities	(333)	(40,014)	(775)
Net cash flows from (used in) financing activities	815	32,593	(957)
Net change in cash and cash equivalents	$ 11,006	$ (6,452)	$ 5,083

During the twelve-months ended December 31, 2025, 2024 and 2023, net cash from operating activities was $10.5 million, $1.0 million and $6.8 million, respectively. The increase in cash from operating activities during the twelve-months ended December 31, 2025 was primarily due to higher cash collections from product sales, a filing fee refund from the FDA related to ET-400 and the collection of a licensing milestone payment. The decrease in cash from operating activities during December 31, 2024 as compared to December 31, 2023, was primarily associated with an increase in prepaid expenses associated with FDA filing fees in addition to higher inventory purchases in the current year.

During the twelve-months ended December 31, 2025, 2024 and 2023, net cash used in investing activities was $0.3 million, $40.0 million and $0.8 million, respectively. The decrease in net cash used in investing activities during the twelve-months ended December 31, 2025 was primarily attributable to one-time cash outflows for the business combination of INCRELEX® and the purchase of product licensing rights associated with GALZIN® and PKU GOLIKE®, which were cash outflows during the twelve-months ended December 31, 2024. During the twelve-months ended December 31, 2023, we purchased the product licensing rights for Nitisinone.

During the twelve-months ended December 31, 2025 and 2024, net cash from financing activities was $0.8 million and $32.6 million, respectively, compared to net cash used in financing activities during the twelve months ended December 31, 2023 of $1.0 million. The decrease in cash from financing activities during the twelve-months ended December 31, 2025 was primarily associated with net proceeds received from expanding our credit agreement with SWK Holdings Corporation ("SWK") and proceeds from common stock issued in a private placement offering in 2024. During the twelve-months ended December 31, 2023, net cash used in financing activities primarily represented $1.2 million in debt repayments to SWK, partially offset by proceeds received from stock option exercises and employee stock purchase plan proceeds.

Non-GAAP Financial Measures

EBITDA, which is derived from GAAP income or loss from operations, then excluding interest, taxes, depreciation and amortization. Adjusted EBITDA is defined as net income or before interest expense, income taxes, depreciation and intangible amortization, stock-based compensation expense, restructuring charges, acquisition and divestiture-related costs, and other non-recurring items, non-GAAP net income and non-GAAP earnings per share are used and provided by us as non-GAAP financial measures. These non-GAAP financial measures are intended to provide additional information on our performance, operations and profitability. Adjustments to our GAAP figures as well as EBITDA includes non-recurring acquisition or divestiture-related costs, fees related to refinancing activities, as well as non-cash items such as share-based compensation, inventory step-up expense, depreciation and amortization, non-cash interest expense, and other non-cash adjustments. Certain other special items or substantive events may also be included in the

non-GAAP adjustments periodically when their magnitude is significant within the periods incurred. We maintain an established non-GAAP policy that guides the determination of what costs or gains will be included in non-GAAP adjustments.

We believe that these non-GAAP financial measures, when considered together with the GAAP figures, can enhance an overall understanding of our financial and operating performance. The non-GAAP financial measures are included with the intent of providing investors with a more complete understanding of our historical financial results and trends and to facilitate comparisons between periods. In addition, these non-GAAP financial measures are among the indicators our management uses for planning and forecasting purposes and measuring our performance. These non-GAAP financial measures should be considered in addition to, and not as a substitute for, or superior to, financial measures calculated in accordance with GAAP. The non-GAAP financial measures used by us may be calculated differently from, and therefore may not be comparable to, non-GAAP financial measures used by other companies.

EBITDA, adjusted EBITDA and non-GAAP net income, and the related per share amounts, were as follows (in thousands, except share and per share amounts):

	December 31, 2025	December 31, 2024
GAAP net loss	$ **(4,601)**	$ **(3,823)**
Depreciation	41	50
Intangible amortization expense	4,003	1,096
Interest expense (including debt discount amortization and non-cash interest expenses)	4,781	2,005
Income tax expense	43	15
EBITDA	$ **4,267**	$ **(657)**
Other non-GAAP adjustments:		
Inventory step-up expense (1)	5,094	—
Stock-based compensation (2)	5,512	3,165
Severance expense (3)	335	—
Acquisition/divestiture-related costs (4)	581	415
Total of Other non-GAAP adjustments	11,522	3,580
Adjusted EBITDA	$ **15,789**	$ **2,923**
GAAP loss before income tax	$ **(4,558)**	$ **(3,808)**
Non-GAAP adjustments:		
Depreciation (5)	41	50
Intangible amortization expense (6)	4,003	1,096
Inventory step-up expense (1)	5,094	-
Stock-based compensation (2)	5,512	3,165
Severance expense (3)	335	—
Acquisition/divestiture-related costs (4)	581	415
Total pre-tax non-GAAP adjustments	15,566	4,726
Income tax effect of pre-tax non-GAAP adjustments (7)	235	49
Total non-GAAP adjustments	15,331	4,677
Non-GAAP Net Income	$ **10,773**	$ **869**
Weighted average number of common shares outstanding, basic	26,908	25,895
Weighted average number of common shares outstanding, diluted	31,046	27,458
GAAP income (loss) per share - Basic	$ **(0.17)**	$ **(0.15)**
Non-GAAP adjustments	0.57	0.18
Non-GAAP earnings per share - Basic	$ **0.40**	$ **0.03**
GAAP income (loss) per share - Basic	$ **(0.17)**	$ **(0.15)**
Non-GAAP adjustments	0.49	0.17
Non-GAAP earnings per share - Diluted	$ **0.32**	$ **0.02**

(1) During the twelve months ended December 31, 2025, we recognized in cost of sales $5,094 for inventory step-up expense primarily attributable to INCRELEX® inventory revalued in connection with this business combination.
(2) Represents share-based compensation expense associated with our stock option and restricted stock unit stock unit grants to our employees and non-employee directors and our employee share purchase plan.
(3) Represents severance and benefit expenses associated with role redundancy within commercial operations during the first quarter of 2025.
(4) Represents legal expense and other divestiture-related costs associated with the out-licensing of the INCRELEX® commercial rights in territories outside of the U.S.
(5) Represents depreciation expense related to our property and equipment.
(6) Intangible amortization expenses are associated with our intellectual property rights related to INCRELEX®, GALZIN®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous and Nitisinone.
(7) Income tax adjustments on pre-tax non-GAAP adjustments represent the estimated income tax impact of each pre-tax non-GAAP adjustment based on the effective income tax rate for the period. As discussed further in Note 14, we are in a full income tax valuation allowance position and the income tax effect on pre-tax non-GAAP adjustments is commensurate with the performance measure.

Critical Accounting Policies

Our financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The preparation of our financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 3 to our Financial Statements included herein, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition for Contracts with Customers

We account for contracts with our customers in accordance with Accounting Standards Codification ("ASC") 606 — Revenue from Contracts with Customers. ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

At contract inception, once we determine the contract falls within the scope of ASC 606, we assess the goods promised within each contract and determine those that are performance obligations and assesses whether each promised good is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Arrangements that include rights to additional goods that are exercisable at a customer's discretion are generally considered options. We assess whether these options provide a material right to the customer and, if so, they are considered performance obligations. The exercise of a material right is accounted for as a contract modification for accounting purposes.

We recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied at a point in time. For the years ended December 31, 2023, 2024 and 2025, all revenues recognized in the Statements of Operations were point in time sales to our customers.

Milestone Payments – If a commercial contract arrangement includes development and regulatory milestone payments, we will evaluate whether the milestone conditions have been achieved and if it is probable that a significant revenue reversal would not occur before recognizing the associated revenue. Milestone payments that are not within our control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

Royalties – For arrangements that include sales-based royalties, including milestone payments based on a level of sales, which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, we will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied.

Significant Financing Component – In determining the transaction price, we will adjust consideration for the effects of the time value of money if the expected period between payment by the licensees and the transfer of the promised goods or services to the licensees will be more than one year.

The Company sells its INCRELEX®, ALKINDI SPRINKLE®, KHINDIVI™, GALZIN®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous, and Nitisinone products to pharmacy distributor customers which provide order fulfilment and inventory storage/distribution services. The Company uses a third-party logistics ("3PL") vendor to process and fulfill orders and has concluded it is the principal in the sales to wholesalers because it controls access to the 3PL vendor services rendered and directs the 3PL vendor activities.

For its INCRELEX®, ALKINDI SPRINKLE®, KHINDIVI™, GALZIN®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous, and Nitisinone products, the Company bills at the initial product list price which are subject to offsets for patient co-pay assistance and potential state Medicaid reimbursements which are recorded as a reduction of net revenues at the date of sale/shipment. Selling prices initially billed to wholesalers may be subject to discounts for prompt payment and subsequent chargebacks when the wholesalers sell products at negotiated discounted prices to members of certain group purchasing organizations ("GPOs") and government programs.

The Company estimates the transaction price when it receives each purchase order taking into account the expected reductions of the selling price initially billed to the wholesaler/distributor arising from all of the above factors. The Company has developed estimates for future returns and chargebacks and the impact of other discounts and fees it pays, although INCRELEX®, ALKINDI SPRINKLE®, KHINDIVI™, GALZIN®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous, and Nitisinone sales are not subject to returns.

The Company stores its INCRELEX®, ALKINDI SPRINKLE®, KHINDIVI™, GALZIN®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous, and Nitisinone inventory at its pharmacy distributor customer locations, and sales are recorded when stock is pulled and shipped to fulfill specific patient orders. The Company recognizes revenue and cost of sales from products sold to wholesalers upon delivery to the wholesaler location. At that time, the wholesalers take control of the product as they take title, bear the risk of loss of ownership and have an enforceable obligation to pay the Company. They also have the ability to direct sales of product to their customers on terms and at prices they negotiate. Although wholesalers have product return rights, the Company does not believe they have a significant incentive to return the product.

Upon recognition of revenue from product sales, the estimated amounts of credit for product returns, chargebacks, distribution fees, prompt payment discounts, state Medicaid and GPO fees are included in sales reserves, accrued liabilities and net accounts receivable. The Company monitors actual product returns, chargebacks, discounts and fees subsequent to the sale. If these amounts end up differing from its estimates, it will make adjustments to these allowances, which are applied to increase or reduce product sales revenue and earnings in the period of adjustment.

Acquisitions

The Company accounts for business acquisitions using the acquisition method of accounting. Under this method of accounting, assets acquired and liabilities assumed are recorded at their respective fair values at the date of the acquisition. When determining the fair values of assets acquired and liabilities assumed, management makes significant estimates and assumptions. The Company's estimates of fair value are based upon assumptions believed to be reasonable but that are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates. Any excess of the purchase price over the fair value of the net assets acquired is recognized as goodwill. The Company also uses best estimates and assumptions to determine the useful lives of those acquired intangible assets that have a finite life.

Critical estimates in valuing certain of the intangible assets acquired include:

* future expected cash flows from customer contracts and license agreements;
* historical and expected customer attrition rates and anticipated growth in revenues from acquired customers; and
* discount rates.

Stock-Based Compensation

The Company accounts for stock-based compensation under the provisions of ASC 718 Compensation – Stock Compensation. The guidance under ASC 718 requires companies to estimate the fair value of the stock-based compensation awards on the date of grant and record expense over the related service periods, which are generally the vesting period of the equity awards. Compensation expense is recognized over the period during which services are rendered by consultants and non-employees until completed. The fair value of these awards and assumptions inputs are measured using the Black-Scholes option-pricing model ("BSM").

The Company estimates the fair value of stock-based option awards using the BSM. The BSM requires the input of subjective assumptions, including the expected stock price volatility, the calculation of expected term, forfeitures and the fair value of the underlying common stock on the date of grant, among other inputs. The risk-free interest rate was determined from the implied yields for zero-coupon U.S. government issues with a remaining term approximating the expected life of the options or warrants. Dividends on common stock are assumed to be zero for the BSM valuation of the stock options. The expected term of stock options granted is based on vesting periods and the contractual life of the options. Expected volatilities are based on the Company's historical volatility subsequent to our IPO, which we believe represents the most accurate basis for estimating expected future volatility under the current conditions. We account for forfeitures as they occur.

