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, 2024

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, 2024 was approximately $80.2 million.

As of March 10, 2025, the registrant had 26,817,535 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 2025 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, 2024, 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 seven commercial rare disease products: INCRELEX®, ALKINDI SPRINKLE®, GALZIN®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous, and Nitisinone. We have six additional product candidates in late-stage development: ET-400, 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.

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, **w**e 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-400 - We submitted to the FDA a New Drug Application ("NDA") for the product in 2024, which was originally scheduled with a Prescription Drug User Fee Amendments ("PDUFA") goal date of February 28, 2025. On February 6, 2025, we were notified by the FDA that it had applied a three-month extension to the original PDUFA goal date of February 28, 2025. The new PDUFA goal date is now May 28, 2025.

ET-600 – ET-600 is under development for the treatment of central diabetes insipidus. We expect to submit an NDA for the product in 2025, which could allow for an approval and launch of the product in 2026.

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). 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 developing this zinc extended release product for the treatment of Wilson disease. We plan to hold a meeting with the FDA in 2025 to discuss the product's clinical pathway.

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
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-400	Endocrinology	Adrenal Insufficiency	NDA Submitted (PDUFA Goal Date of May 28, 2025)
ET-600	Endocrinology	Diabetes Insipidus	Under Development
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 of 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 seven products under our own label with our internal infrastructure and sales force. We market and sell INCRELEX®, ALKINDI SPRINKLE®, 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 eight 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 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. ET-400 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 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 intend to 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, 2024, we had 31 full-time employees, eight of whom are engaged in research and development activities, 18 are engaged in sales and marketing operations and five 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.

Recent Development

As previously reported in our Form 8-K/A filed on March 7, 2025, following the closing of our acquisition of the INCRELEX® product on December 19, 2024, the Company's advisors determined that, under relevant accounting rules and interpretations, the acquisition must be accounted for by the Company as a business combination rather than an asset purchase. As a result of this determination, the Company is required to file an amendment to the Original Report to provide separate audited financial statements and unaudited pro forma financial information for INCRELEX®, specified by Item 9.01 of Form 8-K, no later than 71 calendar days after the date that the Original Report on Form 8-K was required to be filed with the SEC, which was March 7, 2025. While the Company is required to file audited financial statements of INCRELEX® for the years ended December 31, 2023 and 2022 and the nine months ended September 30, 2024 and 2023, as well as unaudited proforma financial information for the years ended December 31, 2024 and 2023, INCRELEX® was accounted for as a single product within Ipsen's consolidated financial statements and not as a separate business. Historical financial statements for the Increlex product do not exist, and as a result, the Company believes that it will be unable to create the required financial statements. Accordingly, the Company has filed a request with the SEC that the SEC waive the aforementioned financial statement filing requirement.

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 11 of this Annual Report, including, but not limited to, the following:

- We may have significant research, regulatory and development expenses as we advance our product candidates.
- 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 have entered into several arrangements with related parties for the development and marketing of certain product candidates and these arrangements present potential conflicts of interest.
- 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.
- Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.
- 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, or if we violate government price reporting 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.

- Third-party coverage and reimbursement and health care cost containment initiatives and treatment guidelines may constrain our future revenues.

- 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 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 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.

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.

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.

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

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval for our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our product candidates. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. For additional information on legislative and regulatory changes, see the Item 1. Business—Healthcare Reform section.

In the United States, the Medicare Modernization Act ("MMA") changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for our product candidates and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Health Care Reform Law, was enacted, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Health Care Reform Law, 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 and 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, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the Health Care Reform Law. Since January 2017, former President Trump had signed two executive orders and other directives designed to delay, circumvent or loosen certain requirements mandated by the Health Care Reform Law. Concurrently, 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. The Tax Act included a provision which repealed, effective January 1, 2019, 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." On January 22, 2018, former President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Health Care Reform Law-mandated fees, including the so-called "Cadillac" tax on certain high-cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, among other things, amended the Health Care Reform Law, effective January 1, 2019, to increase from 50% to 70% 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". On December 14, 2018, a Texas U.S. District Court Judge ruled that the Health Care Reform Law is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. In June 2021, the U.S. Supreme Court overturned the 2018 Texas U.S. District Court decision. It is unclear how subsequent appeals, and other efforts to repeal and replace the Health Care Reform will impact our business. We cannot predict the impact on our business of changes to current laws and regulations. However, any changes that lower reimbursements for products for which we may obtain regulatory approval, or that impose administrative and financial burdens on us, could adversely affect our business.

In addition, other legislative changes have been proposed and adopted in the United States since the Health Care Reform Law was enacted. These changes include, among others, aggregate reductions of Medicare payments to providers of up to 2% per fiscal year. We expect that additional state and federal health care reform measures will be adopted in the future, which may alter or completely replace the existing health care financing structure. Any of these reform measures could limit the amounts that federal and state governments will pay for health care products and services, which could result in reduced demand for any such product candidate that we may have developed or additional pricing pressures on our business.

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 congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, the Trump administration released a "Blueprint" to lower drug prices and reduce out-of-pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out-of-pocket costs of drug products paid by consumers. On January 31, 2019, the U.S. Department of Health and Human Services, Office of Inspector General, proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While some of these and other proposed measures may require additional authorization to become effective, Congress and government administration officials have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs.

The policies of the FDA or similar regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, in December 2016, the 21st Century Cures Act was signed into law. The 21st Century Cures Act, among other things, is intended to modernize the regulation of drugs and biologics and spur innovation, but it has not yet been fully implemented and its ultimate implementation is unclear. Furthermore, the Trump administration has taken several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance and review and approval of marketing applications. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

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, or if we violate government price reporting 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 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

We are currently unable to comply with the requirement to provide separate audited financial statements and unaudited pro forma financial information for the INCRELEX® product acquisition, specified by Item 9.01 of Form 8-K.

As previously reported in our Form 8-K/A filed on March 7, 2025, we are currently unable to file an amendment to our Form 8-K reporting the completion of our acquisition of the INCRELEX® product containing the separate audited financial statements and unaudited pro forma financial information required by Item 9.01 of Form 8-K by the required due date. As such, we are no longer in compliance with our reporting obligations under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Our inability to obtain such information by the deadline has resulted in noncompliance with our reporting obligations under the Exchange Act. Such noncompliance, in turn:

- has, in the absence of receiving the requested waiver from the SEC, rendered us ineligible to use the SEC's short-form registration statement on Form S-3 to register the issuance of our securities for any capital raising activities; and

- could, depending on if and/or when the financial statements are created and become available and we file them, have other material and adverse consequences that are summarized below.

Until the earlier of the date on which we receive the requested waiver or the audited financial statements and unaudited pro forma financial information specified by Item 9.01 of Form 8-K are filed with the SEC, no new registration statement that we file with the SEC seeking to register our securities for issuance, sale or resale, including for capital raising transactions, additional acquisitions or for our employee benefit programs, will be declared effective by the SEC and thus our capital raising activities and ability to provide new equity incentives to our employees will be substantially curtailed during that period.

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.

Future capital raises may dilute our existing stockholders' ownership, could depress the market price for our common stock and have other adverse effects on our operations.

We have an effective Form S-3 registration statement ("Shelf Registration") on file with the SEC which allows us to sell any combination of common stock, preferred stock, debt securities, warrants to purchase any of these securities, subscription rights to purchase any of these securities, and/or units consisting of one or more of the foregoing in one or more offerings up to a total dollar amount of $100 million. The issuance of additional shares of our common stock pursuant to the Shelf Registration, or issuances of securities convertible into or exercisable for our common stock or other equity-linked securities, including preferred stock, warrants, debt securities or units, would dilute the ownership interest of our common shareholders and could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities. If we raise additional funds by issuing debt securities, these debt securities would have rights senior to those of our common stock and the terms of the debt securities issued could impose significant restrictions on our operations, including liens on our assets. If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our technologies or candidate products, or to grant licenses on terms that are not favorable to us.

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, 2024, our remaining federal NOLs were generated after the 2017 tax year. Our significant state NOLs as of December 31, 2024 were generated in IL and TN, which begin to expire in 2037 and 2034, 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 are performing a study to determine if we have triggered any "ownership change" limitations. We may also 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 10, 2025, we had 26,817,535 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.

We may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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.

Our directors and executive officers beneficially own approximately 16.9% 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 5,507 square foot leased office space located at 21925 W. Field Parkway, Suite 235, Deer Park, Illinois 60010. The lease for this facility expires in March 2027.

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, 2024, the last trading date in 2024, was $13.32 per share.

Record Holders

As of March 10, 2025, 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 10, 2025 was $13.69.

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

We are an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases. We currently have seven commercial rare disease products: INCRELEX®, ALKINDI SPRINKLE®, GALZIN®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous, and Nitisinone. The Company has six additional product candidates in late-stage development: ET-400, ET-600, Amglidia®, ET-700, ET-800 and ZENEO® hydrocortisone autoinjector.

Results of Operations

We have realized revenues from the sale of our ALKINDI SPRINKLE®, Carglumic Acid, and Biorphen products in 2022, as well as the launch of Betaine in 2023, and the launch of Nitisinone and PKU GOLIKE® products in 2024. We also realized revenue from the sale of our hospital products portfolio to Dr. Reddy's Laboratories S.A. ("Dr. Reddy's") in 2022, and the sale of our neurology product royalty streams to Azurity in 2023. We anticipate continued growth of our commercialized products as well as commercializing additional product candidates in 2025 and beyond.

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 research and development ("R&D") expenses, respectively, and $22.8 million and $18.9 million of general and administrative ("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.

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.

Research and Development Expenses

We currently have eight employees that support our overall product development function. The majority of our spend in R&D is to third parties we contract with to develop and test our products and development of partner milestone payments.

Year Ended December 31, 2023 Compared to Year Ended December 31, 2022

Net revenues 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 revenues of $21.3 million in 2022 included $10.0 million of licensing revenue, consisting of $5.0 million from Azurity on the launch of Zonisamide and $5.0 million from the hospital products sale to Dr. Reddy's. Net product revenue of $26.1 million in 2023 increased by $14.8 million from $11.3 million in 2022 primarily as a result of product sales growth for ALKINDI SPRINKLE® and Carglumic Acid.

Our 2023 gross profit of $21.1 million was up from $14.3 million in 2022 primarily as a result of growth in ALKINDI SPRINKLE® and Carglumic Acid, as well as the sale of our neurology product royalty streams to Azurity.

For the years ended December 31, 2023 and 2022, we incurred $3.3 million and $4.0 million of R&D expenses, respectively, and $18.9 million and $18.6 million of G&A expenses, respectively. The $0.7 million decrease in R&D was driven by hospital products development in 2022 that were sold and, therefore, did not recur in 2023. The $0.3 million increase in G&A expenses was primarily due to personnel additions to support our growing business. We incurred a net loss of $0.9 million and $9.0 million for the years ended December 31, 2023 and 2022, respectively.

General and Administrative Expenses

G&A expenses consisted primarily of employee compensation expenses, selling and advertising/promotional expenses, legal and professional fees, business insurance and FDA fees. We anticipate that our G&A expenses will increase to support our business growth.

Research and Development Expenses

We had eight employees that supported our overall product development function. The majority of our spend in R&D was to third parties we contracted with to develop and test our products in addition to development partner milestone payments.

Liquidity and Capital Resources

As of December 31, 2024, we had total assets of $76.1 million, cash and cash equivalents of $14.9 million and working capital of $21.1 million. We believe that our existing funding and revenues from our approved products 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 be inaccurate, 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 expect to support our operations.

Cash Flows

The following table sets forth a summary of our cash flows for the years ended December 31, 2024, 2023 and 2022 (in thousands):

	Year ended December 31, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Net cash from operating activities	$ 969	$ 6,815	$ 4,821
Net cash from investing activities	(40,014)	(775)	(2,788)
Net cash flows from financing activities	32,593	(957)	(134)
Net change in cash and cash equivalents	$ (6,452)	$ 5,083	$ 1,899

The decrease in cash from operating activities was primarily the result of an increase in prepaid expenses associated with FDA filing fees in addition to higher inventory purchases in the current year. Investing activities in 2024 consisted of the purchase of product licensing rights associated with INCRELEX®, GALZIN® and PKU GOLIKE®, while investing activities in 2023 and 2022 consist primarily of the purchase of product licensing rights for Nitisinone and Betaine, respectively. The increase in cash from financing activities was primarily the result of net proceeds received from expanding our credit agreement with SWK Holdings Corporation ("SWK") in 2024 and proceeds received from the issuance of common stock in a private placement offering compared to repayment of long-term debt in 2023 and 2022. See Note 6 — Debt for additional information on the SWK loan in Notes to our Financial Statements.

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 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 we determine the contract falls within the scope of ASC 606, we assess the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service 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 or services 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, 2022, 2023 and 2024, 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®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous, and Nitisinone products to pharmacy distributor customers which provide order fulfilment and inventory storage/distribution services. The Company may sell products in the U.S. to wholesale pharmaceutical distributors, who then sell the product to hospitals and other end-user customers. Sales to wholesalers are made pursuant to purchase orders subject to the terms of a master agreement, and delivery of individual shipments represent performance obligations under each purchase order. 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. The Company has no significant obligations to wholesalers to generate pull-through sales.

For its INCRELEX®, ALKINDI SPRINKLE®, 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®, Carglumic Acid, Betaine Anhydrous, and Nitisinone sales are not subject to returns.

The Company stores its INCRELEX®, ALKINDI SPRINKLE®, 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. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then-current fair value of our common stock and updated assumption inputs in 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, 2024, our cash equivalents only included cash deposits at our bank. From time to time, we do have cash investments in short-term money market or U.S. treasury bills. 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.

Item 8. Financial Statements and Supplementary Data

ETON PHARMACEUTICALS, INC.
INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

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. 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 audits provide a reasonable basis for our opinion.

Critical Audit Matters

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

State Medicaid Rebates and Liability

Critical Audit Matter Description

As described in Note 3 of the Notes to 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 determined that auditing management's estimate of the state Medicaid rebates was a critical audit matter because it was especially challenging to evaluate management's judgments related to the data and significant assumptions used to determine the rebates. These include the identification of product sales subject to state Medicaid rebates as well as the historical rebate percentage applied to eligible sales. Additionally, there can be timing differences between when product sales occur and when the Company receives the related state Medicaid rebate invoices, which can vary based on state Medicaid program requirements.