Off-Balance Sheet Transactions

We do not have any off-balance sheet transactions.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

The primary objective of our investment activities is to preserve capital. We do not utilize hedging contracts or similar instruments. We are exposed to certain market risks relating primarily to interest rate risk on our cash and cash equivalents and risks relating to the financial viability of the institutions which hold our capital and through which we have invested our funds. We manage such risks by investing in short-term, liquid, highly rated instruments. As of December 31, 2025, our cash equivalents included cash deposits at our bank and cash investments in short-term money market funds. We do not believe we have any material exposure to interest rate risk in the current interest rate environment and the short duration of the invested funds we hold. Declines in interest rates would reduce our investment income but would not have a material effect on our financial condition or results of operations. We do not currently have exposure to foreign currency risk.

We are subject to interest rate risk in connection with our variable rate credit agreement. Our principal interest rate exposure relates to our credit agreement, which bears interest rates that are indexed against Secured Overnight Financing Rate ("SOFR") plus 6.75%. As of December 31, 2025, we had outstanding borrowings under our credit agreement totaling $30.0 million, excluding unamortized debt issuance costs and accrued exit fees.

Item 8. Financial Statements and Supplementary Data

ETON PHARMACEUTICALS, INC.
INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Eton Pharmaceuticals Inc.

Opinion on the financial statements

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

Basis for opinion

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

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

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

Critical audit matter

The critical audit 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.

Medicaid Rebates and Related Liability

As described further in Note 3 to the financial statements, the Company recognizes revenue from product sales net of estimated sales deductions, including state Medicaid rebates. The state Medicaid rebate and related liability are estimated based on monthly sales, historical experience of claims submitted by the various states and jurisdictions, historical rebate rates and estimated lag time of the rebate invoices. We identified Medicaid rebates as a critical audit matter.

The principal considerations for our determination that Medicaid rebates and the related liability represent a critical audit matter were (i) the significant judgment applied by management in estimating and accruing Medicaid rebates and (ii) the high degree of auditor judgment and effort required to evaluate the assumptions underlying the estimate. In addition, timing differences may arise between when product sales occur and when the Company receives related state Medicaid rebate invoices, which vary based on individual state Medicaid program requirements.

Our audit procedures related to Medicaid rebates and the related liability included, among others, the following:

- Obtaining an understanding of the design of relevant controls over the estimation and recording of Medicaid rebates and the related liability.
- Evaluating state Medicaid rebate invoices received and related payments made during the year and their potential impact on the accrual at December 31, 2025.
- Testing the completeness and accuracy of Medicaid rebate-eligible product sales by agreeing underlying sales data to supporting documentation.
- Recalculating the estimated Medicaid rebate liability using management's assumptions (rebate rates, patient coverage, timing of invoices and billing variability) and inputs, which we assessed for reasonableness based on historical experience and other data.
- Agreeing rebates paid under state Medicaid programs during 2025 to supporting documentation.

/s/ GRANT THORNTON LLP

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

Chicago, Illinois
March 19, 2026

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders and the Board of Directors of Eton Pharmaceuticals, Inc.
Deer Park, Illinois

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Eton Pharmaceuticals, Inc. (the "Company") as of December 31, 2024, the related statements of operations, stockholders' equity, and cash flows for the year ended December 31, 2024, 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 ended December 31, 2024, 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. 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 audits provide a reasonable basis for our opinion.

/s/ Crowe LLP

We served as the Company's auditor from 2024 to 2025

Oakbrook Terrace, Illinois
March 18, 2025

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Eton Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying statements of operations, stockholders' equity, and cash flows of Eton Pharmaceuticals, Inc. (the "Company") for the year ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the results of operations and cash flows of the Company for the year ended December 31, 2023, 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 these financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

/s/ KMJ Corbin & Company LLP

We served as the Company's auditor from 2018 to 2024.

Glendora, California
March 14, 2024

Eton Pharmaceuticals, Inc.
BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 25,942	$ 14,936
Accounts receivable, net	11,757	5,361
Inventories, net	15,419	15,232
Prepaid expenses and other current assets	7,463	5,492
Total current assets	**60,581**	**41,021**
Property and equipment, net	326	34
Intangible assets, net	30,878	34,881
Operating lease right-of-use assets, net	310	175
Other long-term assets, net	19	12
Total assets	$ **92,114**	$ **76,123**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 10,976	$ 4,167
Current portion of long-term debt, net of discount	8,789	—
Accrued Medicaid rebates	9,317	6,866
Accrued liabilities	9,408	8,914
Total current liabilities	**38,490**	**19,947**
Long-term debt, net of discount and including accrued fees	21,769	29,811
Operating lease liabilities, net of current portion	460	107
Other long-term liabilities	5,241	1,830
Total liabilities	**65,960**	**51,695**
Commitments and contingencies (Note 16)		
Stockholders' equity		
Common stock, $0.001 par value; 50,000,000 shares authorized; 27,047,061 and 26,709,084 shares issued and outstanding at December 31, 2025 and 2024, respectively	27	27
Additional paid-in capital	138,621	132,294
Accumulated deficit	(112,494)	(107,893)
Total stockholders' equity	**26,154**	**24,428**
Total liabilities and stockholders' equity	$ **92,114**	$ **76,123**

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

Eton Pharmaceuticals, Inc.
STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	For the years ended		
	December 31, 2025	**December 31, 2024**	**December 31, 2023**
Revenues:			
Licensing revenue	$ 3,286	$ 500	$ 5,500
Product sales and royalties, net	76,664	38,511	26,142
Total net revenues	**79,950**	**39,011**	**31,642**
Cost of Sales:			
Licensing revenue	825	270	1,000
Product sales and royalties	36,385	15,330	9,581
Total cost of sales	37,210	15,600	10,581
Gross profit	**42,740**	**23,411**	**21,061**
Operating expenses:			
Research and development	7,765	3,255	3,322
General and administrative	35,819	22,753	18,931
Total operating expenses	**43,584**	**26,008**	**22,253**
Loss from operations	**(844)**	**(2,597)**	**(1,192)**
Other income (expense):			
Interest and other (expense) income, net	(3,714)	(1,211)	503
Loss before income tax expense	**(4,558)**	**(3,808)**	**(689)**
Income tax expense	43	15	247
Net loss	$ **(4,601)**	$ **(3,823)**	$ **(936)**
Net loss per share, basic and diluted	$ **(0.17)**	$ **(0.15)**	$ **(0.04)**
Weighted average number of common shares outstanding, basic and diluted	**26,908**	**25,895**	**25,645**

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

Eton Pharmaceuticals, Inc.
STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at December 31, 2022	**25,353,119**	**$ 25**	**$ 116,187**	**$ (103,134)**	**$ 13,078**
.					
Stock-based compensation	—	—	3,137	—	3,137
Stock option exercises and vesting of restricted stock units	299,028	1	148	—	149
Employee stock purchase plan	86,782	—	229	—	229
Shares withheld related to net share settlement of stock option exercises	(50,867)	—	(180)	—	(180)
Net loss	—	—	—	(936)	(936)
Balances at December 31, 2023	**25,688,062**	**26**	**119,521**	**(104,070)**	**$ 15,477**
Common stock issued in private placement offering	583,334	1	6,999	—	7,000
Stock-based compensation	—	—	3,165	—	3,165
Stock option exercises and vesting of restricted stock units	356,755	—	1,191	—	1,191
Employee stock purchase plan	80,933	—	248	—	248
Relative fair value of warrants issued in connection with debt	—	—	1,170	—	1,170
Net loss	—	—	—	(3,823)	(3,823)
Balances at December 31, 2024	**26,709,084**	**27**	**132,294**	**(107,893)**	**$ 24,428**
Stock-based compensation	—	—	5,512	—	5,512
Employee stock purchase plan	16,894	0	217	—	217
Stock option exercises and vesting of restricted stock units	321,083	0	598	—	598
Net loss	—	—	—	(4,601)	(4,601)
Balances at December 31, 2025	**27,047,061**	**$ 27**	**$ 138,621**	**$ (112,494)**	**$ 26,154**

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

Eton Pharmaceuticals, Inc.
STATEMENTS OF CASH FLOWS
(In thousands)

	For the years ended		
	December 31, 2025	**December 31, 2024**	**December 31, 2023**
Cash flows from (used in) operating activities			
Net loss	$ (4,601)	$ (3,823)	$ (936)
Adjustments to reconcile net loss to net cash from (used in) operating activities:			
Stock-based compensation	5,512	3,165	3,137
Depreciation and amortization	4,044	1,146	901
Inventory step-up	5,094	—	—
Excess and obsolete inventory reserve	594	529	15
Debt discount amortization	696	1,109	117
Non-cash lease expense	44	70	67
Changes in operating assets and liabilities, net of impact of business acquisition:			
Accounts receivable	(6,396)	(3,118)	(1,559)
Inventories	(5,876)	(1,839)	(369)
Prepaid expenses and other assets	(1,971)	(3,349)	94
Accounts payable	6,808	2,318	53
Accrued Medicaid rebates	2,451	3,239	2,818
Accrued liabilities	1,011	1,484	2,477
Other non-current assets and liabilities	3,114	38	—
Net cash from (used in) operating activities	**10,524**	**969**	**6,815**
Cash from (used in) investing activities			
Purchases of property and equipment	(333)	(26)	—
Acquisition of business	—	(30,000)	—
Purchase of product licensing rights	—	(9,988)	(775)
Net cash from (used in) investing activities	**(333)**	**(40,014)**	**(775)**
Cash flows from (used in) financing activities			
Net proceeds from the issuance of long-term debt	—	25,309	—
Repayment of long-term debt	—	(1,155)	(1,155)
Common stock issued in private placement offering	—	7,000	—
Proceeds from stock option exercises	598	1,191	149
Payment of tax withholding related to net share settlement of stock option exercises	—	—	(180)
Employee stock purchase plan	217	248	229
Net cash from (used in) financing activities	**815**	**32,593**	**(957)**
Change in cash and cash equivalents	**11,006**	**(6,452)**	**5,083**
Cash and cash equivalents at beginning of year	14,936	21,388	16,305
Cash and cash equivalents at end of year	$ 25,942	$ 14,936	$ 21,388
Supplemental disclosures of cash flow information			
Cash paid for interest	$ 3,325	$ 665	$ 842
Cash paid for income taxes	$ 118	$ 82	$ 247
Supplemental disclosures of non-cash investing and financing activities:			
Debt issuance costs	$ —	$ 386	$ —
Fair value of warrants issued in connection with debt agreement	$ —	$ 1,170	$ —
Adjustment of operating lease right-of-use assets and liabilities due to tenant allowance	$ —	$ —	$ 29
Right-of-use assets obtained in exchange for lease liabilities	$ 333	$ 219	$ —

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

Note 1 — Company Overview

Eton is an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases. We currently have eight commercial rare disease products: INCRELEX®, ALKINDI SPRINKLE®, KHINDIVI™, GALZIN®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous and Nitisinone. We have five additional product candidates in late-stage development: ET-600, Amglidia®, ET-700, ET-800 and ZENEO® hydrocortisone autoinjector.

Note 2 — Liquidity Considerations

As of December 31, 2025, the Company had an accumulated deficit of $112,494 and for the year ended December 31, 2025 the Company had a net loss of $4,601.

To date, the Company has generated revenues from multiple products and expects further growth in 2026 and beyond in accordance with additional market penetration from these products plus revenues from additional products where it anticipates FDA approval. The Company currently believes its existing cash and cash equivalents of $25,942 as of December 31, 2025 will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next twelve months from the date of issuance of these financial statements. This estimate is based on the Company's current assumptions, including assumptions relating to estimated sales and its ability to manage its spending. The Company could use its available capital resources sooner than currently expected. Accordingly, the Company could seek to obtain additional capital through equity financings, the issuance of debt or other arrangements. However, there can be no assurance that the Company will be able to raise additional capital if needed or under acceptable terms, if at all. The sale of additional equity may dilute existing stockholders and newly issued shares may contain senior rights and preferences compared to currently outstanding common shares. The Company's existing long-term debt obligation contains covenants and limits the Company's ability to pay dividends or make other distributions to stockholders. If the Company experiences delays in product sales growth and completing its product development and obtaining regulatory approval for its other product candidates and is unable to obtain such additional financing, operations would need to be scaled back or discontinued.

Note 3 — Summary of Significant Accounting Policies

Basis of Presentation

The Company has prepared the accompanying financial statements in accordance with GAAP. Certain prior period amounts, have been reclassified to conform to current year presentation in the financial statements and notes to the financial statements.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, Medicaid program rebates, valuation of inventories, useful lives of assets and the recoverability of long-lived assets, valuation of deferred tax assets, and the valuation of common stock, stock options, warrants, and restricted stock units ("RSUs"). Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates or assumptions.