How the Critical Audit Matter was Addressed in the Audit

Our audit procedures over management's estimated state Medicaid rebates and related liability included the following:

- Evaluated management's method to determine the rebate liability based on (1) product sales subject to state Medicaid rebates and (2) the applicable rebate percentages.
- Tested the completeness and accuracy of state Medicaid rebate-eligible product sales by agreeing sales data to supporting documentation.
- Agreed rebate percentages paid under state Medicaid programs in 2024 to corresponding invoices by product.
- Recalculated the estimated rebate liability.
- Assessed the reasonableness of management's assumption of timing differences between product sales and the receipt of state Medicaid rebate invoices.
- Evaluated subsequent state Medicaid rebate invoices and related payments to identify any information that might require an adjustment to the recorded liability.

Valuation of Acquired Inventory and Intangible Asset for the Increlex Acquisition

Critical Audit Matter Description

As described in Note 4 of the financial statements, on October 2, 2024, the Company entered into an asset purchase agreement to acquire Increlex from Ipsen S.A., with the transaction closing on December 19, 2024. Management determined that the acquisition should be accounted for as a business combination under ASC 805.

We determined that auditing management's valuation of the acquired inventory and intangible asset was a critical audit matter due to the significant judgment and estimation uncertainty involved in determining the fair value of the acquired inventory and intangible asset. Evaluating the valuation of acquired inventory and intangible asset was complex because it involved management's estimates and assumptions regarding:

- Costs to complete and sell inventory, which required assessing expected selling prices and estimated costs to complete and sell acquired inventory.
- Future cash flows, contributory asset charges and discount rates used to value the intangible asset.
- Valuation methodologies and significant assumptions, which required specialized knowledge.

How the Critical Audit Matter was Addressed in the Audit

Our audit procedures over management's valuation of the acquired inventory and intangible asset for the Increlex acquisition included:

- Assessed the methodologies used to value the acquired inventory and intangible asset with assistance from valuation specialists.
- Performed an inventory observation for the acquired inventory and agreed to management's identified quantities in the inventory fair value analysis.
- Assessed inventory valuation estimates by evaluating the reasonableness of management's assumptions for costs to complete and sell acquired inventory.
- Recalculated management's analysis of the inventory value.
- Assessed the reasonableness of the intangible asset valuation by evaluating projected financial data assumptions, contributory asset charges and discount rates used in valuation models.
- Recalculated management's analysis of the intangible asset value.
- Evaluated financial statement disclosures to determine whether the fair value measurement considerations were adequately disclosed.

/s/ Crowe LLP

We have served as the Company's auditor since 2024.

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 balance sheet of Eton Pharmaceuticals, Inc. (the "Company") as of December 31, 2023, the related statements of operations, stockholders' equity, and cash flows for each of the two years in the period 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 financial position of the Company as of December 31, 2023, and the results of its operations and its cash flows for each of the two years in the period 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 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.

/s/ KMJ Corbin & Company LLP

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

Glendora, California
March 14, 2024

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

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 14,936	$ 21,388
Accounts receivable, net	5,361	3,411
Inventories, net	15,232	911
Prepaid expenses and other current assets	5,492	1,129
Total current assets	**41,021**	**26,839**
Property and equipment, net	34	58
Intangible assets, net	34,881	4,739
Operating lease right-of-use assets, net	175	92
Other long-term assets, net	12	12
Total assets	$ **76,123**	$ **31,740**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,167	$ 1,848
Current portion of long-term debt, net of discount	—	5,380
Accrued Medicaid rebates	6,866	3,627
Accrued liabilities	8,914	5,386
Total current liabilities	**19,947**	**16,241**
Long-term debt, net of discount and including accrued fees	29,811	—
Operating lease liabilities, net of current portion	107	22
Other long-term liabilities	1,830	—
Total liabilities	**51,695**	**16,263**
Commitments and contingencies (Note 15)		
Stockholders' equity		
Common stock, $0.001 par value; 50,000,000 shares authorized; 26,709,084 and 25,688,062 shares issued and outstanding at December 31, 2024 and 2023, respectively	27	26
Additional paid-in capital	132,294	119,521
Accumulated deficit	(107,893)	(104,070)
Total stockholders' equity	**24,428**	**15,477**
Total liabilities and stockholders' equity	$ **76,123**	$ **31,740**

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, 2024	**December 31, 2023**	**December 31, 2022**
Revenues:			
Licensing revenue	$ 500	$ 5,500	$ 10,000
Product sales and royalties, net	38,511	26,142	11,251
Total net revenues	**39,011**	**31,642**	**21,251**
Cost of Sales:			
Licensing revenue	270	1,000	1,640
Product sales and royalties	15,330	9,581	5,293
Total cost of sales	15,600	10,581	6,933
Gross profit	**23,411**	**21,061**	**14,318**
Operating expenses:			
Research and development	3,255	3,322	3,996
General and administrative	22,753	18,931	18,582
Total operating expenses	**26,008**	**22,253**	**22,578**
Loss from operations	**(2,597)**	**(1,192)**	**(8,260)**
Other income (expense):			
Interest and other (expense) income, net	(1,211)	503	(761)
Loss before income tax expense	**(3,808)**	**(689)**	**(9,021)**
Income tax expense	15	247	—
Net loss	$ **(3,823)**	$ **(936)**	$ **(9,021)**
Net loss per share, basic and diluted	$ **(0.15)**	$ **(0.04)**	$ **(0.36)**
Weighted average number of common shares outstanding, basic and diluted	25,895	25,645	25,146

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, 2021	**24,626,004**	**$ 25**	**$ 111,718**	**$ (94,113)**	**$ 17,630**
.					
Stock-based compensation	—	—	4,218	—	4,218
Stock option exercises	25,000	—	35	—	35
Employee stock purchase plan	69,884	—	171	—	171
Common stock issued related to restricted stock units	—	—	—	—	—
Stock warrant exercises	632,231	—	45	—	45
Net loss	—	—	—	(9,021)	(9,021)
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
Employee stock purchase plan	80,933	0	248	—	248
Stock option exercises and vesting of restricted stock units	356,755	0	1,191	—	1,191
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**

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, 2024	**December 31, 2023**	**December 31, 2022**
Cash flows from operating activities			
Net loss	$ (3,823)	$ (936)	$ (9,021)
Adjustments to reconcile net loss to net cash from operating activities:			
Stock-based compensation	3,165	3,137	4,218
Depreciation and amortization	1,146	901	1,774
Non-cash lease expense	70	67	62
Debt discount amortization	1,109	117	127
Changes in operating assets and liabilities, net of impact of business acquisition:			
Accounts receivable	(3,118)	(1,559)	3,619
Inventories	(1,310)	(354)	(7)
Prepaid expenses and other assets	(3,349)	94	1,840
Accounts payable	2,318	53	(8)
Accrued Medicaid rebates	3,239	2,818	768
Accrued liabilities	1,484	2,477	1,449
Other non-current assets and liabilities	38	—	—
Net cash from operating activities	**969**	**6,815**	**4,821**
Cash from investing activities			
Purchases of property and equipment	(26)	—	(38)
Acquisition of business	(30,000)	—	—
Purchase of product licensing rights	(9,988)	(775)	(2,750)
Net cash from investing activities	**(40,014)**	**(775)**	**(2,788)**
Cash flows from financing activities			
Net proceeds from the issuance of long-term debt	25,309	—	—
Repayment of long-term debt	(1,155)	(1,155)	(385)
Common stock issued in private placement offering	7,000	—	—
Proceeds from stock option exercises	1,191	149	35
Payment of tax withholding related to net share settlement of stock option exercises	—	(180)	—
Employee stock purchase plan	248	229	171
Stock warrant exercises	—	—	45
Net cash from financing activities	**32,593**	**(957)**	**(134)**
Change in cash and cash equivalents	**(6,452)**	**5,083**	**1,899**
Cash and cash equivalents at beginning of year	21,388	16,305	14,406
Cash and cash equivalents at end of year	$ 14,936	$ 21,388	$ 16,305
Supplemental disclosures of cash flow information			
Cash paid for interest	$ 665	$ 842	$ 730
Cash paid for income taxes	$ 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	$ 219	$ —	$ 188

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 seven commercial rare disease products: INCRELEX®, ALKINDI SPRINKLE®, GALZIN®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous, and Nitisinone. We have six additional product candidates in late-stage development: ET-400, ET-600, Amglidia®, ET-700, ET-800 and ZENEO® hydrocortisone autoinjector.

Note 2 — Liquidity Considerations

As of December 31, 2024, the Company had an accumulated deficit of $107,893 and for the year ended December 31, 2024 the Company had a net loss of $3,823.

To date, the Company has generated revenues from multiple products and expects further growth in 2025 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 $14,936 as of December 31, 2024 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 financial statements and these reclassifications had no impact to prior period 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 seven commercial rare disease products: INCRELEX®, ALKINDI SPRINKLE®, 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 ALKINDI SPRINKLE®, Carglumic Acid, and Betaine Anhydrous products, as well as from Pentec Heath for sales of the Company's PKU GOLIKE® product. For the years ended December 31, 2024, 2023 and 2022, AnovoRx product sales represented 93.6%, 78.2% and 45.5% of net revenues, respectively. As of December 31, 2024 and 2023, AnovoRx product sales represented 96.2% and 97.4% of net accounts receivable. For the years ended December 31, 2024, 2023 and 2022, 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, 2024 and 2023, 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 $238 and $129 as of December 31, 2024 and 2023, 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, 2024, inventories consisted of purchased finished goods, semi-finished goods and raw materials. As of December 31, 2023, inventories consisted of purchased finished goods. At December 31, 2024 inventories are shown net of a reserve for Nitisinone, Betaine Anhydrous, ALKINDI SPRINKLE® and PKU GOLIKE® inventory. As of December 31, 2024, inventories included $5,000 in prepaid raw materials acquired in the INCRELEX® business acquisition.

At December 31, 2023, inventories are shown net of reserve for ALKINDI SPRINKLE® due to the risk of expiry prior to being sold. There was an inventory reserve of $605 and $76 at December 31, 2024 and 2023, respectively.

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.

(in thousands, except share and per share amounts)

Note 3 — Summary of Significant Accounting Policies (continued)

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. In November 2021, the Company purchased the rights for its Carglumic Acid product for $3,250 and that cost is being amortized over ten years. A $750 payment related to the approval of Biorphen had been capitalized in 2019 and that cost was being amortized over five years. As a result of the Biorphen sale to Dr. Reddy's (see Note 15), amortization of that asset was accelerated to record $275 of expense in June 2022 and the remaining $75 of expense in the last six months of the year ended December 31, 2022. A $750 payment related to the approval of Rezipres® had been capitalized in Q1 2022 and that cost was being amortized over five years. As a result of the sale to Dr. Reddy's, amortization of the Rezipres® asset was accelerated to record the remaining $738 in the three-month period ended June 30, 2022. In September 2022, the Company purchased the rights for its Betaine Anhydrous product for $2,125 and that cost is being amortized over five years. In October 2023, the Company purchased the rights for its Nitisinone product for $650 and that cost is being amortized over five years. In March 2024, the Company purchased the rights for its PKU GOLIKE® product which resulted in a $1,868 intangible asset that is being amortized over ten years. In December 2024, the Company completed a business combination of INCRELEX® (mecasermin injection) for $21,250 and that cost is being amortized over ten years. In December 2024, the Company acquired GALZIN® (zinc acetate) for $8,119 and that cost will be amortized over ten years.

The intangible assets, net on the Company's balance sheet reflected $2,381 and $1,286 of accumulated amortization as of December 31, 2024 and 2023. The Company recorded $1,096, $790, and $1,617 of amortization expense for the years ended December 31, 2024, 2023 and 2022 respectively. The table below shows the estimated remaining amortization for these products for each of the five years from 2025 to 2029 and thereafter.

Year	Amortization Expense
2025	$ 4,004
2026	4,004
2027	3,880
2028	3,546
2029	3,449
Thereafter	15,998
Total estimated amortization expense	$ 34,881

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, 2024, 2023 and 2022.

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, 2024 and 2023.

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.

Note 3 — Summary of Significant Accounting Policies (continued)

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, 2024 or 2023.

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 determines 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.

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, 2022, 2023 and 2024, 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.

Note 3 — Summary of Significant Accounting Policies (continued)

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®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous, and Nitisinone products to pharmacy distributor customers which provide order fulfilment and inventory storage/distribution services. The Company may sell products in the U.S. to wholesale pharmaceutical distributors, who then sell the product to hospitals and other end-user customers. Sales to wholesalers are made pursuant to purchase orders subject to the terms of a master agreement, and delivery of individual shipments represent performance obligations under each purchase order. 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. The Company has no significant obligations to wholesalers to generate pull-through sales.

For its INCRELEX®, ALKINDI SPRINKLE®, 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®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous, and Nitisinone sales are not subject to returns.

The Company stores its INCRELEX®, ALKINDI SPRINKLE®, 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.

Note 3 — Summary of Significant Accounting Policies (continued)

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.

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 Series A Preferred, 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 2024, 2023 or 2022 as the Company reported a net loss for the years ended December 31, 2024, 2023 and 2022 and including the effects of common stock equivalents in the diluted earnings per share calculation would have been anti-dilutive (see Note 10).

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.

Note 3 — Summary of Significant Accounting Policies (continued)

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, 2024 and 2023, 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. As of December 31, 2024, $382 is included in the balance sheets for unrecognized tax positions. The Company's practice is to recognize interest and penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties in its balance sheets at December 31, 2024 or 2023, and has not recognized interest and penalties in the Statements of Operations for the years ended December 31, 2024, 2023 and 2022. As of December 31, 2024, 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 2024 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 November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which enhances reportable segment disclosure requirements primarily through expanded disclosures around significant segment expenses. The amendments are effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024. The amendments should be applied retrospectively to all prior periods presented in the financial statements. The Company adopted the new accounting pronouncement on January 1, 2024. The adoption of this guidance did not have an effect on the Company's financial position, results of operations and cash flows.

New Pronouncements Issued

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 is assessing the guidance, noting the adoption impacts disclosure only.

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 assessing the guidance, noting the adoption impacts disclosure only.

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 6, "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.

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 related costs

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

Unaudited actual and pro forma information

For the year ended December 31, 2024, the Company recognized $166 of net sales related to Increlex® in the Statements of Operations.

The following unaudited pro forma summary presents information of the Company, including Increlex®, as if the Purchase Agreement had occurred on January 1, 2023:

	Year Ended December 31,	
	2024	2023
Net sales	$ 53,206	$ 50,362
Net loss	$ (6,590)	$ (1,612)

These pro forma results are for illustrative purposes and are not indicative of the actual results of operations that would have been achieved, nor are they indicative of future results of operations. The unaudited pro forma information for all periods presented was adjusted to give effect to pro forma events that are directly attributable to the Purchase Agreement and are factually supportable. The adjustments are based on information available to the Company at this time. Accordingly, the adjustments are subject to change, and the impact of such changes may be material. The unaudited pro forma results do not include any incremental cost savings that may result from the integration.

Note 5 – Property and Equipment

Property and equipment consist of the following:

	December 31, 2024	December 31, 2023
Computer hardware and software	$ 200	$ 187
Furniture and fixtures	125	111
Equipment	52	52
Leasehold improvements	103	103
Property and equipment, gross	480	453
Less: accumulated depreciation and amortization	(446)	(395)
Property and equipment, net	$ 34	$ 58

Depreciation expense for the years ended December 31, 2024, 2023 and 2022 was $50, $44 and $66, respectively.

(in thousands, except share and per share amounts)

Note 6 – 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. The Company received proceeds of $5,000 at closing and was able to borrow an additional $5,000 upon the FDA approval of a second product developed by the Company. In March 2020, the Company and SWK amended the SWK Credit Agreement, which provided the Company with the option to immediately draw an additional $2,000 and the ability to borrow up to another $3,000 based upon the FDA approval of EM-100 and ALKINDI SPRINKLE® which subsequently occurred in September 2020. Accordingly, the Company borrowed an additional $2,000 in August 2020. Under the terms of the SWK Credit Agreement, the Company was required to maintain a minimum cash balance of $3,000 and pay 5.5% of the loan principal balance commencing in February 2022 and then every three months thereafter until November 2024 at which time the remaining principal balance is due. In February 2021, the Company notified SWK that it will not require additional borrowing capacity under the SWK Credit Agreement and terminated the additional borrowing capacity with SWK.

In connection with the initial $5,000 borrowed in November 2019, the Company issued warrants to SWK to purchase 51,239 shares of the Company's common stock with an exercise price of $5.86 per share. The relative fair value of these 51,239 warrants was $226 and was estimated using the Black-Scholes-Merton option pricing model with the following assumptions: fair value of the Company's common stock at issuance of $5.75 per share; seven-year contractual term; 95% volatility; 0% dividend rate; and a risk-free interest rate of 1.8%. In connection with the additional $2,000 borrowed in August 2020, the Company issued warrants for 18,141 shares of its common stock at an exercise price of $6.62 per share. The relative fair value of the 18,141 warrants was $94 and was estimated using the Black-Scholes-Merton option pricing model with the following assumptions: fair value of the Company's common stock at issuance of $6.85 per share; seven-year contractual term; 95% volatility; 0% dividend rate; and a risk-free interest rate of 0.4%. These warrants (the "SWK Warrants") are exercisable immediately and have a term of seven years from the date of issuance. The SWK Warrants are subject to a cashless exercise feature, with the exercise price and number of shares issuable upon exercise subject to adjustment in connection with stock splits, dividends, reclassifications and other conditions.

In April 2022, the Company and SWK entered into an amendment to the SWK Credit Agreement which allowed for a deferral of loan principal payments until May 2023 and reduced the interest rate to LIBOR 3-month plus 8.0%, subject to a stated LIBOR floor rate of 2.0%. Because LIBOR was phased out as of June 2023, the Company amended the Credit Agreement in August 2023 to refer to Term SOFR, with an interest rate of Term SOFR plus 8.26%, subject to a stated Term SOFR floor rate of 5.0%.

In September 2024, the Company and SWK entered into an amendment to the SWK Credit Agreement, which was contingent upon the closing of the INCRELEX® Purchase Agreement. Under the terms of the amendment, the Company expanded its existing credit facility by $25.7 million to $30.0 million, 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%. In connection with the amendment to the SWK Credit Agreement, the Company issued a warrant to the SWK for the purchase of up to 289,736 shares of common stock at a price of $5.32 per share. The relative fair value of these 289,7369 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%.

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 amended 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 amended 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 amended SWK Credit Agreement is secured by the Company's assets, contains customary default provisions, which include limits on additional indebtedness. As of December 31, 2024 and 2023, the Company was in compliance with all financial covenants.

The Company recorded interest expense of $2,005, $1,060 and $955 in 2024, 2023 and 2022, respectively, which included $1,109, $117 and $127, 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 $182 and $332 as of December 31, 2024 and 2023, respectively, which is included in accrued liabilities in the accompanying balance sheets.

The table below reflects the future annual payments for the SWK loan principal as of December 31, 2024.

Year	Amount
2025	$ —
2026	9,000
2027	21,000
Total payments	30,000
Less: unamortized discount	(559)
Plus: accrued exit fees at December 31, 2024	370
Debt, net of unamortized discount and accrued exit fees	$ 29,811

Note 7 — 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.

(in thousands, except share and per share amounts)

Note 7 — Common Stock (continued)

For the years ended December 31, 2024, 2023 and 2022, the Company issued 266,353, 207,626 (net shares issued after a portion of 407,808 shares was a cashless exercise) and 25,000, respectively, of its common stock resulting from stock option exercises under its 2018 Equity Incentive Plan (see Note 9). 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, 2024, 2023 and 2022, the Company issued 80,933, 86,782 shares and 69,884, respectively, under the Company's Employee Stock Purchase Plan ("ESPP"). For the years ended December 31, 2024, 2023 and 2022, the Company issued 90,402, 91,402 and 0, 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 8 — Common Stock Warrants

Warrants outstanding as of December 31, 2024 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 investors.

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 relative 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%.

A roll forward of warrants outstanding as of December 31, 2024 is listed in the table below:

	No. of Shares	No. of Shares
Balance as of the beginning of the year	69,380	69,380
Issuance of SWK Warrants - Debt (Tranche #3)	289,736	289,736
Balance as of the end of the year	**359,116**	**359,116**

There were 1,067,242 warrants exercised on a cashless basis in 2022 resulting in 632,231 shares of common stock being issued by the Company. There were no warrants exercised in 2023 or 2024.

`Note 9 — 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 692,581 shares available for future issuance under the 2018 Plan as of December 31, 2024.

(in thousands, except share and per share amounts)

Note 9 — 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, 2023, the share reserve was increased by 1,014,124 shares based on the 25,353,119 shares of common stock outstanding at December 31, 2022. 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. 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.

To date, all stock options issued have been non-qualified stock options, and the exercise prices were set at the fair value for the shares at the dates of grant. Options typically have a ten-year life, except for options to purchase 50,000 shares of the Company's common stock granted to product consultants in July 2017 that expired, unexercised, in July 2022 as the Company was not able to file certain product submissions to the FDA prior to the five-year expiration date. Furthermore, these option awards to the Company's product consultants would not vest unless certain product submissions are made to the FDA, and accordingly, the Company has not recorded any expense for these contingently vesting option awards to its product consultants.

In July 2022 and September 2022, the Company's board of directors approved modifications of certain outstanding awards of two senior executives, one of whom retired in May 2022 and the other whose employment was terminated in July 2022. The combined awards had an exercise price range of $1.37 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 April 2023. No other terms were modified. Due to these modifications, the Company incurred a modification expense of approximately $104 that is included in general and administration expense on the Statement of Operations for the year ended December 31, 2022.

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, 2024, 2023 and 2022, the Company's total stock-based compensation expense was $3,165, $3,137 and $4,218, respectively. Of these amounts, $2,899, $2,864, and $3,954 was recorded in general and administrative expenses, respectively, and $266, $273, and $264 was recorded in R&D expenses, respectively.

Stock Options

The following table summarizes stock option activity during the year ended December 31, 2024:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Options outstanding as of January 1, 2024	4,839,226	$ 4.57		
Issued	1,621,118	4.83		
Exercised	(266,353)	4.47		
Forfeited/Cancelled	(275,375)	4.55		
Options outstanding as of December 31, 2024	5,918,616	$ 4.65	7.0	$ 51,316
Options exercisable at December 31, 2024	4,044,105	$ 4.71	6.2	$ 34,837
Options vested and expected to vest at December 31, 2024	5,918,616	$ 4.65	7.0	$ 51,316

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 2024 was $1,867.

(in thousands, except share and per share amounts)

Note 9 — Share-Based Payment Awards (continued)

For the years ended December 31, 2024, 2023 and 2022, there were 266,353, 207,626 and 25,000 shares issued for exercise of stock options, respectively for proceeds of $1,190, $149 and $35, respectively.

The assumptions used to calculate the estimated fair value of options granted during the years ended December 31, 2024, 2023 and 2022 under the BSM were as follows:

	December 31, 2024	December 31, 2023	December 31, 2022
Expected dividends	—%	—%	—%
Expected volatility	70%	70%	70%
Risk-free interest rate	3.5 - 4.4%	3.5 - 4.7%	1.5 - 3.9%
Expected term (in years)	6.2	6.3	5.9
Weighted average grant date fair value	$ 3.22	$ 2.32	$ 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.

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, 2024, there was a total of $5,390 of unrecognized compensation costs related to non-vested stock option awards which will be recognized over a weighted average period of 2.2 years.

Restricted Stock Units (RSUs)

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

	December 31, 2024	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

Stock-based compensation related to RSUs was $241, $239 and $114 for the years ended December 31, 2024, 2023 and 2022, respectively. As of December 31, 2024, there was $740 of unrecognized stock-based compensation expense related to unvested RSUs which will be recognized over a weighted average period of 2.2 years.

(in thousands, except share and per share amounts)

Note 9 — Share-Based Payment Awards (continued)

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 $205, $135, and $128 in 2024, 2023 and 2022, respectively, related to the ESPP. For the years ended December 31, 2024, 2023 and 2022, there were 80,933, 86,782 and 69,884 share issuances, respectively, under the ESPP. The weighted average grant date fair value of share awards in 2024, 2023 and 2022 was $1.35, $1.27, and $1.17 per share, respectively. Employees contributed $283, $230 and $174 to the ESPP during 2024, 2023 and 2022, respectively. Of these amounts, $42 and $24 at December 31, 2024 and 2023, respectively, are included in accrued liabilities in the accompanying balance sheets. As of December 31, 2024, there were 692,581 shares available for issuance under the ESPP.

Note 10 — 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, 2024, 2023 and 2022 were 6,389,345, 5,418,251, and 5,494,153 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, 2024	Year ended December 31, 2023	Year ended December 31, 2022
Net loss	$ (3,823)	$ (936)	$ (9,021)
Weighted average common shares outstanding (basic and diluted)	25,895,086	25,645,366	25,145,657
Net loss per common share (basic and diluted)	$ (0.15)	$ (0.04)	$ (0.36)

Note 11 — 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 as described below.

The Company acquired the exclusive rights to sell the EM-100 product in the United States pursuant to a sales and marketing agreement (the "Eyemax Agreement") dated August 11, 2017 between the Company and Eyemax LLC ("Eyemax"), an entity affiliated with the Company's CEO. Under the terms of the original agreement, the Company would pay Eyemax $250 upon FDA approval and $500 upon the first commercial sale of the product and pay Eyemax a royalty of 10% on the net sales of all products. The Eyemax Agreement was for an initial term of 10 years, subject to successive two-year renewals unless the Company elected to terminate the Eyemax Agreement.

On February 18, 2019, the Company entered into an Amended and Restated Agreement with Eyemax amending the Sales Agreement (the "Amended Agreement"). Pursuant to the Amended Agreement, Eyemax sold the Company all of its right, title and interest in EM-100, including any such product that incorporates or utilizes Eyemax's intellectual property rights. Pursuant to the Amended Agreement, the Company paid Eyemax two milestone payments: (i) one milestone payment for $250 upon regulatory approval in the territory by the FDA of the first single agent product and (ii) one milestone payment for $500 following the first commercial sale of the first single agent product in the territory. The Company realized $1,840 of the non-royalty and royalty revenue throughout the life of the product. The EM-100 asset and its associated product rights were sold to Bausch Health on February 18, 2019 and future potential royalties of twelve percent on Bausch Health sales of the product, named Alaway® Preservative Free by Bausch, which was approved by the FDA in September 2020, were to be split between Eyemax and the Company. There were no amounts due to Eyemax under the terms of the Amended Agreement as of December 31, 2024 or December 31, 2023, and Bausch Health discontinued sales of Alaway® Preservative Free effective March 24, 2023.

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 15). 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 Eton from the DS-200 sale agreement. Selenix is 50% owned by Messa Holdings LLC ("Messa"), which is 100% owned by the CEO. The Company paid $220 to Selenix in October 2024.

Note 12 — 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 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 $82, $67 and $82 for the years ended December 31, 2024, 2023 and 2022, respectively. For the years ended December 31, 2024, 2023 and 2022, cash paid for amounts included in the measurement of operating lease liabilities was $58, $88 and $88, respectively. The ROU asset non-cash lease expense was $70, $67 and $62 for the years ended December 31, 2024, 2023 and 2022, respectively, and is reflected within non-cash lease expense on the Company's Statements of Cash Flows. As of December 31, 2024 and 2023, the weighted average remaining lease term was 2.25 and 1.25 years, respectively and as of December 31, 2024 and 2023, the weighted average discount rate was 8.6% for each period.

(in thousands, except share and per share amounts)

Note 12 — Leases (continued)

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

Assets	Classification	December 31, 2024	December 31, 2023
Operating lease right-of-use assets	Operating lease right-of-use assets, net	$ 175	$ 92
Total leased assets		$ 175	$ 92
Liabilities			
Operating lease liabilities, current	Accrued liabilities	$ 76	$ 53
Operating lease liabilities, noncurrent	Operating lease liabilities, net of current portion	107	22
Total operating lease liabilities		$ 183	$ 75

The Company's future annual lease commitments as of December 31, 2024 are as indicated below:

	Total	2025	2026	2027
Undiscounted lease payments	$ **202**	$ **89**	$ **90**	$ **23**
Less: Imputed interest	**(19)**			
Total lease liabilities	$ **183**			

Note 13 – Income Taxes

The provision for income taxes for the Company consists of the following for the years ended December 31, 2024, 2023 and 2022:

	Year ended December 31, 2024	December 31, 2023	December 31, 2022
Current:			
Federal	$ 24	$ 61	$ —
State	(9)	186	—
Total current expense	15	247	—
Deferred:			
Federal	(223)	(85)	2,272
State	1,150	(31)	812
Change in valuation allowance	(927)	116	(3,084)
Total deferred expense	—	—	—
Total provision	$ 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.

(in thousands, except share and per share amounts)

Note 13 – Income Taxes (continued)

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, 2024 and 2023 are as follows:

	December 31, 2024	December 31, 2023
Deferred tax assets:		
Net operating loss carryforwards	$ 14,145	$ 15,447
Stock-based compensation	2,021	3,372
Accruals and other	4,827	2,866
Total deferred tax assets	20,993	21,685
Valuation allowance	(20,589)	(21,516)
Deferred tax assets	$ 404	$ 169
Deferred tax liabilities:		
Deferred consideration discount	$ (182)	$ —
Right-of-use assets	(45)	(27)
Other deferred tax liabilities	(177)	(142)
Deferred tax liabilities	$ (404)	$ (169)
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, 2024, 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.