Acquisitions

The Company evaluates each of its acquisitions in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 805, Business Combinations ("ASC 805"), to determine whether the transaction is a business combination or an asset acquisition. In determining whether an acquisition should be accounted for as a business combination or an asset acquisition, the Company first performs a screening test to determine whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets. If this is the case, the acquired set is not deemed to be a business and is instead accounted for as an asset acquisition. If this is not the case, the Company then further evaluates whether the acquired set includes, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs. If so, the Company concludes that the acquired set is a business.

Note 3 — Summary of Significant Accounting Policies (continued)

The Company accounts for business acquisitions using the acquisition method of accounting. Under this method of accounting, assets acquired and liabilities assumed are recorded at their respective fair values at the date of the acquisition. When determining the fair values of assets acquired and liabilities assumed, management makes significant estimates and assumptions. The Company's estimates of fair value are based upon assumptions believed to be reasonable, but these assumptions are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates. Any excess of the purchase price over the fair value of the net assets acquired is recognized as goodwill.

During the measurement period, which may be up to one year from the acquisition date, the Company adjusts the provisional amounts of assets acquired and liabilities assumed with the corresponding offset to goodwill to reflect new information obtained about facts and circumstances that existed as of the acquisition date that, if known, would have affected the measurement of the amounts recognized as of that date. Upon the conclusion of the measurement period or final determination of the values of assets acquired or liabilities assumed, whichever comes first, any subsequent adjustments are recorded within the Company's consolidated statements of operations.

Segment Information

The Company operates the business on the basis of a single reportable segment, which includes eight commercial rare disease products: INCRELEX®, ALKINDI SPRINKLE®, KHINDIVI™, GALZIN®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous, and Nitisinone. The Company derives revenues from product sales to specialty pharmacy customers, who then provide order fulfillment, inventory storage and distribution services. The Company's chief operating decision-maker ("CODM") is the Chief Executive Officer, who evaluates the Company's financial performance and results of operations as a single operating segment. The CODM reviews net income or loss as a measure of segment profit or loss in assessing performance and allocating resources. Segment revenues, expenses and profit or loss is reported on the Statements of Operations. Additionally, the measure of segment assets is reported on the Company's balance sheet as total assets.

The Company's revenues and its accounts receivable balances are highly concentrated and consist of sales to and amounts due from AnovoRx and Optime Care for the Company's INCRELEX®, ALKINDI SPRINKLE®, KHINDIVI™, GALZIN®, Carglumic Acid, Betaine Anhydrous and Nitisinone products, as well as from Pentec Health for sales of the Company's PKU GOLIKE® product. For the years ended December 31, 2025, 2024 and 2023, AnovoRx product sales represented 84.6%, 93.6% and 78.2% of net revenues, respectively. As of December 31, 2025 and 2024, AnovoRx product sales represented 88.4% and 96.2% of net accounts receivable. For the year ended December 31, 2025, the Company's revenues from external customers were derived from U.S operations and included product sales to U.S. and foreign countries. During the years ended December 31, 2024 and 2023, the Company's revenues from external customers were entirely derived from U.S operations and did not include any foreign countries. As of December 31, 2025 and 2024, all long-lived assets were domiciled within the U.S.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. All cash and cash equivalents are held in U.S. financial institutions or invested in short-term U.S. treasury bills or high-grade money market funds. From time to time, amounts deposited with its bank exceed federally insured limits. The Company believes the associated credit risk to be minimal.

Accounts Receivable

Accounts receivable are recorded at the invoiced amount and are non-interest bearing. Accounts receivable are recorded net of allowances for credit losses, cash discounts for prompt payment, distribution fees, chargebacks and returns and allowances. The Company considers historical collection rates and the current financial status of its customers, as well as macroeconomic and industry-specific factors when evaluating potential credit losses. Historically, the Company's accounts receivable balances have been highly concentrated with a select number of customers, consisting primarily of specialty pharmacies and large wholesale pharmaceutical distributors. Given the size and creditworthiness of these customers, we have not experienced and do not expect to experience material credit losses. The total for all accounts receivable reserves was $272 and $238 as of December 31, 2025 and 2024, respectively.

Inventories

The Company values its inventories at the lower of cost or net realizable value using the first-in, first-out method of valuation. The Company reviews its inventories for potential excess or obsolete issues on an ongoing basis and records a write-down if an impairment is identified. As of December 31, 2025 and December 31, 2024 , inventories consisted of purchased finished goods, semi-finished goods and raw materials. There was an inventory reserve of $1,199 and $605 at December 31, 2025 and 2024, respectively. As of December 31, 2024, inventories included $5,000 in prepaid raw materials acquired in the INCRELEX® business acquisition.

(in thousands, except share and per share amounts)

Note 3 — Summary of Significant Accounting Policies (continued)

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation of property and equipment is computed utilizing the straight-line method based on the following estimated useful lives. Computer hardware and software is depreciated over three years. Equipment, furniture and fixtures is depreciated over five years. Leasehold improvements are amortized over their estimated useful lives or the remaining lease term, whichever is shorter. Construction in progress is capitalized but not depreciated until it is placed into service.

Maintenance and repairs are charged to expense as incurred, while renewals and improvements are capitalized.

Intangible Assets

The Company capitalizes payments it makes for licensed products when the payment is based on FDA approval for the product and the cost is recoverable based on expected future cash flows from the product. The cost is amortized on a straight-line basis over the estimated useful life of the product commencing on the approval date or the product acquisition date in accordance with ASC 350 — Intangibles - Goodwill and Other. The following table presents the Company's intangible asset as of December 31, 2025 and 2024:

Intangible asset	Useful Life (In years)	Purchase Date	Purchase Price	Accumulated Amortization	Carrying Value
Carglumic Acid	10	November 2021	$ 3,250	$ 1,354	$ 1,896
Betaine	5	September 2022	2,125	1,399	726
Nitisinone	5	October 2023	650	292	358
GoLike	10	March 2024	1,868	327	1,541
Increlex	10	December 2024	21,250	2,200	19,050
Glazin	10	December 2024	8,119	812	7,307
			$ 37,262	$ 6,384	$ 30,878

Intangible asset	Useful Life (In years)	Purchase Date	Purchase Price	Accumulated Amortization	Carrying Value
Carglumic Acid	10	November 2021	$ 3,250	$ 1,029	$ 2,221
Betaine	5	September 2022	2,125	974	1,151
Nitisinone	5	October 2023	650	162	488
GoLike	10	March 2024	1,868	140	1,728
Increlex	10	December 2024	21,250	76	21,174
Glazin	10	December 2024	8,119	—	8,119
			$ 37,262	$ 2,381	$ 34,881

The Company recorded $4,003, $1,096, and $790 of amortization expense for the years ended December 31, 2025, 2024 and 2023 respectively. The table below shows the estimated remaining amortization for these products for each of the five years from 2026 to 2030 and thereafter.

Year	Amortization Expense
2026	$ 4,004
2027	3,880
2028	3,546
2029	3,449
2030	3,449
Thereafter	12,550
Total estimated amortization expense	$ 30,878

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized in the Company’s Statements of Operations for the amount by which the carrying amount of the asset exceeds the fair value of the asset. No impairment was recognized during the years ended December 31, 2025, 2024 and 2023.

Debt Issuance Costs and Debt Discount and Detachable Debt-Related Warrants

Costs incurred to issue debt are deferred and recorded as a reduction to the debt balance in the accompanying balance sheets. The Company amortizes debt issuance costs over the expected term of the related debt using the effective interest method. Debt discounts relate to the relative fair value of warrants issued in conjunction with the debt and are also recorded as a reduction to the debt balance and accreted over the expected term of the debt to interest expense using the effective interest method.

Note 3 — Summary of Significant Accounting Policies (continued)

Leases

The Company accounts for leases in accordance with ASC Topic 842 — Leases. The Company reviews all relevant facts and circumstances of a contract to determine if it is a lease whereby the terms of the agreement convey the right to control the direct use and receive substantially all the economic benefits of an identified asset for a period of time in exchange for consideration. The associated right-of-use assets and lease liabilities are recognized at lease commencement. The Company measures lease liabilities based on the present value of the lease payments over the lease term discounted using the rate it would pay on a loan with the equivalent payments and term for the lease. The Company does not include the impact for lease term options that would extend or terminate the lease unless it is reasonably certain that it will exercise any such options. The Company accounts for the lease components separately from non-lease components for its operating leases.

The Company measures right-of-use assets based on the corresponding lease liabilities adjusted for (i) any prepayments made to the lessor at or before the commencement date, (ii) initial direct costs it incurs, and (iii) any incentives under the lease. In addition, the Company evaluates the recoverability of its right-of-use assets for possible impairment in accordance with its long-lived assets policy.

Operating leases are reflected on the balance sheets as operating lease right-of-use assets, current accrued liabilities and long-term operating lease liabilities. The Company does not have any finance leases as of December 31, 2025 and 2024.

The Company commences recognizing operating lease expense when the lessor makes the underlying asset available for use by the Company and the operating lease expense is recognized on a straight-line basis over the term of the lease. Variable lease payments are expensed as incurred.

The Company does not recognize right-of-use assets or lease liabilities for leases with a term of twelve months or less; such lease costs are recorded in the Statements of Operations on a straight-line basis over the lease term.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the successful award of a patent and the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Concentrations of Credit Risk, Sources of Supply and Significant Customers

The Company is subject to credit risk for its cash and cash equivalents, which are invested in money market funds and U.S. treasury bills from time to time. The Company maintains its cash and cash equivalent balances with one major commercial bank and the deposits held with the financial institution exceed the amount of insurance provided on such deposits and is exposed to credit risk in the event of a default by the financial institutions holding its cash and cash equivalents to the extent recorded on the balance sheets. The Company believes the associated credit risk to be minimal.

The Company is dependent on third-party suppliers for its products and product candidates. In particular, the Company relies, and expects to continue to rely, on a small number of suppliers to manufacture key chemicals, approved products and process its product candidates as part of its development programs. These programs could be adversely affected by a significant interruption in the manufacturing process.

The Company is also subject to credit risk from its accounts receivable related to product sales as it extends credit based on an evaluation of the customer’s financial condition, and collateral is not required. The Company's accounts receivables are evaluated to determine if any allowance should be recorded based on consideration of the current economic environment, expectations of future economic conditions, specific circumstances and the Company's historical collection experience. Additionally, Management monitors its exposure to accounts receivable by periodically evaluating the collectability of the account receivable based on a variety of factors including the length of time the receivables are past due, the financial health of the customer and any prior customer credit loss experience. Based upon the review of these factors, the Company recorded no allowance for credit losses at December 31, 2025 or 2024.

Revenue Recognition for Contracts with Customers

The Company accounts for contracts with its customers in accordance with ASC 606 — Revenue from Contracts with Customers. ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determine those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Arrangements that include rights to additional goods or services that are exercisable at a customer’s discretion are generally

considered options. The Company assesses whether these options provide a material right to the customer and, if so, they are considered performance obligations. The exercise of a material right is accounted for as a contract modification for accounting purposes.

Note 3 — Summary of Significant Accounting Policies (continued)

The Company recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied at a point in time. For the years ended December 31, 2023, 2024 and 2025, all revenues recognized in the Statements of Operations were point in time sales to the Company's customers.

Milestone Payments – If a commercial contract arrangement includes development and regulatory milestone payments, the Company will evaluate whether the milestone conditions have been achieved and if it is probable that a significant revenue reversal would not occur before recognizing the associated revenue. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

Royalties – For arrangements that include sales-based royalties, including milestone payments based on a level of sales, which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, the Company will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied.

The Company sells its INCRELEX®, ALKINDI SPRINKLE®, KHINDIVI™, GALZIN®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous, and Nitisinone products to pharmacy distributor customers which provide order fulfilment and inventory storage/distribution services. The Company uses a third-party logistics ("3PL") vendor to process and fulfill orders and has concluded it is the principal in the sales to wholesalers because it controls access to the 3PL vendor services rendered and directs the 3PL vendor activities.

For its INCRELEX®, ALKINDI SPRINKLE®, KHINDIVI ™, GALZIN®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous, and Nitisinone products, the Company bills at the initial product list price which are subject to offsets for patient co-pay assistance and potential state Medicaid reimbursements which are recorded as a reduction of net revenues at the date of sale/shipment. Selling prices initially billed to wholesalers may be subject to discounts for prompt payment and subsequent chargebacks when the wholesalers sell products at negotiated discounted prices to members of certain group purchasing organizations ("GPOs") and government programs.