Based on the uncertainty of future taxable income at this time, Management believes a 100% valuation reserve for the $20,589 and $21,516 net deferred tax assets at December 31, 2024 and 2023, respectively, is appropriate.

A reconciliation of the income tax adjustments used to derive income tax expense is shown below for the years ended December 31, 2024, 2023 and 2022 as follows:

	Year ended		
	December 31, 2024	December 31, 2023	December 31, 2022
Benefit based on federal statutory rate	$ (800)	$ (145)	$ (1,894)
Stock-based compensation	880	254	24
Change in state tax rate	814	-	-
Warrants	-	-	(476)
State income tax, net of federal tax benefit	(31)	(45)	(785)
Section 162(m) limitation	169	-	-
Other permanent differences	18	299	47
Research and development credits	(277)	-	-
Change in uncertain tax position reserve	382	-	-
Return to provision	(213)	-	-
Change in valuation allowance	(927)	(116)	3,084
Income tax expense	$ 15	$ 247	$ —

For the years ended December 31, 2024, 2023 and 2022, the Company's effective income tax rate was (0.4%), (35.9%) and 0.0%, respectively.

As of December 31, 2024, The Company has gross federal net operating loss of $49,815, which can be carried forward indefinitely, and gross state operating loss of $52,911, which begin to expire in 2034. 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.

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, 2024	December 31, 2023	December 31, 2022
Beginning balance	$ —	$ —	$ —

Gross increases (decreases) related to prior year positions	243	-	-
Gross increases (decreases) related to current year positions	139	-	-
Decreases related to settlements with taxing authorities	-	-	-
Reductions related to statute of limitation expirations	-	-	-
Ending balance	$ 382	$ —	$ —

Note 14 - 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, 2024, 2023 and 2022, the Company made $259, $242, and $172, respectively, in matching contributions.

Note 15 — 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 in addition to those discussed above which are described below.

The three oral solution pediatric neurology product candidates discussed below, Topiramate, Zonisamide and Lamotrigine, were developed by the Company and its various product candidate development partners and the Company subsequently sold all its rights and interests in these three products to Azurity in 2021, but retained rights to certain royalties. The Company has recognized $27,500 in milestone revenues to date from these three products, and in June 2023 the Company amended its asset purchase agreement with Azurity and sold the remaining royalty interests it received back to Azurity for $5,500. Azurity will assume royalty or profit share obligations owed to development partners as well as additional milestone payments based on sales volume targets.

Prior to January 1, 2022, the Company worked with Tulex Pharmaceuticals, Inc. ("Tulex") as a third-party contract manufacturer to develop an oral solution for Topiramate (fka ET-101) which targets a neurological condition. In November 2021, the product received approval from the FDA and was launched by Azurity in December 2021. The Company recognized a $5,000 milestone revenue at launch which was reflected in accounts receivable on the Company's balance sheet at December 31, 2021 and subsequently collected in January 2022.

On January 23, 2019, the Company entered into a Licensing and Supply Agreement (the "Agreement") with Liquimeds Worldwide ("LMW") for Zonisamide oral liquid, a development stage product candidate ("ET-104"). Pursuant to the terms of the Agreement, the Company was to be responsible for regulatory and marketing activities and LMW was responsible for development and manufacturing of ET-104. The Company paid $650 to Azurity upon issuance of patent covering ET-104 listed in the FDA's Orange Book in November 2022.

Note 15 — Commitments and Contingencies (continued)

In March 2020, the Company entered into an Exclusive Licensing 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 will also pay Diurnal $2,500 if the product obtains orphan drug exclusivity status from the FDA.

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 October 2021, the Company acquired the U.S. marketing rights to Carglumic Acid Tablets. The product's Abbreviated New Drug Application ("ANDA"), which is owned by Novitium Pharma, was approved by the FDA in October 2021. The product is an AB-rated, substitutable generic version of Carbaglu®. The Company paid $3,250 upon signing and retains 50% of the product profits with the balance being distributed to the licensor and manufacturer. The Company launched this product in December 2021.

In June 2022, the Company sold its rights in Cysteine Hydrochloride, Biorphen®, and Rezipres® to Dr. Reddy's. Under the terms of the transaction, Dr. Reddy's assumed immediate ownership of Eton's rights and interest in the products. The Company received $5,000 at closing, recorded as licensing revenue in the twelve months ended December 31, 2022. In accordance with the terms of the agreement, $812 of Sintetica profit share receivables were expensed as cost of goods sold in the twelve months ended December 31, 2022.

In September 2022, the Company acquired an FDA-approved ANDA for Betaine Anhydrous for oral solution. The ANDA was approved by the FDA in January 2022. The Company paid $2,000 upon signing and an additional $125 in November 2023, and could pay up to $1,000 in commercial milestones. The Company will retain 65% of the product profits with the balance being distributed to the licensor.

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 October 2023, the Company acquired an FDA-approved ANDA for Nitisinone. The ANDA was approved by the FDA in May 2023. The Company paid $150 to the seller and an additional $500 of cure amounts owed to the manufacturer upon signing. The Company will retain 80% of the product profits with the balance being distributed to the manufacturer.

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, consisting of one-time $500 payments when net sales in a year reach $4 million, $8 million, $15 million, and $20 million. 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 could receive additional payments of up to $6,500 based on the achievement of certain future regulatory and commercial milestones related to DS-*200*. The Company will retain 45% of the proceeds 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 New Drug Application ("NDA") submission. The Company intends to hold a meeting with the FDA in 2025. Under the terms of the licensing agreement, the Company will not make any upfront payments and retains the right to terminate the licensing agreement based on FDA meeting results prior to any payments being owed. The Company could pay up to $2,350 as follows: $500 following the receipt of FDA minutes; $550 upon NDA acceptance for review by 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 and paid an additional $7,500 for product inventory. The Company will also make payments to seller of $2,500 on each of the first and second anniversaries of closing. 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. See Note 4 — Business Combination for further discussion.

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, 2024 or 2023.

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, 2024, 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, 2024.

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, 2024, 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, 2024.

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, 2024 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, 2024, 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 2025 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, 2024, 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).

Exhibit No.	Description
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	Registration Rights Agreement dated June 19, 2017 by and among the Registrant and certain of its stockholders (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.2†	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).
10.3	Amended and Restated Agreement relating to sales and marketing dated February 18, 2019 between the Registrant and Eyemax, LLC (incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019).
10.4†	Sales/Marketing Agreement (DS-300) dated November 17, 2017 by and among AL Pharma, Inc., SCS National, LLC, Dry Creek Project, LLC and the Registrant (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.5+	Offer Letter Agreement by and between the Registrant and Sean E. Brynjelsen, dated as of May 17, 2017 (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.6+	Offer Letter Agreement by and between the Registrant and James Gruber, dated as of March 25, 2022.
10.7+	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
10.8+	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).
10.9	Amendment No. 1 dated August 29, 2018 to Sales/Marketing Agreement (DS-300) dated November 17, 2017 between AL Pharma, Inc. and the Registrant (incorporated by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.10	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).
10.11	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).
10.12	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).
10.13	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).
10.14	Licensing Agreement by and between the Company and AMMTek dated as of November 22, 2024.
10.15	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).
10.16	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).
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, 2024, 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, 2024, 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 18, 2025

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 18, 2025
/s/ James Gruber James Gruber	Chief Financial Officer, Treasurer and Secretary *(Principal Financial and Accounting Officer)*	March 18, 2025
/s/ Jennifer M. Adams Jennifer M. Adams	Director	March 18, 2025
/s/ Charles J. Casamento Charles J. Casamento	Director	March 18, 2025
/s/ Paul V. Maier Paul V. Maier	Director	March 18, 2025
/s/ Norbert G. Riedel, Ph.D. Norbert G. Riedel, Ph.D.	Director	March 18, 2025

Exhibit 10.11

Certain information has been excluded from this exhibit because it is both not material and is the type that the registrant treats as private or confidential

Execution Version

ASSET PURCHASE AND SALE AGREEMENT

Between

IPSEN BIOPHARMACEUTICALS, INC.

AND

ETON PHARMACEUTICALS, INC.

List of Exhibits, Schedules and Seller Disclosure Schedule

Exhibits:

Exhibit A: Form of Assignment & Assumption Agreement

Schedules:

Schedule 1.1.4	Assigned Contracts
Schedule 1.1.9	Inventory Statement
Schedule 1.1.12	Data Room Documentation
Schedule 1.1.14	Excluded Indications
Schedule 1.1.18	Field
Schedule 1.1.20	Governmental Approval
Schedule 1.1.29	Remaining Inventory
Schedule 1.1.30	Ipsen Excluded IT
Schedule 2.1.(a)(vii)	Marketing Authorizations
Schedule 5.2(c)(iv)	Tender Contract Countries
Schedule 5.5	Terminating Contracts
Schedule 5.16	Rebates, Chargebacks and Price Reporting
Schedule 5.17	FDA Program Fee
Schedule 5.21	Data Processing Addendum
Schedule 7.3(c)	Closing Consent
Schedule 7.3(d)	Seller FDA Letter
Schedule 7.3(d)(ii)	Purchaser FDA Letter
Schedule 3	Seller Disclosure Schedules

ASSET PURCHASE AND SALE AGREEMENT

This Asset Purchase and Sale Agreement, dated October 2, 2024 (the "**Agreement**"), between Ipsen Biopharmaceuticals, Inc., a company incorporated under the laws of Delaware, having a registered address at One Main Street, 7th floor, Cambridge, MA 02142, U.S.A. ("**Ipsen**" or "**Seller**"), acting in its name and on its own behalf and in the name and on behalf of its Affiliates listed in **Schedule 1** ("**Seller Affiliates**") and Eton Pharmaceuticals, Inc., a company incorporated under the laws of Delaware, having a registered address at 21925 W. Field Parkway, Suite 235, Deer Park, IL 60010 U.S.A. ("**Eton**" or "**Purchaser**").

Seller and Purchaser each, a "**Party**" and collectively, the "**Parties**".

WITNESSETH

WHEREAS, Tercica Medica, Inc. (now Ipsen Biopharmaceuticals, Inc.) and [information redacted] entered into that certain: (a) License and Collaboration Agreement effective [information redacted], as subsequently amended ("**US Increlex License Agreement**"), and (b) International License and Collaboration Agreement, effective [information redacted], as subsequently amended ("**International Increlex License Agreement**"), pursuant to which Ipsen was granted certain rights [information redacted] including a license to manufacture and an exclusive license to develop, import, sell and commercialize any pharmaceutical preparation in final form containing a recombinant insulin-like growth factor-1 (IGF-1) product, alone or in combination with one or more additional active ingredients for sale by prescription, over the counter or any other method in all dosage strength, releases and formulation that is registered and commercialized in the Field under the brand name Increlex® ("**Increlex Product**"), but excluding the Excluded Indications, in the United States, its districts, territories and possessions (under the US Increlex License Agreement) and in all other countries in the world (under the International Increlex License Agreement) (such agreements, as amended by that certain: (i) First Amendment to The License and Collaboration Agreement dated [information redacted], (ii) Second Amendment to The License and Collaboration Agreement dated as of [information redacted], (iii) Amendment to U.S. and International IGF-1 License and Collaboration Agreements dated [information redacted], (iv) Consent to Grant a Sublicense for U.S. IGF-1 Rights and Amendment to Definition of "Affiliate" dated [information redacted], and (v) Amendment to U.S. and International IGF-1 License and Collaboration Agreements dated [information redacted], and as may be further amended from time to time, collectively, "**Increlex License Agreements**").

WHEREAS, since the entry into the Increlex License Agreements, Seller is engaged in business operations and activities involving or relating to developing, manufacturing and commercializing the Increlex Product in the Territory in the Field, but excluding the Excluded Indications (the "**Business**").

WHEREAS, Seller desires to sell, convey, assign, transfer and deliver to Purchaser, and Purchaser desires to purchase, acquire and accept from Seller, all of Seller's rights to the Increlex Product and assets and rights Related to the Business, and assume, pay, perform and discharge from Seller certain Liabilities Related to the Business, in each case, upon the terms and subject to the conditions set forth herein.

WHEREAS, in consideration of the respective representations, warranties, covenants and agreements herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

1. INTERPRETATION

1.1 Definitions

1.1.1 "**Accounting Standards**" means the IFRS (as defined below). Each accounting term used herein that is not specifically defined herein should be determined in accordance with IFRS accounting principles, as consistently applicable at the time when these amounts are calculated.

1.1.2 "**Affiliate**" means, with respect to any party, any entity that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such party, but for only so long as such control exists. As used in this Section, "control" means (a) to possess, directly or indirectly, the power to direct the management or policies of an entity, whether through ownership of voting securities, by contract relating to voting rights or corporate governance; or (b) direct or indirect beneficial ownership of more than fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital or other equity interest in such entity.

1.1.3 "**Ancillary Agreements**" means (a) the Transitional Services Agreement, (b) the Assignment and Assumption Agreement and (c) Transition Safety Data Exchange Agreement.

1.1.4 "**Assigned Contracts**" means all (a) contracts Related to the Business and any rights or claims arising thereunder and (b) the portion of all Shared Contracts to the extent Related to the Business, other than the Terminating Contracts, in each case of (a) and (b), including those listed at **Schedule 1.1.4**, as may be updated by written consent of the Parties from time to time prior to Closing.

1.1.5 "**Austrian Foreign Investment Clearance**" means the Austrian *Bundesministerium für Digitalisierung und Wirtschaftsstandort* shall have: (a) confirmed in writing that the transactions contemplated by this Agreement are not subject to the prior authorization of the *Austrian Bundesministerium für Digitalisierung und Wirtschaftsstandort* pursuant to the *Investitionskontrollgesetz* or (b) authorized, or be deemed to have authorized in accordance with applicable laws, the transaction contemplated by this Agreement in accordance with said *Investitionskontrollgesetz*.

1.1.6 "**Business Day**" means any day other than a Saturday, a Sunday or a day on which banks in Paris, France or Boston, MA, U.S.A are authorized or obligated by law or executive order to close.

1.1.7 "**Business Information**" means all current and historical books, policies, records, files, ledgers, documentation, sales literature or similar information, in whatever medium (including paper, copies of original documents and electronic media), that are Related to the Business or necessary or useful for to develop, manufacture, commercialize, and otherwise exploit the Increlex Product including those listed on **Schedule 1.1.7** in each case that are owned or controlled by or otherwise in possession of Seller as of the Closing Date but excluding, in each case, all Excluded Information, being however specified that, with respect to Excluded Information listed under subsection (d) and (e) of **Section 1.1.15** (Definition of Excluded Information) hereunder, redacted versions of said Excluded Information, if partially Related to the Business, shall be considered as Business Information. Business Information shall also include any and all MAA in their current form, including all supporting files, writings, data, studies and reports, in each case as submitted to the competent local Governmental Authority for granting of all Governmental Authorizations, as well as ongoing variations.

1.1.8 "**Current Good Manufacturing Practices**" or "**cGMP**" means the following to the extent having jurisdiction over the production of the Increlex Product: (a) the good manufacturing practices required by the FDA and set forth in the U.S. Federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 et. seq.) or FDA regulations (including 21 CFR 210 and 211); (b) the practices and principles promulgated by the EMA (European Medicines Agency), including EC Directive 2003/94/EC; and (c) the relevant applicable guidelines to good manufacturing practices then in effect in countries outside the United States or Europe having jurisdiction over the manufacture of the Increlex Product, as applicable.

1.1.9 "**Closing Inventory**" means the Inventory of the Increlex Product existing at the Closing Date, comprising: (a) the US Closing Inventory located in the United States having the applicable shelf-life at the Signing Date and Closing as listed in **Schedule 1.1.9** and (b) the Transferred Drug Substance.

1.1.10 "**Commercially Reasonable Efforts**" means, with respect to each Party, those commercially reasonable efforts and resources that are substantially similar to the level of effort and resources used by a pharmaceutical company of similar size and resources to such Party to accomplish a similar objective under similar circumstances and, in the case of Purchaser's efforts with respect to the Increlex Product, with respect to drugs or drug candidates of similar commercial potential and is at a similar stage of development or product lifecycle, taking into consideration all relevant factors at the time such efforts are expended, which may include, as applicable, issues of safety and efficacy, projected costs to develop such Transferred Asset and, the competitiveness of alternative Third Party products to such Transferred Asset, the patent and other proprietary position of such Transferred Asset, the freedom to operate or other patent or intellectual property infringement concerns, the likelihood of Governmental Approval, and the expected pricing, sales, reimbursement, financial return, commercial potential and profitability of such Transferred Asset. Notwithstanding anything to the contrary, for purposes of determining Commercially Reasonable Efforts hereunder, Purchaser shall not be entitled to take into account any amounts due to Seller pursuant to this Agreement or the Increlex License Agreements between Ipsen and Genentech, or any other related agreement.

1.1.11 "**Confidentiality Agreement**" means that that certain Non-Disclosure Agreement entered into between Ipsen Bioscience, Inc. and Eton Pharmaceuticals, Inc. [information redacted].

1.1.12 "**Data Room**" shall mean the virtual data room comprising the documents and other information established by, or on behalf of, the Seller and hosted by [information redacted], to which the Purchaser, its representatives, employees, advisors, have had access [information redacted]. The content of the Data Room has been recorded on a USB stick, copies of which have been signed by the Parties and delivered to Purchaser and Seller [information redacted].

1.1.13 "**EMA**" means the European Medicines Agency, a decentralized body of the European Union, or any successor agency thereto performing similar functions.

1.1.14 "**Excluded Indications**" means the use of IGF-1 as a therapeutic or potential therapeutic treatment for any human disease or condition of the central nervous system ("**CNS**"), including CNS diseases and conditions arising out of the causes set forth [information redacted].

1.1.15 "**Excluded Information**" means (a) any employee records, (b) any emails, (c) any Tax Returns (and related work papers, schedules and other documents), financial statements and corporate or other entity filings, (d) any books, records, files, ledgers, documentation or similar information that any Seller is required by law (including laws relating to privilege or data privacy) to retain and not to disclose, (e) all books, records, files, ledgers, documentation or similar information to the extent related to, used or held by a Seller or any of its Affiliates in connection with an Excluded Asset (but not primarily Related to the Business), (f) all records and reports prepared or received by or for any Seller and its Affiliates in connection with the sale of the Business, and the transactions contemplated hereby, including all analyses Related to the Business, (g) all confidentiality agreements with prospective purchasers of the Business or any portion thereof, and all bids and expressions of interest received from Third Parties with respect thereto, and (h) any minute books, articles of incorporation, bylaws, amendments thereto, stock ledgers and stock certificates of Ipsen.

1.1.16 "**Extended Long-Stop Date**" means the date falling [information redacted] after the Closing Date.

1.1.17 "**FDA**" means the United States Food and Drug Administration or any successor federal agency thereto performing similar functions.

1.1.18 "**Field**" shall mean uses in human and in *in vitro* uses, including the therapeutic treatment, prevention or diagnosis of the indications as set forth in [information redacted], but shall specifically exclude the Excluded Indications.

1.1.19 "**Fundamental Warranties**" shall mean the representations and warranties set forth in Sections 3.1 (Organization and Qualification), 3.2 (Corporate Authority), 3.3 (Consent and Approvals), 3.5 (Ownership of Tangible Assets), 3.7 (Intellectual Property) and 3.10 (Marketing Approvals).

1.1.20 "**Governmental Approval**" means any approval or consent from any Governmental Authority required to consummate the transactions contemplated hereby, including those set forth in **Schedule 1.1.20**.

1.1.21 "**Governmental Authority**" means any supranational, national, federal, state, provincial, regional or local judicial, legislative, executive or regulatory authority or agency or any other government, quasi-governmental entity, or other governmental or regulatory body, including for the avoidance of any doubt, any Regulatory Authority and the governmental authority as having jurisdiction with respect to [information redacted].

1.1.22 "**Governmental Authorizations**" means all licenses, approvals, permits, exemptions, registrations, listings, clearances, consents, orders and other authorizations of any Governmental Authority or Regulatory Authority that may be necessary or useful to develop, manufacture, commercialize, and otherwise exploit the Increlex Product, the Transferred Assets, or to carry out the Business. For the avoidance of doubt, the term Governmental Authorization includes MAA.

1.1.23 "**Governmental Order**" means any order, writ, judgment, injunction, decree, stipulation, determination, award or similar order entered by or with any Governmental Authority of competent jurisdiction.

1.1.24 "**Handover Date**" means, for each country in the Territory, the date that the relevant Governmental Authority of the Territory confirms the transfer of the MAA or Governmental Authorizations for such country from Seller (or, as applicable, any Seller Affiliates or Third Party designated by Ipsen that holds the MAA or the Governmental Authorizations on behalf of Seller in such country) to Purchaser, its Affiliates or its designee (or an equivalent date on which the transfer is deemed effective pursuant to local regulatory requirements in such country).

1.1.25 "**IFRS**" means the International Financial Reporting Standards, the set of Accounting Standards and interpretations and the framework in force on the Closing Date and adopted by the European Union as issued by the International Accounting Standards Board (IASB) and the International Financial Reporting Interpretations Committee (IFRIC), as such accounting standards may be amended from time to time.

1.1.26 "**Increlex Global Registry**" means a [information redacted], non-interventional, post- MAA authorization surveillance registry [information redacted] intended to [information redacted] after the end of treatment in children and adolescents with Severe Primary Insulin-like Growth Factor-1 Deficiency being injected with the Increlex Product based on the prescriber's information as approved by the relevant Regulatory Authorities of the Territory and to follow the effectiveness of treatment.

1.1.27 "**Intellectual Property**" means any and all rights in, arising out of, or related to any of the following, under the laws of any relevant jurisdiction in the world, whether unregistered or registered, whether now or hereafter existing, created, acquired or held: the Patent Rights, trademark rights, copyrights, domain names, Know-How and any other intellectual property or similar proprietary rights.

1.1.28 "**Inventory**" means (a) all inventory of finished goods of Increlex Product labeled under the Ipsen Brands, (b) all inventory of bulk naked vials of the Increlex Product, and (c) all drug substance of the Increlex Product and any inventories of raw materials, manufactured and purchased parts of the Increlex Product, and any and all rights to use, market and/or sell such Inventory in case of (c), held for use specifically in connection with the manufacture of the Increlex Product (the "**Drug Substance**"), and, in each case of (a) to (c) owned by Seller or any of its Affiliates whether located at a facility of Seller or any of its Affiliates, at a contract manufacturer or in transit.

1.1.29 "**Inventory Value**" means (a) the amount, expressed in US Dollars, of the fair value of the Closing Inventory as of the Closing Date and (b) the amount, expressed in Euros, of the fair value of the Remaining Inventory as of the Remaining Inventory Transfer Date as determined in accordance with IFRS and as set forth in **Schedule 1.1.29**.

1.1.30 "**Ipsen Excluded IT**" means all information technology hardware, software and systems listed on **Schedule 1.1.30.**

1.1.31 "**Know-How**" means any data, inventions, methods, proprietary information, processes, trade secrets, techniques, protocols and technology, whether patentable or not, including discoveries, formulae, methods, plans, know-how, processes, documented ideas, observations and conclusions, test data (including pharmacological, toxicological and clinical information and test data), analytical and quality control data, and marketing, pricing, distribution, costs and sales data and descriptions.

1.1.32 "**Liabilities**" means any and all debts, liabilities, Taxes, commitments, damages, losses, claims or other claims, charges, demands, actions, suits, causes of action, judgments, assessments, payments, settlements, costs, fees, expenses and obligations of any kind, whether due or to become due, fixed or contingent, matured or unmatured, liquidated or unliquidated, accrued or not accrued, asserted or not asserted, known or unknown, determined, determinable or otherwise, whenever or however arising (including, whether arising out of any contract or tort based on negligence or strict liability) and whether or not the same would be required by IFRS to be recorded or reflected in financial statements or disclosed in the notes thereto.

1.1.33 "**Licensed Intellectual Property**" means, collectively, all Intellectual Property licensed or sublicensed to Ipsen under the Increlex License Agreements.

1.1.34 "**Long-Stop Date**" means [information redacted] after the Signing Date.

1.1.35 "**Loss**" means any and all damages, losses, claims, charges, Taxes, penalties, obligations, causes of action, judgments, assessments, payments, settlements and reasonable out-of-pocket costs and fees and expenses (including reasonable attorneys' fees and disbursements) sustained or incurred by the affected Person.

1.1.36 "**MAA**" or "**Marketing Authorization**" means the (a) marketing authorization application filed with the EMA, (b) the new drug application ("**NDA**") and subsequent biologics license application ("**BLA**") filed with the FDA and (c) similar product registration or application filed with any other Governmental Authority in each case to obtain approval for the marketing, commercialization, distribution and sale of the Increlex Product, together with any supplements and amendments thereto.

1.1.37 "**Net Sales**" means the gross revenues, determined in accordance with IFRS as consistently applied by Seller, invoiced by Seller, its Affiliates, licensees and sublicensees in connection with the sale, lease or other transfer for value of the Increlex Product to unaffiliated Third Parties in the applicable country ("**Gross Sales**"); in all cases after deduction of the following, determined in each case, in accordance with IFRS as consistently applied by Seller: (a) customary trade and quantity discounts actually allowed and taken; (b) amounts actually allowed or credited due to returns of the Increlex Product previously sold as reflected in written invoices (and not to exceed the original invoice amount); (c) cost of shipping, freight and insurance, to the extent separately invoiced and charged; (d) credits, allowances and rebates actually given pursuant to federal, state and/or government-mandated programs, which require a manufacturer/distributor rebate; (e) value added or import/export Taxes, Sales Taxes, excise Taxes or customs duties, to the extent applicable to such sale, and included in the invoice in respect of such sale and actually paid and (f) reasonable, out-of-pocket expenses paid by the Seller or its Affiliates to unaffiliated Third Parties arising in connection with the provision of services by the Seller or its Affiliates to the Purchaser under the Transitional Services Agreement; *provided* that, in the case of (f), Seller shall seek Purchaser's prior written approval (not to be unreasonably withheld, conditioned or delayed) before incurring any such expenses exceeding in the aggregate from the Signing Date [information redacted]. In the case of any sale or other disposal of the Increlex Product between or among Purchaser or its Affiliates or sublicensees for resale, Net Sales will be calculated only on the value charged or invoiced on the first arm's-length sale thereafter to a Third Party (other than a sublicensee).

1.1.38 "**Owned Equipment**" means all equipment owned by Ipsen that is Related to the Business, except, in each case, to the extent included in the Excluded Assets.

1.1.39 "**Owned Inventory**" means all Inventory owned and paid for by Seller and/or its Affiliates that is Related to the Business, having passed Ipsen's (or its Affiliate's) quality control procedures, including any such Inventory that is owned by Ipsen that remains in the possession or control of Seller after the Closing Date for distribution and sale by Seller, its Affiliates and/or their respective Third Party distributor, or Seller (as applicable) during the Transition Phase.

1.1.40 "**Patent Right**" means any and all (a) national, regional and international issued patents; (b) pending patent applications and any related patent applications filed in the future claiming priority thereto, including all provisional applications, non-provisional applications, international (PCT) applications, substitutions, continuations, continuations in part, divisions, renewals, and all patents granted thereon or issuing therefrom; (c) all patents of addition, reissues, re-examinations and extensions or restorations by existing or future extension or restoration mechanisms, including supplementary protection certificates or the equivalent thereof; (d) registration patents, inventor's certificates or confirmation patents; and (e) any form of government-issued right substantially similar to any of the foregoing, in each case in any country or patent examining or granting jurisdiction.

1.1.41 "**Person**" means any individual or corporation, association, partnership, limited liability company, joint venture, joint stock, or other company, business trust, trust, organization, labor union, Governmental Authority, or other entity of any kind.

1.1.42 "**Post-Closing Tax Period**" means any taxable period (or portion thereof) beginning after the Closing Date.

1.1.43 "**Real Property**" means real property, together with all buildings, structures and improvements located thereon and all fixtures attached thereto, together with all easements, rights-of-way, appurtenances and other rights benefiting such real property.

1.1.44 "**Regulatory Authority**" means (a) in the U.S., the FDA; (b) in the EU, the EMA or the European Commission; or (c) in any other jurisdiction anywhere in the world, any Governmental Authority with similar regulatory authority over pharmaceutical or biotechnology products.

1.1.45 "**Regulatory Laws**" means all applicable laws related to the development, manufacturing, commercialization and exploitation of the Increlex Product, including the U.S. Federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 et. seq.), the U.S. Public Health Service Act (42 U.S.C. § 262), all rules, regulations, and agency guidance promulgated or issued thereunder, all terms and conditions of any MAA or Governmental Authorization, and any and all other comparable federal, state, or foreign laws applicable to the Increlex Product or the Business.

1.1.46 "**Related to the Business**" means related to, or used or held in connection with, the Business and the Increlex Product as conducted by Ipsen in the twelve (12) months prior to the Closing.