The Company estimates the transaction price when it receives each purchase order taking into account the expected reductions of the selling price initially billed to the wholesaler/distributor arising from all of the above factors. The Company has developed estimates for future returns and chargebacks and the impact of other discounts and fees it pays, although INCRELEX®, ALKINDI SPRINKLE®, KHINDIVI™, GALZIN®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous, and Nitisinone. sales are not subject to returns.

The Company stores its INCRELEX®, ALKINDI SPRINKLE®, KHINDIVI™, GALZIN®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous, and Nitisinone. inventory at its pharmacy distributor customer locations, and sales are recorded when stock is pulled and shipped to fulfill specific patient orders. The Company may recognize revenue and cost of sales from products sold to wholesalers upon delivery to the wholesaler location. At that time, the wholesalers take control of the product as they take title, bear the risk of loss of ownership and have an enforceable obligation to pay the Company. They also have the ability to direct sales of product to their customers on terms and at prices they negotiate. Although wholesalers have product return rights, the Company does not believe they have a significant incentive to return the product.

Upon recognition of revenue from product sales, the estimated amounts of credit for product returns, chargebacks, distribution fees, prompt payment discounts, state Medicaid and GPO fees are included in sales reserves, accrued liabilities and net accounts receivable. The Company monitors actual product returns, chargebacks, discounts and fees subsequent to the sale. If these amounts end up differing from its estimates, it will make adjustments to these allowances, which are applied to increase or reduce product sales revenue and earnings in the period of adjustment.

The state Medicaid rebate and related liability are estimated based on monthly sales, historical experience of claims submitted by the various states and jurisdictions, historical rebate rates and estimated lag time of the rebate invoices.

Cost of Product Sales

Cost of product sales consists of the profit-sharing and royalty fees with the Company's product licensing and development partners, the purchase costs for finished products from third-party manufacturers, the amortization of certain intangible assets, and freight and handling/storage costs from the Company's 3PL logistics service providers. The cost of sales for profit-sharing and royalty fees and costs for purchased finished products and the associated inbound freight expense is recorded when the associated product sale revenue is recognized in accordance with the terms of shipment to customers while outbound freight and handling/storage fees charged by the 3PL service provider are expensed as they are incurred. Cost of sales also reflects any write-downs or reserve adjustments for the Company's inventories.

Note 3 — Summary of Significant Accounting Policies (continued)

Research and Development Expenses

Research and development ("R&D") expenses include both internal R&D activities and external contracted services. Internal R&D activity expenses include salaries, benefits and stock-based compensation and other costs to support the Company's R&D operations. External contracted services include product development efforts such as certain product licensor milestone payments, clinical trial activities, manufacturing and control-related activities and regulatory costs. R&D expenses are charged to operations as incurred. The Company reviews and accrues R&D expenses based on services performed and may, from time to time, make estimates of those costs applicable as to the stage of completion of each project. Actual results could differ from the Company's estimates.

Upfront payments and milestone payments made for the licensing of technology for products that are not yet approved by the FDA are expensed as R&D in the period in which they are incurred. Nonrefundable advance payments for goods or services to be received in the future for use in R&D activities are recorded as prepaid expenses and are expensed as the related goods are delivered or the services are performed.

Income (Loss) Per Share

Basic net income (loss) per common share is computed by dividing net income (loss) attributable to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders for the period by the weighted average number of common and common equivalent shares, such as unvested restricted stock, stock options and warrants that are outstanding during the period. Common stock equivalents are excluded from the computation when their inclusion would be anti-dilutive. No such adjustments were made for 2025, 2024 or 2023 as the Company reported a net loss for the years ended December 31, 2025, 2024 and 2023 and including the effects of common stock equivalents in the diluted earnings per share calculation would have been anti-dilutive (see Note 11).

Stock-Based Compensation

The Company accounts for stock-based compensation under the provisions of ASC 718 Compensation – Stock Compensation. The guidance under ASC 718 requires companies to estimate the fair value of the stock-based compensation awards on the date of grant and record expense over the related service periods, which are generally the vesting period of the equity awards. Compensation expense is recognized over the period during which services are rendered by consultants and non-employees until completed.

The Company estimates the fair value of stock-based option awards using the Black-Scholes option-pricing model ("BSM"). The BSM requires the input of subjective assumptions, including the expected stock price volatility, the calculation of expected term, forfeitures and the fair value of the underlying common stock on the date of grant, among other inputs. The risk-free interest rate was determined from the implied yields for zero-coupon U.S. government issues with a remaining term approximating the expected life of the options or warrants. Dividends on common stock are assumed to be zero for the BSM valuation of the stock options. The expected term of stock options granted is based on vesting periods and the contractual life of the options. Expected volatilities are based on the Company's historical volatility subsequent to our IPO, which we believe represents the most accurate basis for estimating expected future volatility under the current conditions. The Company accounts for forfeitures as they occur.

Income Taxes

As part of the process of preparing the Company's financial statements, the Company must estimate the actual current tax liabilities and assess temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included within the balance sheets. The Company must assess the likelihood that the deferred tax assets will be recovered from future taxable income and, to the extent the Company believes that recovery is not likely, a valuation allowance must be established. To the extent the Company establishes a valuation allowance or increase or decrease to this allowance in a period, the impact will be included in income tax expense in the Statements of Operations. As of December 31, 2025 and 2024, the Company has established a 100% valuation reserve against its deferred tax assets.

The Company accounts for income taxes under the provisions of ASC 740 - Income Taxes. The Company's practice is to recognize interest and penalties related to income tax matters in income tax expense. For the years ended December 31, 2025 2024 and 2023, the Company recognized interest and penalties in the Statements of Operations for $3, $6 and $0, respectively. As of December 31, 2025, the Company is subject to taxation in the United States and certain individual states – primarily Illinois and Tennessee. The Company's tax losses from 2017 through 2025 are subject to examination by the federal and state tax authorities due to the carryforward of unutilized net operating losses ("NOLs").

Fair Value Measurements

We measure certain of our assets and liabilities at fair value. Fair value represents the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value accounting requires characterization of the inputs used to measure fair value into a three-level fair value hierarchy as follows:

Level 1 – Inputs based on quoted prices in active markets for identical assets or liabilities. An active market is a market in which transactions occur with sufficient frequency and volume to provide pricing information on an ongoing basis.

Level 2 – Observable inputs that reflect the assumptions market participants would use in pricing the asset or liability developed based on market data obtained from sources independent from the entity.

Level 3 – Unobservable inputs that reflect the entity's own assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available.

Note 3 — Summary of Significant Accounting Policies (continued)

Fair value measurements are classified based on the lowest level of input that is significant to the measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment, which may affect the valuation of the assets and liabilities and their placement within the fair value hierarchy levels. The determination of the fair values stated below takes into account the market for the Company's financials, assets and liabilities, the associated credit risk and other factors as required. The Company considers active markets as those in which transactions for the assets or liabilities occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

The Company's financial instruments included cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities and long-term debt obligation. The carrying amounts of these financial instruments, except for the long-term debt obligation, approximate their fair values due to the short-term maturities of these instruments. Based on borrowing rates currently available to the Company, the carrying value of the long-term debt obligation approximate its fair value.

Impact of Recent Accounting Pronouncements

The Company's management has evaluated all of the recently issued, but not yet effective, accounting standards that have been issued or proposed by the FASB or other standards-setting bodies through the filing date of these financial statements and does not believe the future adoption of any such pronouncements will have a material effect on the Company's financial position, results of operations and cash flows.

New Pronouncements Adopted

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which includes amendments that further enhance income tax disclosures, primarily through standardization and disaggregation of rate reconciliation categories and income taxes paid by jurisdiction. The amendments are effective for the Company's annual periods beginning January 1, 2025, with early adoption permitted, and may be applied either prospectively or retrospectively. The Company has adopted this new guidance in its financial statements on a prospective basis.

New Pronouncements Issued

In November 2024, the FASB issued ASU 2024-03, Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40). Additionally, in January 2025, the FASB issued ASU 2025-01 to clarify the effective date of ASU 2024-03. The standard provides guidance to expand disclosures related to the disaggregation of income statement expenses. The standard requires, in the notes to the financial statements, disclosure of specified information about certain costs and expenses, which includes purchases of inventory, employee compensation, depreciation and intangible asset amortization included in each relevant expense caption. This guidance is effective for fiscal years beginning after December 15, 2026, and interim periods within annual reporting periods beginning after December 15, 2027, on a retrospective or prospective basis, with early adoption permitted. The Company is currently evaluating the effect of this new guidance on its financial statements.

Note 4 – Business Combination

On October 2, 2024, the Company and Ipsen Biopharmaceuticals, Inc. ("Ipsen"), a subsidiary of Ipsen S.A., entered into an Asset Purchase Agreement (the "Purchase Agreement"), whereby the Company agreed to acquire Increlex® (mecasermin injection) from Ipsen. Increlex® is a biologic product used to treat children and adolescents from two-to 18-years-old who suffer from severe primary insulin-like growth factor 1 deficiency (SPIGFD). The primary reason for the Increlex® product acquisition was due to the Company's expertise and strong relationships in pediatric endocrinology in addition to leveraging the Company's existing sales team to increase awareness of SPIGFD.

Under the terms of the Purchase Agreement, the Company acquired Increlex® for $22,500 at closing, plus an additional $7,500 for product inventory. The Company will also make payments to Ipsen of $2,500 on each of the first and second anniversaries of closing. In addition, the Company will be obligated to purchase additional inventory over 30 months, in an amount not to exceed €15,000. The Company also entered into an amendment to its existing credit agreement with SWK Holdings Corporation ("SWK") that was contingent upon the closing of the Purchase Agreement. Under the terms of the amendment, the Company expanded its existing credit facility by $25,700 to $30,000, extended the facility's maturity to three years from closing, and reduced the facility's annual interest rate to Secured Overnight Financing Rate ("SOFR") plus 6.75%. - refer to Note 7, "Debt" for further details. In connection with the closing of Purchase Agreement, the Company issued a warrant to the lender for the purchase of up to 289,736 shares of common stock at a price of $5.32 per share. On December 19, 2024, the Company completed the acquisition of Increlex®.

The Company determined that the asset purchase agreement met the definition of a business under ASC 805; therefore, the Company accounted for the Purchase Agreement as a business combination and applied the acquisition method of accounting.

(in thousands, except share and per share amounts)

Note 4 – Business Combination (continued)

The allocation of the purchase consideration was as follows:

	Purchase Price Allocation
Cash consideration	$ 30,000
Deferred payments (1)	4,276
Total consideration	$ 34,276
Inventory (2)	13,010
Intangible assets (3)	21,250
Goodwill (4)	16
Assets acquired	34,276
Net assets acquired	$ 34,276

(1) Deferred payments represent the acquisition date fair value of the $5,000 in deferred consideration to be paid to Ipsen. The Company will make payments of $2,500 on each of the first and second anniversaries of closing, which the closing date of the acquisition was December 19, 2024. The Company will accrete the $724, which represents the difference between the total deferred payments amount due of $5,000 and the acquisition date fair value of $4,276, to interest expense in its Statements of Operations over the course of the two-year period using the effective interest rate methodology.

(2) Inventory consists of raw materials, semi-finished goods and finished goods. Finished goods, semi-finished goods and raw materials inventory were valued on the acquisition date at fair value and resulted in a $5,510 step-up in inventory value compared to a $7,500 carrying value. Determining the fair value of inventory included making estimates of costs to complete and to sell semi-finished and finished goods inventory.

(3) Intangible assets consist of the transferred intellectual property as a part of the license agreement. The estimated fair value of the intangible asset was determined using the multi-period excess earnings method ("MPEEM"), which is a form of income approach, which incorporates the estimated future cash flows to be generated from the product utilizing the existing customer base. Excess earnings are the earnings remaining after deducting the market rates of return on the estimated value of contributory assets, including debt-free net working capital, tangible assets, other long-term assets and other identifiable intangible assets. The excess earnings are thereby calculated from each year of a multi-year projection period and discounted to present value. The primary components of this method consist of the discount rate and contributory asset charges. The imputed fair value of the Increlex® intangible asset of $21,250 will be amortized over its useful life of ten years.

(4) Goodwill represents the excess of the purchase price consideration over the fair value of the net assets acquired. Due to the immateriality of the implied value of goodwill, the Company elected to expense the $16 in goodwill, which was expensed to general and administrative expenses for the year ended December 31, 2024 in the Company Statements of Operations.

Transition services agreement

Concurrent with the Purchase Agreement, the Company entered into a transition services agreement (the "TSA") with Ipsen to govern Ipsen providing transitional pharmaceutical marketing services, distribution services and other related support and assistance with operations outside the U.S. The services being provided under the TSA have been priced at market rates, and the Company is not receiving a discount from Ipsen for these services. As a result, there was no portion of the purchase price allocated to the TSA consideration. The separate consideration under the TSA will be expensed as occurred and when services are received.