1.1.47 "**Remaining Inventory Transfer Date**" means the date that is six (6) months after the Closing Date.

1.1.48 "**Sales Tax**" means any and all transfer, value added, sales, use, gross receipts, business, consumption and other similar Taxes, levies and charges (other than income Taxes and together with any interest, penalties and additions to Tax).

1.1.49 "**Seller Insurance Policies**" means all current or previous insurance policies of a Seller and its Affiliates, including all environmental, directors' and officers' liability, fiduciary liability, employed lawyers, property and casualty flood, ocean marine and contaminated products insurance policies and all other insurance policies or programs arranged or otherwise provided or made available by such Seller or its Affiliates that cover (or covered) any of the assets and Persons at any time prior to the Closing.

1.1.50 "**Shared Contracts**" means any contract entered into prior to the Closing to which Ipsen or its Affiliates is a party that both Related to the Business and any other business of Seller other than the Business.

1.1.51 "**Signing Date**" or "**Signing**" means the date of signature of this Agreement.

1.1.52 "**Tax**" means any domestic or foreign, state, local, provincial or municipal taxes collected by any Tax Authority, including the following: net income, gross income, individual income, capital, value added tax, good and services, gross receipts, personal property, service, service use, withholding, excise, stamp, customs, and all other taxes, fees, duties, assessments, deductions, withholdings or similar charges payable to any Tax Authority, however denominated and whether estimated or final, together with any interest and penalties, additions to tax or additional amounts imposed or assessed with respect thereto.

1.1.53 "**Tax Return**" means any return (including estimated returns), declaration, filing, report, claim for refund, information return or other statement relating to Taxes (whether in tangible, electronic or other form), including any schedule, supplement, appendices and exhibits or attachment thereto and any amendment thereof made, prepared, filed or required to be made, prepared or filed by law in respect of Taxes.

1.1.54 "**Tax Authority**" means any Governmental Authority with responsibility for, and competent to impose, collect or administer any form of Tax.

1.1.55 "**Territory**" means worldwide.

1.1.56 "**Third Party**" means any person other than a Party.

1.1.57 "**Trademark Rights**" means, collectively, all trademarks, service marks and names, trade and brand names, slogans, logos, symbols, trade dress or other similar source or origin identifiers (whether statutory or common law, whether registered or unregistered), together with all: (a) registrations and applications for any of the foregoing, (b) extensions or renewals of any of the foregoing, (c) goodwill connected or associated with or symbolized by any of the foregoing, (d) rights and privileges arising under applicable law with respect to any of the foregoing and (e) rights corresponding to any of the foregoing.

1.1.58 "**Transaction**" means the sale by Seller and the purchase by Purchaser of the Transferred Assets, the assumption by Purchaser of the Assumed Liabilities and the consummation of the other transactions contemplated by this Agreement and the Ancillary Agreements.

1.1.59 "**Transferred Domain Names**" means the Internet domain names registrations that is exclusively Related to the Business and owned or controlled by Ipsen or one or more of its Affiliates as of the Closing Date and that is useful or necessary for the development, manufacture, commercialization or exploitation of the Increlex Product.

1.1.60 "**Transferred Drug Substance**" means all the Drug Substance owned by Seller or any of its Affiliates as of the Closing Date, comprising [information redacted] of drug substance of the Increlex Product and certain other inventories of raw materials, manufactured and purchased parts of the Increlex Product.

1.1.61 "**Transferred Intellectual Property**" means the Transferred Domain Names, Transferred Patent Rights, Transferred Trademark Rights, and any and all other Intellectual Property that is Related to the Business and owned or controlled by Ipsen or one or more of its Affiliates and that is useful or necessary for the development, manufacture, commercialization or exploitation of the Increlex Product, including the Licensed Intellectual Property, including as listed on **Seller Disclosure Schedule 3.7(a)**.

1.1.62 "**Transferred Patent Rights**" means the Patent Rights set forth on **Schedule 1.1.62**.

1.1.63 "**Transferred Trademark Rights**" means the Trademark Rights set forth on **Schedule 1.1.63**.

1.1.64 "**Transfer Taxes**" means any transfer, conveyance, documentary, real estate transfer, mortgage recording, use, stamp, registration, and other similar taxes and fees (including any penalties and interest in respect thereof) imposed with respect to the Transactions other than VAT.

1.1.65 "**Transition Safety Data Exchange Agreement**" means the agreement between Ipsen or one or more of its Affiliates, on the one hand, and the Purchaser or Affiliates of Purchaser, on the other hand, and to be executed concurrently with the Closing or at a later date as agreed to by the Parties in writing to provide for the pharmacovigilance procedures between the Parties that would apply until the effective Handover Dates and transfer of the MAA and Governmental Authorizations to Purchaser while Ipsen will remain the holder of the MAA and Governmental Authorization under the Transitional Services Agreement in the given country of the Territory.

1.1.66 "**Transitional Services Agreement**" means the agreement between Seller and/or one or more of its Affiliates, on the one hand, and the Purchaser or Affiliates of Purchaser, on the other hand, to be executed concurrently with the Signing with respect to Seller's performing certain distribution of the Increlex Product and rendering certain services for the benefit of the Purchaser(s) or Affiliate(s) of Purchaser.

1.1.67 "**US Closing Inventory**" means an Inventory of [information redacted] the Increlex Product, comprising (a) inventory of finished goods of Increlex Product labeled under the Ipsen Brands and (b) inventory of bulk naked vials of the Increlex Product, [information redacted].

1.2 **Additional Definitions**

The following table identifies the location of definitions set forth in various Sections of the Agreement.

Defined Terms	**Section**
Applicable Cap Amount	9.1.2(a)
Assignment and Assumption Agreement	2.4(c)
Assumed Liabilities	2.1(c)
Basket Threshold	9.1.2
BLA	1.1.36
Business	Recitals
Business Customers	3.11
Business Suppliers	3.11
Claim	9.2
Closing	2.3
Closing Consent	7.3(c)
Closing Date	2.3
Closing Inventory Payment	2.2(b)
CNS	1.1.14
Commission	TSA
Competing Indications	5.18(a)
Competing Product	5.18(a)
Confidentiality Agreement	5.1
Consent	5.4
Deferred Payment	2.2(d)
EORI	5.2(b)
Excluded Asset	2.1(b)
GDPR	5.22
Genentech	Recitals
Increlex License Agreements	Recitals
Increlex Product	Recitals
Ipsen Brands	5.20
International Increlex License Agreement	Recitals
Inventory Statement	3.5(b)
Ipsen Registered IP	3.7(a)

Gross Sales	1.1.37
Licensed Intellectual Property	3.7(a)
Local Asset Sale Agreement	5.19(e)
Marketing Materials	2.1(a)(viii)
NDA	1.1.36
Personal Information	5.22
Post-Closing US Inventory	2.6.4
Program Fee	5.17
Purchaser FDA Letter	7.3(d)
Remaining Inventory	5.19(c)
Remaining Inventory Statement	5.19(d)
Remaining Inventory Value	5.19(d)
Remaining Inventory Value Payment	2.2(c)
Seller Account	2.2(a)
Seller Affiliates	Recitals
Seller Disclosure Schedule	3
Seller FDA Letter	7.3(d)
Trademark License Term	5.20
Transferred Asset	2.1(a)
Transition Phase	5.19
Upfront Payment	2.2(a)
US Increlex License Agreement	Recitals

2. PURCHASE AND SALE OF ASSETS

2.1 Purchase and Sale of Ipsen Assets

(a) Ipsen's Transferred Assets. On the terms and subject to the conditions set forth herein, at the Closing of this Agreement, Ipsen shall, and shall cause its Affiliates to, sell, convey, transfer, assign, irrevocably grant and deliver to Purchaser, and Purchaser shall purchase and accept from Ipsen and its Affiliates, all of Ipsen's and its Affiliates' rights, title and interests, as of the Closing, in and to all of the assets of Ipsen and its Affiliates (other than the Excluded Assets), whether tangible or intangible, real, or personal, Related to the Business, including the following assets ("**Transferred Assets**") free and clear of all liens or encumbrances (other than Assumed Liabilities and liens created by or through Purchaser or any of its Affiliates):

(i) the Owned Equipment;

(ii) the Assigned Contracts, including the contracts listed in **Schedule 1.1.4**;

(iii) in accordance with **Section 5.14** (Delivery of Information), the Business Information;

(iv) the Transferred Intellectual Property;

(v) all credits, prepaid expenses, deferred charges, advance payments, security deposits, prepaid items and duties to the extent Related to the Business;

(vi) all guaranties, warranties, representations, indemnities and similar rights in favor of Ipsen primarily Related to the Business or related to any Transferred Asset;

(vii) each IND (investigational new drug application), CTA (clinical trial application), MAA and Governmental Authorization Related to the Business, including as listed on **Schedule 2.1(a)(vii)**;

(viii) all advertising, marketing, promotional and sales materials and other literature, catalogues and other sales-related materials (in any and all formats available to the Seller or its Affiliates) Related to the Business (the "**Marketing Materials**") and any Intellectual Property rights of Seller or its Affiliates pertaining thereto;

(ix) the lists of prescribers, customers and historical data broken down by customer of the Increlex Product for each country of the Territory where the Increlex Product was commercialized prior to the Closing Date;

(x) any other existing assets owned by Seller or any of its Affiliates that are either (1) exclusively dedicated to the operations of the Business as it is conducted by the Seller (or any of its Affiliates) as at the date of this Agreement or (2) to the extent such asset is not exclusively dedicated to the operations of the Business, the portion of such asset to the extent Related to the Business;

(xi) all past, present and future goodwill that are Related to the Business; and

(xii) subject to **Section 5.19**, the Closing Inventory and the Remaining Inventory.

(b) Ipsen's Excluded Assets. Notwithstanding any provision to the contrary in this **Section 2.1** (Purchase and Sale of Ipsen Assets) or otherwise in this Agreement, Ipsen and its Affiliates shall retain all of their existing rights, title and interests in and to, and there shall be excluded from the sale, conveyance, assignment or transfer to Purchaser, any and all assets held by Ipsen or any of its Affiliates, that are not expressly included in the Transferred Assets (the "**Excluded Assets**"), including, for the avoidance of doubt:

(i) the Ipsen Excluded IT;

(ii) all Seller Insurance Policies or rights to proceeds, refunds due from, or payments due on, claims under such Seller Insurance Policies in respect of Losses related to periods, or arising, prior to the Closing;

(iii) any Tax assets, including Tax refunds, Tax Losses, credits relating to the Transferred Assets or the Business that are in existence as of the Closing;

(iv) the Excluded Information with respect to Ipsen, its Affiliates and the Increlex Product;

(v) all rights of Ipsen under this Agreement and the Ancillary Agreements;

(vi) all contracts other than the Assigned Contracts;

(vii) any employees of Ipsen or its Affiliates;

(viii) any accounts receivable accrued prior to the Closing Date;

(ix) cash, cash equivalents, bank accounts, bank deposits and marketable securities on hand and in transit of Seller or any of its Affiliates;

(x) the Ipsen Brands; and

(xi) all assets and properties to the extent not related to the Business.

In addition to the above, Seller shall have the right to retain, following the Closing, copies of any book, record, literature, list and any other written or recorded information constituting Business Information to which Ipsen in good faith determines it is reasonably likely to need access solely for Tax purposes and for the provision of services under the Transitional Services Agreement (in which case said right to retain for the provision of services under the Transitional Services Agreement shall automatically expire with said Transitional Services Agreement).

(c) Assumption of Liability. On the terms and subject to the conditions set forth herein, at the Closing and effective as of the Closing Date, Purchaser shall assume, be responsible for and discharge Ipsen and perform when due all "**Assumed Liabilities**" as follows:

(i) all Liabilities first arising from the ownership, exploitation and operation of the Transferred Assets, in each case, solely to the extent arising or accruing on or after the Closing Date;

(ii) all Liabilities relating to or arising out of or resulting from actions or claims brought in respect of any of the Increlex Product or the Transferred Assets to the extent relating solely to events, occurrences, acts or omissions occurring after the Closing Date;

(iii) all Liabilities with respect to the Transferred Assets under any products liability laws or similar laws concerning defective products to the extent (1) relating to the Increlex Product ordered in the ordinary course of business but not yet shipped as of the Closing Date or (2) arising out of or relating to any claims, complaint, actions, suit proceeding, hearing or investigation arising from the ownership, exploitation and operation of the Increlex Product solely with respect to the period on or after the Closing Date;

(iv) all Liabilities under the Assigned Contracts to the extent solely relating to events, occurrences, acts or omissions occurring after the Closing Date (but, for the avoidance of doubt, only the assumed portion of the Shared Contracts);

(v) all open purchase orders and trade and other accounts payable, in each case to the extent Related to the Business and listed on **Schedule 2.1(c)(v)**; and

(vi) all Liabilities for (A) Transfer Taxes as described in Section 6.1 and (B) Taxes (other than Transfer Taxes) attributable to the Transferred Assets or the operations or the income of the Business for any Post-Closing Tax Period, to the extent that such Liabilities do not relate to any failure to perform or other breach, default or violation by Seller or any of its Affiliates or Affiliates prior to or at the Closing.

(d) Exclusion of Liability. Any Liability of the Seller or its Affiliates other than the Assumed Liabilities (the "**Excluded Liabilities**") shall be retained and the Purchaser shall not hereunder assume or become liable therefor, including:

(i) any Liability in respect of, or relating to, Seller's or any of its Affiliates' ownership or operation of the Business incurred as a result of an event which has occurred prior to the Closing Date (including any product liabilities pertaining to the Increlex Product manufactured or shipped prior to the Closing);

(ii) any Liability for accounts payable and accrued expenses to the extent that they arise or are incurred prior to the Closing Date, even if such Liabilities are invoiced after the Closing Date; *provided* that to the extent any such accounts payable and accrued expenses relate to periods both before and after the Closing Date, they will be allocated on a *per diem* basis, unless otherwise provided in the underlying contractual documentation;

(iii) any Liability arising out of, or relating to, the performance or non-performance of the Assigned Contracts prior to the Closing Date;

(iv) any Terminating Contracts;

(v) any Liability with respect to the development, manufacture, commercialization and other exploitation of the Increlex Product released or manufactured prior to the Closing Date (including any Increlex Product recalls), including without limitation any liability in respect of Batch No. 32 of drug substance of the Increlex Product manufactured in March 2024 as set forth in **Seller Disclosure Schedule 3.8**; and

(vi) any Liability arising from or in connection with the employment of any person employed by the Seller or its Affiliates;

(vii) any Taxes of the Seller and its Affiliates (other than any Taxes for which the Purchaser is responsible pursuant to **Section 6.1** (VAT and Other Similar Taxes)).