Acquisition/divestiture related costs

For the years ended December 31, 2025 and December 31, 2024, the Company incurred acquisition and divestiture related costs of $581 and $415, respectively, which were expensed as incurred and included in general and administrative expenses in the Statements of Operations.

(in thousands, except share and per share amounts)

Note 5 – Property and Equipment

Property and equipment consist of the following:

	December 31, 2025	December 31, 2024
Computer hardware and software	$ 200	$ 200
Furniture and fixtures	265	125
Equipment	52	52
Leasehold improvements	295	103
Property and equipment, gross	812	480
Less: accumulated depreciation and amortization	(486)	(446)
Property and equipment, net	$ 326	$ 34

Depreciation expense for the years ended December 31, 2025, 2024 and 2023 was $41, $50 and $44, respectively.

Note 6 – Inventory

Inventory consisted of the following:

	December 31, 2025	December 31, 2024
Raw materials	$ 557	$ 5,355
Semi-finished goods	9,431	3,288
Finished goods	6,630	7,194
Less: excess and obsolete inventory reserve	(1,199)	(605)
Inventory, net	$ 15,419	$ 15,232

During the years ended December 31, 2025, 2024 and 2023, provision reserves for excess and obsolete inventory was $594, $529 and $15, respectively.

Note 7 – Debt

SWK Loan

In November 2019, the Company entered into a credit agreement (the "SWK Credit Agreement") with SWK, which provided for up to $10,000 in debt financing. As a result of subsequent amendments to the SWK Credit Agreement, the Company expanded its credit facility to $30,000, extended the facility's maturity to three years from closing with a loan maturity date of December 17, 2027, and reduced the facility's annual interest rate to Secured Overnight Financing Rate ("SOFR") plus 6.75%.

Interest payments are payable quarterly, with quarterly principal payments of $3,000 beginning in May 2026 with a final principal payment of $9,000 due at maturity in December 2027. The SWK Credit Agreement includes a 5.0% exit fee payable at maturity and this exit fee payable will be accreted to interest expense in the Company's Statement of Operations using the effective interest expense method. The SWK Credit Agreement contains a mandatory prepayment clause that can compel the Company to partially prepay the loan upon certain triggering events, which the Company has deemed to be remote. Borrowing under the SWK Credit Agreement is secured by the Company's assets, contains customary default provisions, which include limits on additional indebtedness. As of December 31, 2025 and 2024, the Company was in compliance with all financial covenants.

The Company recorded interest expense of $4,781, $2,005 and $1,060 in 2025, 2024 and 2023, respectively, which included $696, $1,109 and $117, respectively, of debt discount amortization. For the year ended December 31, 2024, debt discount included $1,170, which was associated with the issuance of warrants to SWK. The Company had accrued interest of $425 and $182 as of December 31, 2025 and 2024, respectively, which is included in accrued liabilities in the accompanying Balance Sheets. As of December 31, 2025 and 2024, the effective interest rate was 14.62% and 14.46%, respectively.

(in thousands, except share and per share amounts)

The table below reflects the future annual payments for the SWK loan principal as of December 31, 2025.

	Amount
2026	$ 9,000
2027	21,000
Total payments	30,000
Less: unamortized discount	(330)
Plus: accrued exit fees at December 31, 2025	888
Debt, net of unamortized discount and accrued exit fees	$ 30,558

Note 8 — Common Stock

The Company has 50,000,000 authorized shares of $0.001 par value common stock under its Amended and Restated Certificate of Incorporation.

For the years ended December 31, 2025, 2024 and 2023, the Company issued 161,933, 266,353 and 207,626 (net shares issued after a portion of 407,808 shares was a cashless exercise), respectively, of its common stock resulting from stock option exercises under its 2018 Equity Incentive Plan (see Note 10). The Company withheld 50,867 shares for payroll tax obligations totaling $180 for the year ended December 31, 2023. For the years ended December 31, 2025, 2024 and 2023, the Company issued 16,894, 80,933 shares and 86,782, respectively, under the Company's Employee Stock Purchase Plan ("ESPP"). For the years ended December 31, 2025, 2024 and 2023, the Company issued 159,150, 90,402 and 91,402 respectively, in shares of its common stock due to the vesting of restricted stock units.

On December 10, 2024, the Company entered into a securities purchase agreement with an institutional investor, pursuant to which the Company issued 583,334 shares of its common stock at an offering price of $12.00 per common share for gross proceeds to the Company of $7,000 before deducting any related offering expenses.

Note 9 — Common Stock Warrants

Warrants outstanding as of December 31, 2025 is listed in the table below:

Description of Warrants	Warrant Issuance Date	No. of Shares	Exercise Price
SWK Warrants – Debt (Tranche #1)	11/13/2019	51,239	$ 5.86
SWK Warrants – Debt (Tranche #2)	8/11/2020	18,141	$ 6.62
SWK Warrants – Debt (Tranche #3)	9/30/2024	289,736	$ 5.32
Total shares and weighted average exercise price		**359,116**	**$ 5.46**

The holders of these warrants or their permitted transferees, are entitled to rights with respect to the registration under the Securities Act of their shares that are converted to common stock, including demand registration rights and piggyback registration rights. These rights are provided under the terms of a registration rights agreement between the Company and the holders.

On September 30, 2024, in connection with the Company's amendment to expand its existing credit facility to $30.0 million with SWK, the Company issued 289,736 warrants to SWK at a price of $5.32 per share. The fair value of these 289,736 warrants was $1,170 and was estimated using the BSM with the following assumptions: fair value of the Company's common stock at issuance of $6.00 per share with an exercise price of $5.32; seven-year contractual term; 63.8% volatility; 0% dividend rate; and a risk-free interest rate of 3.67%.

There were no warrants exercised in 2023, 2024 or 2025.

Note 10 — Share-Based Payment Awards

The Company's board of directors and stockholders approved the Eton Pharmaceuticals, Inc. 2017 Equity Incentive Plan in May 2017 (the "2017 Plan"), which authorized the issuance of up to 5,000,000 shares of the Company's common stock. In conjunction with the Company's IPO in November 2018, the Company's stockholders and board of directors approved the 2018 Equity Incentive Plan, as amended (the "2018 Plan") which succeeded the 2017 Plan. The Company has granted RSAs, stock options and RSUs for its common stock under the 2017 Plan and 2018 Plan as detailed in the tables below. There were 2,099,847 shares available for future issuance under the 2018 Plan as of December 31, 2025.

(in thousands, except share and per share amounts)

Note 10 — Share-Based Payment Awards (continued)

Shares that are expired, terminated, surrendered or canceled without having been fully exercised will be available for future awards under the 2018 Plan. In addition, the 2018 Plan provides that commencing January 1, 2019 and through January 1, 2028, the share reserve will be increased by 4% of the total number of shares outstanding as of the preceding December 31, subject to a reduction at the discretion of the Company's board of directors. On January 1, 2024, the share reserve was increased by 1,027,522 shares based on the 25,688,062 shares of common stock outstanding at December 31, 2023. On January 1, 2025, the share reserve was increased by 1,068,363 shares based on the 26,709,084 shares of common stock outstanding at December 31, 2024. On January 1, 2026, the share reserve was increased by 1,081,882 shares based on the 27,047,061 shares of common stock outstanding at December 31, 2025.The exercise price for stock options granted is not less than the fair value of common stock as determined by the board of directors as of the date of grant. The Company uses the closing stock price on the date of grant as the exercise price.

Stock options typically have a ten-year life, are issued in the form of non-qualified stock options, and the exercise prices were set at the fair value for the shares at the dates of grant.

In August 2024, the Company's board of directors approved a modification of certain outstanding awards of a senior executive who retired in August 2024. The combined awards had an exercise price range of $3.47 to $8.61 which were set to expire 90 days after retirement or termination as the case may be, and the Company extended the expiration dates to November 2025 in conjunction with ongoing consulting services. No other terms were modified. Due to these modifications, the Company incurred a modification expense of $75 that is included in general and administration expense on the Statements of Operations for the year ended December 31, 2024.

For the years ended December 31, 2025, 2024 and 2023, the Company's total stock-based compensation expense was $5,512, $3,165 and $3,137, respectively. Of these amounts, $5,330, $2,899, and $2,864 was recorded in general and administrative expenses, respectively, and $182, $266, and $273 was recorded in R&D expenses, respectively. The tax deductions related to stock compensation expense during the years ending December 31 2025, 2024 and 2023, were approximately $1,006, $530, and $486, respectively, on a tax-effected basis.

Stock Options

The following table summarizes stock option activity during the year ended December 31, 2025:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Options outstanding as of January 1, 2025	5,918,616	$ 4.65		
Issued	471,059	13.12		
Exercised	(161,933)	3.70		
Forfeited/Cancelled	(316,220)	4.99		
Options outstanding as of December 31, 2025	5,911,522	$ 5.35	6.1	$ 68,325
Options exercisable at December 31, 2025	4,684,707	$ 4.94	5.6	$ 56,093
Options vested and expected to vest at December 31, 2025	5,911,521	$ 5.35	6.1	$ 68,325

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had strike prices lower than the fair value of the Company's common stock at December 31. The intrinsic value of the options exercised during the twelve-months ended December 31, 2025 and 2024 was $1,852 and $1,867, respectively.

For the years ended December 31, 2025, 2024 and 2023, there were 161,933, 266,353 and 207,626, shares issued for exercise of stock options, respectively for proceeds of $598, $1,191 and $149, respectively.

The assumptions used to calculate the estimated fair value of options granted during the years ended December 31, 2025, 2024 and 2023 under the BSM were as follows:

	December 31, 2025	December 31, 2024	December 31, 2023
Expected dividends	—%	—%	—%
Expected volatility	65%	70%	70%
Risk-free interest rate	3.9 - 4.7%	3.5 - 4.4%	3.5 - 4.7%
Expected term (in years)	6.1	6.2	6.3
Weighted average grant date fair value	$ 8.44	$ 3.22	$ 2.32

Expected Term — The Company has opted to use the "simplified method" for estimating the expected term of options granted to employees and directors, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option (generally 10 years). The expected term of options granted to non-employees equals the contractual life of the options.

Expected Volatility — Expected volatilities are based on the Company's historical volatility subsequent to our IPO, which we believe represents the most accurate basis for estimating expected future volatility under the current conditions.

Risk-Free Interest Rate — The risk-free rate assumption is based on the U.S. Treasury instruments with maturities similar to the expected term of the Company's stock options.

(in thousands, except share and per share amounts)

Expected Dividend — The Company has not issued any dividends in its history and does not expect to issue dividends over the life of the options and therefore has estimated the dividend yield to be zero.

Fair value of Common Stock —The Company uses the closing stock price on the date of grant for the fair value of the common stock.

As of December 31, 2025, there was a total of $4,995 of unrecognized compensation costs related to non-vested stock option awards which will be recognized over a weighted average period of 2.5 years.

Restricted Stock Units (RSUs)

The following table summarizes restricted stock unit activity during the years ended December 31, 2025 and 2024:

	Number of Shares	Weighted Average Grant-Date Fair Value Per Unit
Outstanding and unvested as of January 1, 2024	274,204	$ 2.63
Granted	65,266	$ 6.74
Vested	(90,402)	$ 2.63
Forfeited	(23,000)	$ 2.63
Outstanding and unvested as of December 31, 2024	226,068	$ 3.82
Granted	255,956	$ 14.02
Vested	(159,150)	$ 9.29
Forfeited	(44,373)	$ 6.92
Outstanding and unvested as of December 31, 2025	278,501	$ 9.57

Stock-based compensation related to RSUs was $1,985, $241 and $239 for the years ended December 31, 2025, 2024 and 2023, respectively. As of December 31, 2025, there was $2,032 of unrecognized stock-based compensation expense related to unvested RSUs which will be recognized over a weighted average period of 2.4 years.

Employee Stock Purchase Plan

In December 2018, the Company's board of directors adopted an initial offering of the Company's common stock under the Company's ESPP. The Company's ESPP provides for an initial reserve of 150,000 shares and this reserve is automatically increased on January 1 of each year by the lesser of 1% of the outstanding common shares at December 31 of the preceding year or 150,000 shares, subject to reduction at the discretion of the Company's board of directors.

The terms of the ESPP permit employees of the Company to use payroll deductions to purchase stock at a price per share that is at least the lesser of (1) 85% of the fair market value of a share of common stock on the first date of an offering or (2) 85% of the fair market value of a share of common stock on the date of purchase. After the initial offering period, subsequent twelve-month offering periods automatically commence over the term of the ESPP on the day that immediately follows the conclusion of the preceding offering, each consisting of two purchase periods approximately six months in duration ending on or around June 10 and December 10 each year, subject to a restart feature if the Company's stock price drops at the end of a six-month period within the twelve-month offering period.

The Company recorded an expense of $97, $205, and $135 in 2025, 2024 and 2023, respectively, related to the ESPP. For the years ended December 31, 2025, 2024 and 2023, there were 16,894, 80,933 and 86,782 share issuances, respectively, under the ESPP. The weighted average grant date fair value of share awards in 2025, 2024 and 2023 was $12.83, $1.35, and $1.17 per share, respectively. Employees contributed $217, $283 and $230 to the ESPP during 2025, 2024 and 2023, respectively. Of these amounts, $45 and $42 at December 31, 2025 and 2024, respectively, are included in accrued liabilities in the accompanying balance sheets. As of December 31, 2025, there were 825,687 shares available for issuance under the ESPP.

(in thousands, except share and per share amounts)

Note 11 — Basic and Diluted Net Loss per Common Share

Basic and diluted net loss per share is computed using the weighted average number of shares of common stock outstanding during the period. Common stock equivalents (using the treasury stock and "if converted" method) from stock options, RSUs, and warrants at December 31, 2025, 2024 and 2023 were 7,780,895, 6,389,345, and 5,418,251 respectively, and are excluded from the calculation of diluted net loss per share because the effect is anti-dilutive. Included in the basic and diluted net loss per share calculation were RSUs awarded to directors that had vested, but the issuance and delivery of the shares are deferred until the director retires from service as a director.

The following table shows the computation of basic and diluted net loss per common share:

	Year ended December 31, 2025	Year ended December 31, 2024	Year ended December 31, 2023
Net loss	$ (4,601)	$ (3,823)	$ (936)
Weighted average common shares outstanding (basic and diluted)	26,907,725	25,895,086	25,645,366
Net loss per common share (basic and diluted)	$ (0.17)	$ (0.15)	$ (0.04)

Note 12 — Related-Party Transactions

Chief Executive Officer

The CEO has a partial interest in a company that the Company has partnered with for its EM-100/Alaway Preservative Free eye allergy product.

Previously, the Company acquired DS-200 and all related intellectual property pursuant to an asset purchase agreement (the "Selenix Agreement") dated June 23, 2017 between the Company and Selenix LLC ("Selenix"), an entity affiliated with the CEO. On August 30, 2024, the Company amended the Selenix Agreement in tandem with an agreement to sell DS-200 in August 2024 (see Note 12). Pursuant to the terms of the amended Selenix Agreement, Selenix waived its rights to future milestone payments and 50% of DS-200 profit in exchange for 45% of proceeds received by the Company from the DS-200 sale agreement. Selenix is 50% owned by Messa Holdings LLC ("Messa"), which is 100% owned by the CEO. In March 2025, the Company recognized licensing revenue of $1,500 and $675 in cost of sales from a development milestone. In June 2025, the Company paid $675 to Selenix.

Note 13 — Leases

The Company recognizes a right-of-use ("ROU") asset and a lease liability on the balance sheet for substantially all leases, including operating leases, and separates lease components from non-lease components related to its office space lease.

In May 2025, the Company entered into an amendment to its office lease agreement to expand its office space, from 5,507 square feet, to 8,079 square feet and to renew its lease term. The amendment to the lease agreement is effective September 1, 2025 and the renewal period for the office lease is for a sixty-five month period through January 2031 and which includes tenant improvement allowances. The Company removed its existing ROU asset and liability and recorded $333 in ROU assets, $189 in tenant improvement allowances and $522 in operating lease liabilities in association with the lease extension. In June 2024, the Company renewed its office lease for a two-year period through March 2027 and recorded $219 in ROU assets and $219 in operating lease liabilities in association with the lease extension.

The Company's operating lease cost as presented as G&A in the Statements of Operations was $92, $82 and $67 for the years ended December 31, 2025, 2024 and 2023, respectively. For the years ended December 31, 2025, 2024 and 2023, cash paid for amounts included in the measurement of operating lease liabilities was $68, $58 and $88, respectively. The ROU asset non-cash lease expense was $44, $70 and $67 for the years ended December 31, 2025, 2024 and 2023, respectively, and is reflected within non-cash lease expense on the Company's Statements of Cash Flows. As of December 31, 2025 and 2024, the average remaining lease term was 5.17 and 2.25 years, respectively and as of December 31, 2025 and 2024, the average discount rate was 11.8% and 8.6%. respectively, for each period.

The table below presents the lease-related assets and liabilities recorded on the balance sheet as of December 31, 2025 and December 31, 2024:

Assets	Classification	December 31, 2025	December 31, 2024
Operating lease right-of-use assets	Operating lease right-of-use assets, net	$ 310	$ 175
Total leased assets		$ 310	$ 175
Liabilities			
Operating lease liabilities, current	Accrued liabilities	$ 65	$ 76
Operating lease liabilities, noncurrent	Operating lease liabilities, net of current portion	460	107
Total operating lease liabilities		$ 525	$ 183

(in thousands, except share and per share amounts)

The Company's future annual lease commitments as of December 31, 2025 are as indicated below:

	Total	2026	2027	2028	2029	2030 & thereafter
Undiscounted lease payments	$ 710	$ 123	$ 134	$ 138	$ 142	$ 173
Less: Imputed interest	(185)					
Total lease liabilities	$ 525					

Note 14 – Income Taxes

The provision for income taxes for the Company consists of the following for the years ended December 31, 2025, 2024 and 2023:

	Year ended December 31, 2025	December 31, 2024	December 31, 2023
Current:			
Federal	$ (16)	$ 24	$ 61
State	59	(9)	186
Total current expense	43	15	247
Deferred:			
Federal	—	(223)	(85)
State	—	1,150	(31)
Change in valuation allowance	—	(927)	116
Total deferred expense	—	—	—
Total provision	$ 43	$ 15	$ 247

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income taxes. The significant components of the Company's deferred tax assets as of December 31, 2025 and 2024 are as follows:

	December 31, 2025	December 31, 2024
Deferred tax assets:		
Net operating loss carryforwards	$ 14,089	$ 14,145
Stock-based compensation	2,551	2,021
Research & development capitalization	1,286	2,007
Research & development credits	1,438	42
Medicare reserves	2,390	1,767
Accruals and other	2,829	1,011
Total deferred tax assets	24,583	20,993
Valuation allowance	(23,101)	(20,589)
Deferred tax assets	$ 1,482	$ 404
Deferred tax liabilities:		
Prepaid expenses	$ (838)	$ (174)
IRC 481(a) adjustments	(483)	—
Deferred consideration discount	(62)	(182)
Right-of-use assets	(79)	(45)
Other deferred tax liabilities	(20)	(3)
Deferred tax liabilities	$ (1,482)	$ (404)
Net deferred tax assets (liabilities)	$ —	$ —

In assessing the realizability of deferred tax assets, the Company considers all available positive and negative evidence to evaluate whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. As of December 31, 2025, the Company believes it is more likely than not that the Company's net deferred tax assets would not be realized and continues to record a full valuation allowance on its net deferred tax assets. The Company's valuation allowance represents the amount of tax benefits that are likely to not be realized.

The Company has gross federal net operating losses of $49,697, which can be carried forward indefinitely, and gross state net operating losses of $52,400, which begin to expire in 2035. The Company's federal net operating losses, and certain state net operating losses, are subject to an 80% annual utilization limitation. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change (by value) in its equity ownership over a

three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited.

(in thousands, except share and per share amounts)

A reconciliation of the provision for income taxes to the amount computed by applying the statutory federal income tax rate to income taxes after the adoption of ASU 2023-09 is as follows:

	Year ended December 31, 2025	
	Amount	%
U.S federal statutory tax rate	$ (957)	21.00%
State and local income taxes (1)		
State income tax, net of federal tax benefit	(170)	3.75%
Change in valuation allowance	207	(4.54%)
Change in state tax rate	21	(0.47%)
Change in uncertain tax position reserve	(22)	0.48%
Return to provision related to tax credit study	23	(0.51%)
Income tax credits		
Research and development tax credits	(63)	1.37%
Orphan drug tax credits	(391)	8.58%
Return to provision related to tax credit study	(741)	16.25%
Changes in valuation allowance	2,305	(50.59%)
Nontaxable or nondeductible items		
Section 162(m) limitation	389	(8.53%)
Stock-based compensation	(424)	9.30%
Return to provision adjustments	64	(1.41%)
Other	9	(0.15%)
Changes in unrecognized tax benefits	(207)	4.53%
Effective tax rate	$ 43	(0.94%)

(1) The state jurisdiction that contributes to the majority (greater than 50%) of the tax effect in this category is Tennessee.

A reconciliation of the provision for income taxes to the amount computed by applying the statutory federal income tax rate to income before income taxes after the adoption of ASU 2023-09 is as follows:

	Year ended	
	December 31, 2024	December 31, 2023
Benefit based on federal statutory rate	$ (800)	$ (145)
Stock-based compensation	880	254
Change in state tax rate	814	-
State income tax, net of federal tax benefit	(31)	(45)
Section 162(m) limitation	169	-
Other permanent differences	18	299
Research and development credits	(277)	-
Change in uncertain tax position reserve	382	-
Return to provision	(213)	-
Change in valuation allowance	(927)	(116)
Income tax expense	$ 15	$ 247

The Company recognizes tax benefits from uncertain positions if it is more likely than not that the tax position will be sustained by the tax authority upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits of the position. If a tax position meets the more likely than not threshold, the Company measures the tax position as the largest amount of benefit that is greater than 50% likely to be realized upon ultimate settlement. A reconciliation of uncertain tax positions at the beginning and end of the years below is as follows:

	Year ended		
	December 31, 2025	December 31, 2024	December 31, 2023
Beginning balance	$ 382	$ —	$ —
Gross increases (decreases) related to prior year positions	(61)	243	-
Gross increases (decreases) related to current year positions	113	139	-
Ending balance	$ 434	$ 382	$ —

(in thousands, except share and per share amounts)

As of December 31, 2025, approximately $434, would reduce the Company's annual effective tax rate, if recognized. The Company recognizes interest and, if applicable, penalties for any uncertain tax positions. Interest and penalties related to uncertain tax positions are recorded as a component of income tax expense. The Company accrued for interest and penalties associated with unrecognized tax benefits for the years ended December 31, 2025 and 2024 in the amount of $3 and $6, respectively. No interest or penalties associated with unrecognized tax benefits were accrued for in the year ended December 31, 2023.

The Company files income tax returns in the U.S. federal jurisdiction and various state jurisdictions. With the exception of tax attributes created in prior years that may potentially be adjusted, the federal statute of limitations remains open for the 2022 tax year to present and the state statutes of limitations generally remain open for the 2021 tax year to present.

The amounts of cash income taxes, net of refunds, paid by the Company during the year ended December 31, 2025 was as follows:

Federal	$	—
Tennessee		75
Other states		43
Total net payments (refunds)	$	118

The amount of cash income taxes, net of refunds, paid by the Company during the years ended December 31, 2024 and 2023 was $82 and $247, respectively.

Note 15 - Employee Savings Plan

The Company established an employee savings plan pursuant to Section 401(k) of the Internal Revenue Code, effective January 1, 2018. The plan allows participating employees to deposit into tax deferred investment accounts up to 100% of their salary, subject to annual limits. The Company makes certain matching contributions to the plan in amounts up to 4% of the participants' annual cash compensation, subject to annual limits. For the years ended December 31, 2025, 2024 and 2023, the Company made $350, $259, and $242, respectively, in matching contributions.

Note 16 — Commitments and Contingencies

Legal

The Company is subject to legal proceedings and claims that may arise in the ordinary course of business. The Company is not aware of any pending or threatened litigation matters at this time that may have a material impact on the operations of the Company.

License and Product Development Agreements

The Company has entered into various agreements which are described below.