2.2 **Purchase Price**

On the terms and subject to the conditions set forth herein, in consideration of the sale, assignment, conveyance and delivery of the Transferred Assets to Purchaser, subject to the terms and conditions of this Agreement, Purchaser shall, in addition to the assumption of the Assumed Liabilities, pay the Upfront Payment**,** the Closing Inventory Payment, the Remaining Inventory Value Payment and the Deferred Payment (collectively together the "**Purchase Price**") as follows:

(a) Upfront Payment. As partial consideration for the Transferred Assets, Purchaser shall on the Closing Date, make a non-refundable payment to Seller, by wire transfer of immediately available funds, to Seller's designated bank account ("**Seller Account**"), in an amount in cash of US$22,500,000 (twenty-two million five hundred thousand US Dollars), by wire transfer of immediately available funds (the "**Upfront Payment**").

(b) Closing Inventory Payment. As consideration for the Closing Inventory to be transferred in accordance with **Section 2.6**, Purchaser shall on the Closing Date, make a non-refundable payment to Seller, by wire transfer of immediately available funds, to the Seller Account, in an amount in cash of US$7,500,000 (the "**Closing Inventory Payment**"), for:

(i) the US Closing Inventory and Post-Closing US Inventory, equal to [information redacted]; and

(ii) the Transferred Drug Substance, equal to [information redacted]

At least two (2) Business Days before Closing Date, the Seller shall provide the Purchaser with an updated Inventory Statement for the US Closing Inventory and the Transferred Drug Substance.

For clarity, the total amount of non-refundable cash payment due and owed by Purchaser to Seller and wired to Seller Account on the Closing Date shall be US$30,000,000 (US Dollars thirty million).

(c) Remaining Inventory Value Payment. As consideration for the Remaining Inventory to be transferred in accordance with **Section 5.19(c)**, and as calculated in accordance with **Section 5.19(d)**, Purchaser shall make non-refundable payments to the Seller Account, equal to [information redacted], the "**Remaining Inventory Value Payment**"). Each [information redacted] installment shall be due and payable at the end of [information redacted] until the total Remaining Inventory Value is fully made. The Remaining Inventory Value Payment shall be made by Purchaser by wire transfer in [information redacted] in immediately available funds to such bank account as Seller may designate by written notice to Purchaser.

(d) Deferred Payment. As additional consideration for the Transferred Assets, Purchaser shall pay to Seller, two (2) payment(s) in the aggregate amount of US$5,000,000 (Five Million US Dollars) (each, a "**Deferred Payment**") as follows:

Table 2.2(d) Deferred Payment Dates	**Payment Amount US$**
First anniversary of the Closing Date	2,500,000
Second anniversary of the Closing Date	2,500,000

Purchaser shall pay, or cause to be paid to Ipsen, by wire transfer of immediately available funds to the Seller Account, the applicable non-creditable Deferred Payment as set forth in **Table 2.2(d)** above on the Deferred Payment date to which such payment amount relates.

(e) Overdue Payments. Any undisputed Remaining Inventory Value Payment and Deferred Payment not paid when due shall bear interest from the due date until the date of payment at a rate that is [information redacted], calculated on the total number of days that the payment is delinquent, [information redacted]. The payment of such interest shall not limit Seller from exercising any other rights it may have as a consequence of the lateness of any payment.

2.3 **Closing; Closing Date**

The completion of the purchase and sale of the Transferred Assets and the assumption of the Assumed Liabilities (the "**Closing**") shall take place as soon as possible at [information redacted] after the date on which the conditions set forth in **Section 7** (Conditions to Closing) have been satisfied or waived by Purchaser or Seller (as applicable). The date on which the Closing occurs is called the "**Closing Date**".

2.4 **Purchaser's Closing Deliverables**

At the Closing, Purchaser shall deliver, or cause to be delivered to Seller, the following:

(a) an amount equal to the Upfront Payment in cash by wire transfer of immediately available funds to the Seller Account,

(b) an amount equal to the Closing Inventory Payment in cash by wire transfer of immediately available funds to the Seller Account,

(c) a signed assignment and assumption agreement, in the form attached hereto as **Exhibit A** and dated as of the Closing Date, pursuant to which Purchaser shall assume the Assigned Contracts and the Assumed Liabilities related thereto (the "**Assignment and Assumption Agreement**"), duly executed by Purchaser;

(d) a signed counterpart of each of the Ancillary Agreements to which Purchaser is a party, duly executed by Purchaser.

2.5 **Seller's Closing Deliverables**

At the Closing, Seller shall deliver, or cause to be delivered to Purchaser, the following:

(a) fully executed copies of the Closing Consents;

(b) a counterpart of the Assignment and Assumption Agreements, duly executed by such Seller or its Affiliates, as applicable;

(c) a counterpart of each of the Ancillary Agreements to which such Seller is a party, duly executed by the applicable Seller or its Affiliates, as applicable; and

(d) a valid and properly completed Internal Revenue Service Form W-9 of the Seller.

2.6 **Delivery of Closing Inventory and Transferred Drug Substance**

2.6.1 At least [information redacted] prior to the Closing, Seller shall deliver to Purchaser (or a designee of Purchaser) [information redacted].

2.6.2 On the Closing Date, Seller shall deliver to Purchaser (or a designee of Purchaser) [information redacted].

2.6.3 On the Closing Date, a purchase order shall be delivered by Purchaser to Seller for the purchase and payment of the Transferred Drug Substance equal to US$5,000,000 (US Dollars five million), with a delivery date on or before the Remaining Inventory Transfer Date. Seller shall deliver to Purchaser (or a designee of Purchaser) the Transferred Drug Substance on or before the Remaining Inventory Transfer Date.

2.6.4 In the event that the US Closing Inventory delivered by Seller (or its Affiliate(s)) to Purchaser as of the Closing comprises fewer than 5,230 vials of Increlex Product, Seller shall deliver to Purchaser (or a designee of Purchaser) such number of vials of Inventory, comprising (a) inventory of finished goods of Increlex Product labeled under the Ipsen Brands and (b) inventory of bulk naked vials of the Increlex Product (together, the "**Post-Closing US Inventory**"), as is equal to 5,230 vials *minus* the number of vials delivered by Seller (or its Affiliate(s)) to Purchaser as of the Closing, at the earlier of (x) as soon as reasonably practicable after the secondary packaging campaign run of finished goods of the Increlex Product has been released from Tjoapack for the United States and (y) on or before January 31, 2025.

2.6.5 All deliveries made pursuant to this **Section 2.6** shall be delivered to Purchaser on [information redacted] basis to the Eton's designated warehouse. Title and risk of loss or other risks in relation to such US Closing Inventory and Transferred Drug Substance, as applicable, shall pass to Purchaser in accordance with the abovementioned Incoterms upon delivery of such Inventory in accordance with this **Section 2.6**.

3. REPRESENTATIONS & WARRANTIES OF IPSEN

Seller represents and warrants to Purchaser as of the Signing Date and the Closing Date (and in the case of Section 3.15, as of the Remaining Inventory Transfer Date) that, except as set forth in the disclosure schedule provided by Seller to Purchaser ("**Seller Disclosure Schedule**"):

3.1 Organization and Qualification.

Ipsen is duly incorporated or organized, as applicable, validly existing under the laws of the jurisdiction of its incorporation. Each of Ipsen and its Affiliates have all requisite corporate or other power and authority to own, lease and operate the Transferred Assets held by it.

3.2 Corporate Authority.

Ipsen has all requisite corporate power and authority and has taken all corporate action necessary in order to execute, deliver and perform its obligations under this Agreement, each Ancillary Agreement, the Seller FDA Letters, the Purchaser FDA Letters, and any other agreements, certificates or documents to which it is a party and to consummate the Transactions. This Agreement is, and when executed and delivered by Ipsen, each Ancillary Agreement to which it is a party will be, a valid and binding agreement of Ipsen enforceable against Ipsen in accordance with its terms. Ipsen has the authority to bind its Affiliates to the provisions of this Agreement and hereby agrees that it will cause each of its Affiliates to be bound by, and to take any action that is required under, this Agreement and each Ancillary Agreement as if such Affiliate were a party to this Agreement or Ancillary Agreement, as applicable.

3.3 Consent and Approvals.

Except as set forth in **Seller Disclosure Schedule 3.3**, no notices, applications, reports or other filings are required to be made by Ipsen with any Governmental Authority, nor are any consents required to be obtained by Ipsen from any Governmental Authority, in connection with the execution, delivery and performance of this Agreement or any Ancillary Agreement to which Ipsen is a party and the consummation by Ipsen of the Transactions.

3.4 Non-Contravention.

(a) The execution, delivery and performance of this Agreement and each Ancillary Agreement to which Ipsen is a party do not, and the consummation by Ipsen or its Affiliates of the Transactions will not, constitute or result in: (i) a breach or violation of, or a default under, the certificate of incorporation or by-laws of Ipsen, (ii) a breach or violation of any obligations on the Transferred Assets, and in particular those pursuant to any Assigned Contract or any other commitment of Seller or any of its Affiliates, (iii) the breach of, or a default under any law applicable to Seller and/or any such Affiliates, in each case, assuming the making of all notices and the obtaining of all consents referred to in Section 3.3 (Consent Approvals) and in **Seller Disclosure Schedule 3.3**.

(b) There is no pending legal proceeding involving Seller or, to the knowledge of Seller, threatened against Seller or its relevant Affiliates, that questions or challenges the validity of this Agreement or seeks to prevent, enjoin, alter or delay any other transactions contemplated hereby or any action to be taken pursuant to this Agreement or any Ancillary Agreement.

3.5 Ownership of Tangible Assets.

(a) Ipsen does not own any Real Property Related to the Business, nor will Ipsen assign any lease for the occupancy of a Real Property to Purchaser at Closing.

(b) The Inventory is in good working order, has (or is reasonably expected to) pass Ipsen's (or its Affiliate's) quality control procedures, and has no more than reasonable wear and tear. The applicable shelf life estimated [information redacted]. The US Closing Inventory comprises [information redacted] of the Increlex Product, comprising (a) inventory of finished goods of Increlex Product labeled under the Ipsen Brands and (b) inventory of bulk naked vials of the Increlex Product, [information redacted]. As of immediately prior to Closing or, in the case of the Post-Closing US Inventory, as of immediately prior to Seller's delivery of such Inventory to Purchaser pursuant to **Section 2.6**, all US Closing Inventory and Post-Closing US Inventory is owned by Seller and/or its Affiliates and located in the United States.

(c) The Inventory has no more than reasonable wear and tear, is in good and saleable condition and usable in the ordinary course of business for its intended purposes and has been manufactured and stored in compliance with cGMP and with the specifications of the Increlex Product and Business as defined in the relevant MAAs and Governmental Authorizations (including without limitation all specifications set forth in the applicable dossier for the Increlex Product).

(d) Seller has, or its Affiliates (as applicable) have, good title to, or valid and enforceable contract rights in and to, the Transferred Assets, free and clear of all encumbrances other than the permitted encumbrances. The Transferred Assets, in the form delivered to the Purchaser in accordance with this Agreement: (i) are adequate to conduct the Business as it is presently being conducted and as it was conducted in the twelve (12) months prior to Closing and (ii) include all of the Governmental Authorizations, registered Intellectual Property Rights and other assets necessary for the Purchaser to conduct the Business as it is presently being conducted and as it was conducted in the twelve (12) months prior to Closing.

3.6 Assigned Contracts and Shared Contracts.

(a) All Assigned Contracts and all Shared Contracts are in full force and effect and are enforceable against each party thereto in accordance with the express terms thereof. There does not exist under any Assigned Contract nor under any Shared Contracts (to the extent Related to the Business), any violation, breach or event of default, or alleged violation, breach or event of default, or event or condition that, after notice or lapse of time or both, would constitute a violation, breach or event of default thereunder on the part of Seller, and to Ipsen's knowledge there does not exist under any Assigned Contract nor under any Shared Contracts (to the extent Related to the Business), any violation, breach or event of default, or alleged violation, breach or event of default, or event or condition that, after notice or lapse of time or both, would constitute a violation, breach or event of default thereunder on the part of any third-party.

(b) As of the Signing Date and [information redacted] prior to the Closing Date, neither Seller nor any of its Affiliates that are Parties thereto has received from any Third Party to any of the Assigned Contracts or Shared Contracts (to the extent Related to the Business):

(i) any written notice that any such co-contracting Third Party intends to terminate any such Assigned Contract or Shared Contract (to the extent Related to the Business); or

(ii) except as set forth in **Seller Disclosure Schedule 3.8**, any written claim of material breach, violation of other default of the Seller or such Affiliates pursuant to any such Assigned Contract or Shared Contract (to the extent Related to the Business).

(c) Ipsen has satisfied all payment obligations, and no payment obligations remain, under the Increlex License Agreements, now or in the future, by Seller or any of its Affiliates or, following the Closing, under the Increlex License Agreements (unless due to action by Purchaser or any of its Affiliates, for which Purchaser shall remain liable for any such payment obligation to Genentech) [information redacted].

3.7 Intellectual Property.

(a) Seller is and, immediately prior to the Closing, will be, the holder of a valid license under the Licensed Intellectual Property, free and clear of any liens or encumbrances. Other than the Licensed Intellectual Property, Seller owns, and immediately prior to the Closing, will own all other Intellectual Property necessary for or that has been used to develop, manufacture, commercialize or otherwise exploit the Increlex Product. None of the execution, delivery or performance by the Seller or the consummation of any transactions contemplated hereby shall result in the loss or impairment of, or give rise to any right of a third party to terminate, any rights of the Seller in any of the foregoing rights. **Seller Disclosure Schedule 3.7(a)** sets forth a correct, current and complete list of all: (x) Transferred Intellectual Property registered or applied for in the name of Ipsen or any of its Affiliates as of the date of this Agreement (the "**Ipsen Registered IP**"), and (y) Licensed Intellectual Property and, in each case, the legal owner thereof. All Transferred Intellectual Property are valid, enforceable and subsisting and in full force and effect.

(b) All registration, application, maintenance and renewal fees, costs, charges and Taxes required for or in connection with the maintenance of the Transferred Intellectual Property, that are due and payable prior to the Closing Date, have been or will be duly paid on time by Seller, and all necessary documents, recordations and certifications in connection with the Ipsen Registered IP have been filed with the relevant Governmental Authorities and domain name registrars, as the case may be, for the purposes of maintaining ownership of, or rights to, such Ipsen Registered IP and recording ownership by the Seller of such Ipsen Registered IP.