In March 2020, the Company entered into an Exclusive License and Supply Agreement (the "Alkindi License Agreement") with Diurnal for marketing ALKINDI SPRINKLE® in the United States. In September 2020, ALKINDI SPRINKLE®'s New Drug Application (NDA) was approved by the FDA as a replacement therapy for pediatric patients with adrenocortical insufficiency. For the initial licensing milestone fee, the Company paid Diurnal $3,500 in cash and issued 379,474 shares of its common stock to Diurnal, which were valued at $1,264 based on the Company's closing stock price of $3.33 on March 26, 2020. The Company paid Diurnal $1,000 for a 2023 sales milestone in January 2024 that was recorded as licensing cost of sales in December 2023 and could pay up to $44,000 in additional commercial net sales milestones. The Company will pay tiered royalties of 11.5% to 17.0% on net sales and could pay Diurnal $2,500 if the product obtains orphan drug exclusivity status from the FDA. In December 2024, the Company and Diurnal entered into an amendment to the Alkindi License Agreement to extend the agreement terms to incorporate both ALKINDI SPRINKLE® and KHINDIVI™ in the existing agreement terms.

In June 2021, the Company acquired U.S. and Canadian rights to Crossject's ZENEO® hydrocortisone needleless autoinjector, which is under development as a rescue treatment for adrenal crisis. The Company paid Crossject $500 upon signing, $500 in March 2022 upon a completion of a successful technical batch and could pay up to $3,500 in additional development milestones and up to $6,000 in commercial milestones, as well as a 10% royalty on net sales.

In March 2023, the Company acquired rare disease endocrinology product candidate ET- 600 from Tulex. The Company paid $450 to Tulex in July 2023 as a result of successful manufacturing of registration batches. The Company will pay Tulex $200 upon acceptance by the FDA of the NDA for the product, $250 upon first commercial sale of the product, and tiered royalties of 12.5% to 17.0% on net sales.

In March 2024, the Company acquired the U.S. rights to PKU GOLIKE® from Relief Therapeutics Holding SA. The Company paid $2,200 and could pay up to $2,000 in additional commercial milestones. The Company will pay the seller a royalty of 30% of net sales, which will include the cost of the product.

In August 2024, the Company entered into an agreement to sell its DS-200 product candidate. The Company received $500 upfront and in March 2025, the Company recognized licensing revenue of $1,500 from a development milestone. In addition, the Company could receive additional milestone payments of up to $5,000 based on the achievement of certain future development and commercial milestones related to DS-200, of which the Company could recognize 45% of the proceeds from future milestone from the transaction, with the balance being distributed to other partners.

In November 2024, the Company entered into a licensing agreement with AMMTeK. pursuant to which the Company has agreed to acquire the U.S. rights to Amglidia (glyburide oral suspension). Amglidia was approved by the European Medicines Agency in 2018 and has been granted Orphan Drug Designation by the U.S. FDA. AMMTeK. has conducted a post-approval study tracking five years of real-world safety and efficacy in European patients, which will be used to support the Company's s NDA submission. In July 2025, the Company paid $500 to AMMTek upon the receipt of FDA meeting minutes and under the terms of the licensing agreement, the Company could pay up to $1,850 as follows: $550 upon NDA acceptance for review by the FDA and $1,300 upon NDA approval by the FDA and first commercial sale. The Company would also be required to pay a royalty of 14% of net sales to AMMTek.

In December 2024, the Company acquired GALZIN® (zinc acetate) from Teva Pharmaceuticals USA, Inc and assumed the commercialization of the product in the U.S. during March of 2025. The Company accounted for the purchase as a product acquisition and paid $7,000 and paid an additional $200 for product inventory. The Company will pay the seller a royalty of 10% of U.S. net sales through the tenth anniversary of the Company's first commercial sales of the product in the U.S.

In December 2024, the Company acquired INCRELEX® (mecasermin injection) from Ipsen S.A. The Company paid $22,500 for the product and paid an additional $7,500 for product inventory. The Company determined that the asset purchase agreement met the definition of a business under ASC 805; therefore, the Company accounted for the asset purchase agreement as a business combination and applied the acquisition method of accounting. In addition, the Company will also make payments to seller of $2,500 on each of the first and second anniversaries of closing, of which $2,500 was paid to Ipsen S.A. in December 2025. As of December 31, 2025, the present value of the deferred consideration was $2,259, with $241 to be accreted to interest expense over the remainder of the deferred consideration term using the effective interest rate method. As of December 31, 2025, $2,259 was classified as accrued liabilities in the accompanying Balance Sheets.

In connection with the INCRELEX® product acquisition, the Company assumed the commercial manufacturing and supply agreement between Baxter Oncology GmbH and Ipsen Pharma SAS. The commercial manufacturing and supply agreement was executed in November 2020 and expires in November 2027. The commercial manufacturing and supply agreement is associated with the production of INCRELEX® for commercial usage and contains an annual production obligation and a maximum annual obligation. For each contract year, there is an annual obligation of two batches, with a maximum obligation of three batches at batch price of 5,000 Euros.

Additionally, in connection with the INCRELEX® product acquisition, the Company assumed a manufacturing services agreement between Lonza Ltd and Ipsen Pharma SAS, as amended. The manufacturing services agreement was executed in December 2022 and expires in December 2026. The manufacturing services agreement is associated with the production of INCRELEX® bulk drug substance and contains an annual production obligation and a maximum obligation. For each contract year, there is an annual obligation and the fixed pricing for each batch that will vary according to the yield on that particular batch and in accordance with the target yield in kilograms and number of ordered batches.

In March 2025, the Company out-licensed the commercial rights to INCRELEX® in territories outside of the U.S. to Esteve Pharmaceuticals, S.A. (“Esteve”). Under the terms of the licensing agreement, Esteve paid the Company in July 2025 €4,000 to license the rights to INCRELEX® for up to ten years, and Esteve also received an option to acquire the international rights in the future for a purchase price of up to €6,000. In accordance with the accounting pronouncement guidance in ASC 606 with respect to the license and supply agreements between the Company and Esteve, the Company recognized in March 2025, $4,327 in accounts receivable, licensing revenues of $1,786 and deferred revenues of $2,541. With respect to deferred revenues, $457 and $1,762 are reflected in accrued liabilities and other long-term liabilities, respectively in the Company's Balance Sheets as of December 31, 2025. Deferred revenues will be amortized to licensing revenues over the course of the agreements based on quarterly INCRELEX® product sales, and at the end of the license agreement, a deferred revenue residual will be recognized at the end of the initial term of the license agreement. In addition, the Company also entered into a supply agreement with Esteve, and beginning in the third quarter of 2025, the Company began supplying product to Esteve at a fixed transfer price. During the twelve months ended December 31, 2025, the Company recognized $322 in deferred revenues associated with the supply agreement.

In June 2025, in connection with the asset purchase agreement with Ipsen S.A, the Company purchased $11,540 in inventory. Under the terms of the inventory purchase agreement, the Company will be required to make eight equal quarterly installment payments to Ipsen S.A, beginning in the third quarter of 2025. Accordingly, as of December 31, 2025, the Company has classified $6,926 in accounts payable and $3,463 as other long-term liabilities in in the accompanying Balance Sheets. During the twelve months ended December 31, 2025, the Company recognized $5,094 in inventory step-up expense associated with the inventory purchase from Ipsen S.A.

Indemnification

As permitted under Delaware law and in accordance with the Company’s Amended and Restated Bylaws, the Company is required to indemnify its officers and directors for certain events or occurrences while the officer or director is or was serving in such capacity. The Company is also party to indemnification agreements with its directors and officers. The Company believes the fair value of the indemnification rights and agreements is minimal. Accordingly, the Company has not recorded any liabilities for these indemnification rights and agreements as of December 31, 2025 or 2024.

Note 17 — Subsequent Events

In January 2026, the Company entered into a licensing and supply agreement for the U.S. marketing rights for an ultra-rare disease metabolic product candidate. Under the terms of the licensing and supply agreement, the Company paid $1,000 upon execution of the agreement and will pay seller $1,000 upon approval of the Abbreviated New Drug Application and commercial launch. The Company will pay profit sharing of 30.0% on net sales of the product candidate.

In February 2026, the Company announced that the FDA approved an NDA for DESMODA™ (desmopressin acetate) Oral Solution for the management of central diabetes insipidus, also known as arginine vasopressin deficiency, as antidiuretic replacement therapy for patients of all ages.

In February 2026, the Company entered into a license agreement with Pierre Fabre Medicament Sas (“Pierre Fabre”) for the exclusive rights to Hemangeol®, a product used for the treatment of proliferating infantile hermangioma. Under of the terms of the license agreement, the Company paid $14,000 and will also purchase approximately $1,500 of inventory. The Company will also purchase approximately $700 in additional inventory in May 2026. The Company will pay royalties to Pierre Fabre of 8.0% on net sales of Hemangeol®.

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

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our CEO and our CFO, to allow timely decisions regarding required disclosure. In designing and evaluating these disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective.

As of December 31, 2025, an evaluation was conducted under the supervision and with the participation of our management, including our CEO and CFO, of the effectiveness of our disclosure controls and procedures. Based on this evaluation, such officers have concluded that our disclosure controls and procedures are effective as of December 31, 2025.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for our Company, as such term is defined in Rule 13a-15(f) under the Exchange Act. Our management conducted an evaluation, with the participation of our CEO and CFO, of the effectiveness of our internal control over financial reporting as of December 31, 2025, based on the criteria set forth in the 2013 Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2025.

This report does not include an attestation report of our independent registered public accounting firm regarding our internal control over financial reporting, in accordance with applicable SEC rules that permit us to provide only management's report in this report.

Changes in Internal Control over Financial Reporting

There has not been any change in our internal control over financial reporting (as defined in Rules 13a-15(f) under the Exchange Act) that occurred during the quarter ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our principal executive officer and principal financial officer, do not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Item 9B. Other Information

Insider Trading Arrangements and Related Disclosure

During the three months ended December 31, 2025, none of our directors or officers adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

We are committed to promoting high standards of ethical business conduct and compliance with applicable laws, rules and regulations. As part of this commitment, we have adopted our Insider Trading Policy governing the purchase, sale, and/or other dispositions of our securities by our directors, officers, employees and designated contractors. We believe our Insider Trading Policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, and the exchange listing standards applicable to us. A copy of our Insider Trading Policy, including any amendments thereto, is filed as Exhibit 19.1 to this Annual Report on Form 10-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item and not set forth below will be set forth in the section headed "*Election of Directors*" and "*Executive Officers*" in our Proxy Statement for our 2026 Annual Meeting of Stockholders ("Proxy Statement"), to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2025, and is incorporated herein by reference.

We have adopted a code of ethics for directors, officers (including our principal executive officer, principal financial officer and principal accounting officer) and employees, known as the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at *http://ir.etonpharma.com* under the Corporate Governance section of our Investor Relations page. We will promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals that is required to be disclosed pursuant to SEC rules and regulations, the name of such person who is granted the waiver and the date of the waiver.

Item 11. Executive Compensation

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

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

The information required by this item will be set forth in the section headed "*Security Ownership of Certain Beneficial Owners and Management*" in our Proxy Statement and is incorporated herein by reference.

The information required by Item 201(d) of Regulation S-K will be set forth in the section headed "*Executive Compensation*" in our Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be set forth in the section headed "*Transactions With Related Persons*" in our Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

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

PART IV

Item 15. Exhibits, Financial Statement Schedules

(1) *Index to Financial Statements*

The following financial statements of Eton Pharmaceuticals, Inc. and the Report of the Independent Registered Public Accounting Firm are included in Part II, Item 8 of this Annual Report on Form 10-K:

(2) *Financial Statement Schedules*

Financial statement schedules have been omitted in this report because they are not applicable, not required under the instructions, or the information requested is set forth in the financial statements or related notes thereto.

(3) *Exhibits*

The following exhibits have been filed or are being filed herewith and are numbered in accordance with Item 601 of Regulation S-K:

EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed November 20, 2018).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed November 20, 2018).
4.1	Specimen Certificate representing shares of common stock of Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
4.2	Form of Underwriter's Warrant (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
4.3	Warrant dated November 13, 2019 issued to SWK Holdings LLC. (incorporated by reference to Exhibit 4.5 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2019 filed March 5, 2020).
10.1†	Asset Purchase Agreement (DS-200) dated June 23, 2017 between Selenix, LLC and the Registrant (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.2+	Amended Offer Letter Agreement by and between the Registrant and Sean E. Brynjelsen, dated as of June 27, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2025, filed on August 7, 2025).
10.3+	Amended Offer Letter Agreement by and between the Registrant and David Krempa, dated as of June 27, 2017 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2025, filed on August 7, 2025).
10.4+	Amended Offer Letter Agreement by and between the Registrant and James Gruber, dated as of June 27, 2017 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2025, filed on August 7, 2025).
10.5+	Amended Offer Letter Agreement by and between the Registrant and Ipek Erdogan-Trinkaus, dated as of June 27, 2017 (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2025, filed on August 7, 2025).
10.6+	2018 Equity Incentive Plan as amended December 2020 (incorporated by reference to Exhibit 10.11 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2020 filed on March 16, 2021).

Exhibit No.	Description
10.7+	2018 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.8	Credit Agreement dated as of November 13, 2019, by and among the Company and SWK Funding LLC (incorporated by reference to Exhibit 10.14 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2019 filed March 5, 2020) (as amended on April 5, 2022 and such amendment is incorporated by reference to exhibit 10.1 to the Registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2022).
10.9	Asset Purchase Agreement by and between the Company and Ipsen Biopharmaceuticals, Inc., dated as of October 2, 2024 (portions of the exhibit have been redacted)(incorporated by reference to Exhibit 10.11 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2024, filed on March 18, 2025).
10.10	Fifth Amendment to Credit Agreement by and among the Company SWK Funding LLC dated as of September 30, 2024 (incorporated by reference to Exhibit 10.1 of the Registrants Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, filed on November 12, 2024).
10.11	Second Amendment to Warrant Agreement by and among the Company and SWK Funding LLC dated as of September 30, 2024 (incorporated by reference to Exhibit 10.2 of the Registrants Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, filed on November 12, 2024).
10.12	Licensing Agreement by and between the Company and AMMTek dated as of November 22, 2024 (incorporated by reference to Exhibit 10.14 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2024, filed on March 18, 2025).
10.13	Form of Securities Purchase Agreement by and between the Company and an institutional investor dated as of December 10, 2024 (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K dated December 12, 2024).
10.14	Asset Purchase Agreement dated December 31, 2024, between Teva Pharmaceuticals USA, Inc. and the Registrant (portions of the Exhibit have been redacted) (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K dated January 3, 2025).
23.1	Consent of Independent Registered Public Accounting Firm (Crowe LLP - PCAOB ID: 173)
23.2	Consent of Independent Registered Public Accounting Firm (KMJ Corbin & Company LLP - PCAOB ID: 170)
23.3	Consent of Independent Registered Public Accounting Firm (Grant Thornton LLP - PCAOB ID: 248)
19.1	Insider Trading Policy (incorporated by reference to Exhibit 19.1 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the SEC on March 14, 2024.
31.1*	Certification of President and Chief Executive Officer (Principal Executive Officer), pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer (Principal Financial and Accounting Officer), pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certifications of President and Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial and Accounting Officer), pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97	Policy Relating to Recovery of Erroneously Awarded Compensation
101	The following financial information from the Company's Annual Report on Form 10-K for the year ended December 31, 2025, formatted in Inline Extensible Business Reporting Language (iXBRL): (i) the Balance Sheets, (ii) the Statements of Operations, (iii) the Statement of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit), (iv) the Statements of Cash Flows and (v) Notes to Financial Statements.
104	The cover page from the Company's Annual Report on Form 10-K for the year ended December 31, 2025, formatted in Inline XBRL (included as Exhibit 101)

† Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.
+ Indicates management compensatory plan, contract or arrangement.
* These certifications are being furnished solely to accompany this Annual Report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

ETON PHARMACEUTICALS, INC.

March 19, 2026

By: */s/ Sean E. Brynjelsen*
Sean E. Brynjelsen
President and Chief Executive Officer
(Principal Executive Officer)

By: */s/ James Gruber*
James Gruber
Chief Financial Officer
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints each of Sean Brynjelsen and James Gruber, his or her true and lawful attorney-in-fact and agent, each with full power of substitution and resubstitution, severally, for him or her and in his or her name, place and stead, in any and all capacities, to sign this Annual Report on Form 10-K of Eton Pharmaceuticals, Inc., and any or all amendments thereto, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof. This power of attorney may be executed in counterparts.

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

Signature	Title	Date
/s/ Sean E. Brynjelsen Sean E. Brynjelsen	President, Chief Executive Officer, and Director *(Principal Executive Officer)*	March 19, 2026
/s/ James Gruber James Gruber	Chief Financial Officer, Treasurer and Secretary *(Principal Financial and Accounting Officer)*	March 19, 2026
/s/ Jennifer M. Adams Jennifer M. Adams	Director	March 19, 2026
/s/ Charles J. Casamento Charles J. Casamento	Director	March 19, 2026
/s/ Paul V. Maier Paul V. Maier	Director	March 19, 2026
/s/ Norbert G. Riedel, Ph.D. Norbert G. Riedel, Ph.D.	Director	March 19, 2026

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statements on Form S-8 Nos. 333-228493, 333-230572, 333-270707, 333-278234, 333-291656 and 333-294094 of Eton Pharmaceuticals, Inc. of our report dated March 18, 2025 on the balance sheet of Eton Pharmaceuticals, Inc. as of December 31, 2024 and the related statements of operations, stockholders' equity, and cash flows, and the related notes thereto, for the year ended December 31, 2024, appearing in this Annual Report on Form 10-K of Eton Pharmaceuticals, Inc. for the year ended December 31, 2025.

/s/ Crowe LLP

Oakbrook Terrace, Illinois
March 19, 2026

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-228493, 333-230572, 333-270707, 333-278234, 333-291656 and 333-294094 on Form S-8 of our report dated March 14, 2024, relating to the statements of operations, stockholders' equity, and cash flows for the year ended December 31, 2023 of Eton Pharmaceuticals, Inc., appearing in this Annual Report on Form 10-K of Eton Pharmaceuticals, Inc. for the year ended December 31, 2025.

KMJ Corbin & Company LLP

Glendora, California
March 19, 2026

Exhibit 23.3

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 19, 2026, with respect to the financial statements included in the Annual report of Eton Pharmaceuticals, Inc. on Form 10-K for the year ended December 31, 2025. We consent to the incorporation by reference of said report in the Registration Statements of Eton Pharmaceuticals, Inc. on Forms S-8 (File No. 333-228493, 333-230572, 333-270707, 333-278234, 333-291656 and 333-294094).

/s/ GRANT THORNTON LLP

Chicago, Illinois
March 19, 2026

Exhibit 31.1

CERTIFICATION 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

I, Sean E. Brynjelsen, certify that:

1. I have reviewed this Annual Report on Form 10-K of Eton Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 19, 2026

By: */s/ Sean E. Brynjelsen*
Sean E. Brynjelsen
Principal Executive Officer

Exhibit 31.2

CERTIFICATION 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

I, James Gruber, certify that:

1. I have reviewed this Annual Report on Form 10-K of Eton Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 19, 2026

By: */s/ James Gruber*
James Gruber
Principal Financial and Accounting Officer

Exhibit 32.1

ETON PHARMACEUTICALS, INC.
PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Sean E. Brynjelsen, President and Chief Executive Officer of Eton Pharmaceuticals, Inc. (the "Company"), and James Gruber, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2025 (the "Annual Report"), to which this Certification is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 19th day of March, 2026.

/s/ Sean E. Brynjelsen	*/s/ James Gruber*
Sean E. Brynjelsen	James Gruber
President and Chief Executive Officer	Chief Financial Officer
(*Principal Executive Officer*)	(*Principal Financial and Accounting Officer*)

* This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Eton Pharmaceuticals, Inc.
Clawback Policy

Introduction

The Board of Directors (the "**Board**") of Eton Pharmaceuticals, Inc. (the "**Company**") believes that it is in the best interests of the Company and its stockholders to adopt a policy that reflects that portion of the Company's compensation philosophy related to incentive compensation. The Board has therefore adopted this policy which provides for the recoupment of certain executive compensation in the event of an accounting restatement resulting from material noncompliance with financial reporting requirements under the federal securities laws (the "**Policy**"). This Policy is designed to comply with Section 10D of the Securities Exchange Act of 1934 (the "**Exchange Act**") and Nasdaq Listing Rule 5608 (the "**Clawback Listing Standards**").

Administration

This Policy shall be administered by the Board or, if so designated by the Board, the Compensation Committee, in which case references herein to the Board shall be deemed references to the Compensation Committee. Any determinations made by the Board shall be final and binding on all affected individuals.

Covered Executives

This Policy applies to the Company's current and former executive officers, as determined by the Board in accordance with the definition in Section 10D of the Exchange Act and the Clawback Listing Standards, who may from time to time be deemed subject to the Policy by the Board ("**Covered Executives**").

Recoupment; Accounting Restatement

In the event the Company is required to prepare an accounting restatement of its financial statements due to the Company's material noncompliance with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period, the Board will require reimbursement or forfeiture of any excess Incentive Compensation received by any Covered Executive during the three completed fiscal years immediately preceding the date on which the Company is required to prepare an accounting restatement.

Incentive Compensation

For purposes of this Policy, Incentive Compensation means any of the following; provided that, such compensation is granted, earned, or vested based wholly or in part on the attainment of a financial reporting measure:

- Annual bonuses and other short- and long-term cash incentives.
- Stock options.
- Stock appreciation rights.
- Restricted stock.
- Restricted stock units.
- Performance shares.
- Performance units.

Financial reporting measures include:

- Company stock price.
- Total shareholder return.
- Revenues.
- Net income.
- Earnings before interest, taxes, depreciation, and amortization (EBITDA).
- Funds from operations.
- Liquidity measures such as working capital or operating cash flow.
- Return measures such as return on invested capital or return on assets.
- Earnings measures such as earnings per share.

Excess Incentive Compensation: Amount Subject to Recovery

The amount to be recovered will be the excess of the Incentive Compensation paid to the Covered Executive based on the erroneous data over the Incentive Compensation that would have been paid to the Covered Executive had it been based on the restated results, as determined by the Board, without regard to any taxes paid by the Covered Executive in respect of the Incentive Compensation paid based on the erroneous data.

If the Board cannot determine the amount of excess Incentive Compensation received by the Covered Executive directly from the information in the accounting restatement, then it will make its determination based on a reasonable estimate of the effect of the accounting restatement.

Method of Recoupment

The Board will determine, in its sole discretion, the method for recouping Incentive Compensation hereunder which may include, without limitation:

(a) requiring reimbursement of cash Incentive Compensation previously paid;

(b) seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards;

(c) offsetting the recouped amount from any compensation otherwise owed by the Company to the Covered Executive;

(d)) cancelling outstanding vested or unvested equity awards; and/or

(e) taking any other remedial and recovery action permitted by law, as determined by the Board.

No Indemnification

The Company shall not indemnify any Covered Executives against the loss of any incorrectly awarded Incentive Compensation.

Interpretation

The Board is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy. It is intended that this Policy be interpreted in a manner that is consistent with the requirements of Section 10D of the Exchange Act, any applicable rules or standards adopted by the Securities and Exchange Commission, and the Clawback Listing Standards.

Effective Date

This Policy shall be effective as of November 10, 2023 (the "**Effective Date**") and shall apply to Incentive Compensation that is received by Covered Executives on or after the Effective Date, even if such Incentive Compensation was approved, awarded, or granted to Covered Executives prior to the Effective Date.

Amendment; Termination

The Board may amend this Policy from time to time in its discretion and shall amend this Policy as it deems necessary to reflect final regulations adopted by the Securities and Exchange Commission under Section 10D of the Exchange Act and to comply with the Clawback Listing Standards and any other rules or standards adopted by a national securities exchange on which the Company's securities are listed. The Board may terminate this Policy at any time.

Other Recoupment Rights

Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any similar policy in any employment agreement, equity award agreement, or similar agreement and any other legal remedies available to the Company.

Relationship to Other Plans and Agreements

The Board intends that this Policy will be applied to the fullest extent of the law. The Board may require that any employment agreement, equity award agreement, or similar agreement entered into on or after the Effective Date shall, as a condition to the grant of any benefit thereunder, require a Covered Executive to agree to abide by the terms of this Policy. In the event of any inconsistency between the terms of the Policy and the terms of any employment agreement, equity award agreement, or similar agreement under which Incentive Compensation has been granted, awarded, earned or paid to a Covered Executive, whether or not deferred, the terms of the Policy shall govern.

[Acknowledgment

The Covered Executive shall sign an acknowledgment form [in the form attached hereto as Exhibit [INSERT EXHIBIT NUMBER OR LETTER] in which they acknowledge that they have read and understand the terms of the Policy and are bound by the Policy.]

Impracticability

The Board shall recover any excess Incentive Compensation in accordance with this Policy unless such recovery would be impracticable, as determined by the Board in accordance with Rule 10D-1 of the Exchange Act and the listing standards of the national securities exchange on which the Company's securities are listed.

Successors

This Policy shall be binding and enforceable against all Covered Executives and their beneficiaries, heirs, executors, administrators or other legal representatives.