(c) Seller has no knowledge that, and has not received any written or other offer of, a license or any charge, complaint, claim, demand or notice, in any such case challenging the ownership, use, enforceability, registrability or validity of any of the Transferred Intellectual Property or alleging or implying that the operation of the Business or the development, manufacture, commercialization and other exploitation of the Increlex Product or the use or practice of any Transferred Intellectual Property infringes, misappropriates or violates the Intellectual Property of any third party. Seller has no knowledge of actual or potential infringement, misappropriation or other violation of any Transferred Intellectual Property.

(d) **Seller Disclosure Schedule 3.7(d)** lists all licenses of, options to or covenants not to sue or assert with respect to, any Transferred Intellectual Property by the Seller to any third party or any other instruments to which the Seller is a party, pursuant to which any third party has obtained any rights, title or interests in or to any Transferred Intellectual Property. None of Seller or, to the knowledge of Seller, any other party is in breach, violation or default of, or has repudiated, any provision of any such agreement.

3.8 Litigation.

Except as set forth in **Seller Disclosure Schedule 3.8**, there is no action pending or, to the knowledge of Ipsen, threatened, against or relating to Ipsen or any of its Affiliates in connection with the Transferred Assets (including the Inventory) or the Business. None of the Transferred Assets (including the Inventory) or the Business is subject to any Governmental Order.

During the [information redacted] period prior to the Closing Date, neither Seller nor its Affiliates have received any written notice of an investigation, claim, suit, proceeding, hearing, enforcement action, audit, or arbitration by a Governmental Authority in the Territory that relate to: (a) the development, manufacture, commercialization and other exploitation of the Increlex Products, (b) any of the Transferred Assets (including the Inventory) or (c) the Business.

During the [information redacted] period prior to the Closing Date, neither Seller nor its Affiliates have received any written injunction from any Governmental Authority, or any written request from any other person, in the Territory, to recall any Increlex Product or to inform their customers of a defect or any danger caused by a defect in the Increlex Product or linked to its use.

3.9 Labor Matters.

There are no claims or potential claims relating to the employment of employees by Ipsen or any of its Affiliates, Related to the Business or in connection with the Agreement, and to the knowledge of Ipsen, no potential claims are pending against Ipsen or any of its Affiliates.

3.10 Marketing Approvals.

(a) **Schedule 2.1(a)(vii)** sets forth a list of all Governmental Authorizations (including MAAs) issued to Seller, its Affiliates and/or Third Party designated by Seller, relating to the development, manufacture, commercialization and other exploitation of the Increlex Product or the Business in the Territory. Each of the Governmental Authorizations listed on **Schedule 2.1(a)(vii)** has been validly issued by the appropriate Governmental Authority and is in full force and effect, and Seller, its Affiliate or Third Party designated by Seller specified therein is the sole and exclusive registered owner of the Governmental Authorization set forth opposite its name. No suspension, cancellation or modification is pending or, to the knowledge of Seller, threatened, with respect to any Governmental Authorization.

(b) During the [information redacted] period prior to the Closing Date, (i) Seller, its Affiliates or Third Party designated by Seller have fulfilled and performed all material obligations with respect to each Governmental Authorization and neither the Seller, its Affiliates or Third Party designated by Seller is in breach or violation of, or default under, any such Governmental Authorization, and no event has occurred that would or would reasonably be likely to cause the revocation, termination or material impairment of the rights of the holder of any Governmental Authorization and (ii) neither Seller nor any of its Affiliates has received any notice from any Governmental Authority that it has commenced or has threatened to commence any action to terminate, limit, modify or suspend the development, manufacture, commercialization and other exploitation of any Increlex Product.

3.11 Suppliers and Customers.

Seller Disclosure Schedule 3.11 sets forth a list of all suppliers or vendors ("**Business Suppliers**") and customers ("**Business Customers**") of the Business [information redacted]. No Business Supplier or Business Customer has canceled, reduced, terminated or, to the knowledge of Seller, threatened to cancel, reduce, terminate or otherwise materially and adversely modify its relationship with Seller or its Affiliates [information redacted], including by reducing the quantities ordered, the services provided, the price paid or otherwise by adversely modifying the conditions to the contract with Seller. The terms of the Seller's contract with each Business Supplier provides that such Business Supplier will, and except for those matters disclosed on **Seller Disclosure Schedule 3.8** the Seller is not aware of any fact or circumstance that could adversely affect a Business Supplier's ability to, deliver goods or services to Purchaser in sufficient quantities to continue the Business as presently conducted and as proposed to be conducted. Seller has not experienced, and there does not currently exist, any material quality control or similar problems with the supplies with respect to the Business by any of the Business Suppliers.

3.12 Compliance with Regulatory Laws and Health Care Laws.

Except for those matters disclosed on **Seller Disclosure Schedule 3.12**, the Increlex Product and the Transferred Assets are being, [information redacted], have been, developed, manufactured, commercialized and otherwise exploited in compliance with all Governmental Authorizations and Regulatory Laws, including relating to Current Good Manufacturing Practices, Good Laboratory Practices, Good Clinical Practices, establishment registration, product listing and labeling, promotional practices, advertising, record keeping, and filing of reports, and all Health Care Laws. None of Seller, its Affiliates, or to Seller's knowledge, none of the Third Party manufacturer of the Increlex Product engaged by Seller or its Affiliates, has received any written notices, complaints, or communications from any Governmental Authority or Third Party that alleges or suggests the Increlex Product, the Transferred Assets or the Business is not in compliance with applicable Regulatory Laws or Health Care Laws and, to the knowledge of the Seller, there are no facts or circumstances that would be reasonably likely to result in such action. Neither the Seller nor its Affiliates: (i) acts as a "Covered Entity" or "Business Associate" as those terms are defined under HIPAA or (ii) receives access to or otherwise accesses protected health information (as defined under HIPAA) or other patient identifying information.

3.13 Compliance with Laws.

(a) Seller or its Affiliates and/or Third Party designated by Seller hold all Governmental Authorizations necessary to hold the Transferred Assets (including the Inventory) and to operate the Business as currently operated. The Business has been operated in compliance with all applicable laws and regulations in all material respects.

(b) Neither Seller nor any of its Affiliates that owns any of the Transferred Assets (including the Inventory) has received any written notice that Seller or any such Affiliate is not in compliance with any law with respect to the Business or the Transferred Assets (including the Inventory).

(c) All sales made and orders taken prior to the Closing Date have been accepted by Seller (or any of its Affiliates) in the ordinary course of business in a manner that is consistent with past practice, and no action or measure has been taken with a view to materially increasing the volume of sales (including, the delay of acceptance of orders of the Increlex Product from, or shipment of the Increlex Product to, third party customers).

3.14 Taxes. All Taxes required by applicable law have been properly paid to the appropriate Tax Authority, and the Seller has complied in all material respects with all information reporting and backup withholding requirements with respect to the Transferred Assets or the Business. The Seller is not a party to or bound by any Tax indemnity, Tax sharing, Tax allocation or similar agreement with respect to the Transferred Assets or the Business other than commercial agreements entered into in the ordinary course of business and the principal purpose of which is not indemnification for Taxes.

3.15 Remaining Inventory Transfer. As of the Remaining Inventory Transfer Date:

3.15.1 The Remaining Inventory is in good working order, has passed (or is reasonably expected to pass) Ipsen's (or its Affiliate's) quality control procedures, and has no more than reasonable wear and tear. The Remaining Inventory at the Remaining Inventory Transfer Date shall be commercially saleable and have a minimum shelf life as follows of at least:

(1) for the Increlex Product in final packaged form labelled with [information redacted], for distribution to end users, [information redacted] will have a minimum shelf life of [information redacted] and the rest will have a minimum shelf life of [information redacted]; and

(2) [information redacted] for the Increlex Product in bulk naked vial form.

3.15.2 The Remaining Inventory is in good and saleable condition and usable in the ordinary course of business for its intended purposes and have been manufactured and stored in compliance with cGMP and with the specifications of the Increlex Product and Business as defined in the relevant MAAs and Governmental Authorizations (including without limitation all specifications set forth in the applicable dossier for the Increlex Product).

3.16 No Other Representations or Warranties.

Except for the representations and warranties contained in this **Section 3** (Representations & Warranties of Ipsen), and as otherwise provided under the Transitional Services Agreement, neither Ipsen nor any of its Affiliates makes any express or implied representation or warranty on behalf of Ipsen.

4. REPRESENTATION & WARRANTIES OF PURCHASER

Purchaser hereby represents and warrants to Seller as of the Signing Date and the Closing Date, as set forth below:

4.1 Organization and Qualification.

Purchaser is duly incorporated or organized, as applicable, validly existing and to the extent such concept is recognized in a given jurisdiction, in good standing under the laws of the jurisdiction of its incorporation or organization. Purchaser has all requisite corporate power and authority to own and operate its properties and assets and to carry on its business as currently conducted. Purchaser is duly qualified to do business and is in good standing in each jurisdiction where the ownership or operation of its properties and assets or the conduct of its business requires such qualification.

4.2 Corporate Authorization.

Purchaser has all requisite corporate power and authority and has taken all corporate action necessary in order to execute, deliver and perform its obligations under this Agreement and each Ancillary Agreement to which it is a party and to consummate the Transactions. No vote of the holders of securities of Purchaser is required for Purchaser to enter into or consummate the Transaction. This Agreement is, and when executed and delivered by Purchaser each Ancillary Agreement to which Purchaser is a party will be, a valid and binding agreement of Purchaser enforceable against Purchaser in accordance with its terms.

4.3 Consents and Approvals.

No Governmental Approvals, notices, reports, other filings or other Third Party consents are required to be made by Purchaser or any of its Affiliates with any government entity or Third Party, nor are any government consents required to be obtained by Purchaser or any of its Affiliates in connection with the execution and delivery of this Agreement or any Ancillary Agreement to which Purchaser is a party and the consummation by Purchaser of the Transactions, except for the Purchaser FDA Letters and the required Austrian Foreign Investment Clearance as set forth in Section 5.15.

4.4 Non-Contravention.

The execution, delivery and performance of this Agreement and each Ancillary Agreement to which Purchaser is a party do not, and the consummation by Purchaser of the Transactions will not, constitute or result in: (a) a breach or violation of, or a default under, the certificate of incorporation, by-laws or comparable organizational documents of Purchaser, (b) a conflict with, breach or violation of, or a default under, any obligation to which Purchaser is subject to prevent, materially impair or materially delay the ability of Purchaser to consummate the Transactions or (c) with respect to any party, the acceleration or creation of any right to accelerate, terminate, modify, cancel or require any notice, or any right of first offer or refusal, consent or waiver or (d) result in any Loss of any right or privilege under any contract to which Purchaser is a party or by which Purchaser is bound, or result in the creation or imposition of any encumbrance of any nature whatsoever upon Purchaser's assets, except which do not and would not reasonably be expected to materially and adversely affect Purchaser's ability to consummate the Transaction contemplated hereby.

4.5 Litigation.

There is no claim, complaint, suit, investigation or action pending or, to the knowledge of Purchaser, threatened against or relating to Purchaser, before any Governmental Authority or arbitral body against Purchaser, that would prevent, materially impair or materially delay the ability of Purchaser to consummate the Transaction. Purchaser is not subject to any Governmental Order to prevent, materially impair or materially delay the ability of Purchaser to develop, manufacture, commercialize or otherwise exploit the Increlex Product following the Closing.

4.6 Availability of Funds.

(a) Purchaser has or will have sufficient cash or other sources of immediately available funds to enable it to effect the Closing (including the payment of the Upfront Payment, the Closing Inventory Payment and all other costs and expenses contemplated to be paid by Purchaser under this Agreement and the Ancillary Agreements to which it is a Party) and will have sufficient resources (including sufficient cash, available lines of credit or other sources of immediately available funds) to enable it to pay the Deferred Payments and the other amounts referred to in **Sections 2.2(d)** (Deferred Payment) as and when they become due.

(b) Purchaser has not and will not incur any obligation, commitment, restriction or liability of any kind that would impair or adversely affect such resources or its ability to effect the Closing. Purchaser acknowledges that its obligations hereunder are not in any respect subject to any equity or debt financing contingency.

4.7 Purchaser's Acknowledgments.

Purchaser is experienced and sophisticated with respect to transactions of the type contemplated by this Agreement and the Ancillary Agreements to which it is a Party. In consultation with experienced counsel and advisors of its choice, Purchaser has conducted its own independent review and analysis of the Business, the Transferred Assets, the Assumed Liabilities and the rights and obligations it is acquiring and assuming under this Agreement and the Ancillary Agreements to which it is a party on the basis of the information and documents made available in the Data Room and of the correspondence with management uploaded in the USB stick. Purchaser acknowledges that it and its representatives have been permitted access to a list of documents made available in the Data Room, and that it and its representatives have had an opportunity to meet with the officers and other employees of Seller to discuss the Business, the Transferred Assets and the Assumed Liabilities.

4.8 No Reliance.

Purchaser acknowledges that it is a sophisticated purchaser and together with its Affiliates and representatives, has made its own investigation, review and analysis regarding the Increlex Product, the Transferred Assets, the Assumed Liabilities and the Transaction. Purchaser acknowledges that (a) none of Seller, its Affiliates or representatives is making, and Purchaser is not relying on, any statement, representation or warranty, oral or written, express or implied, regarding the Increlex Product, the Transferred Assets or the Assumed Liabilities, except for those representations and warranties expressly set forth in **Section 3** or in any Ancillary Agreement and (b) without limiting the generality of the foregoing, none of Seller or any of its Affiliates or representatives shall have any liability to Purchaser or any of its Affiliates or representatives pursuant to this Agreement in connection with the use of, any information, documents or materials made available to Purchaser or its Affiliates or representatives, whether orally or in writing, in any confidential information memoranda, virtual data rooms, presentations, projections, due diligence discussions, or in any other form in expectation of the Transaction, except in each case (x) to the extent any such information, documents or materials are the subject of any representation or warranty expressly set forth in **Section 3** or in any Ancillary Agreement or (y) in the event of fraud or intentional misrepresentation by the Seller or any of its Affiliates or representatives.

4.9 No Other Representations or Warranties.

Except for the representations and warranties contained in this **Section 4** (Representations & Warranties of Purchaser), and as otherwise provided under the Transitional Services Agreement, neither Purchaser nor any of its Affiliates or representatives makes any express or implied representation or warranty on behalf of Purchaser.

5. COVENANTS AND OTHER AGREEMENTS

5.1 **Pre-Closing Access and Information**.

Prior to the Closing, subject to reasonable rules and regulations of Seller and any applicable laws, Seller shall keep Purchaser informed of all material developments relevant to the Increlex Product and its ability to consummate the Transaction contemplated hereby. Subject to compliance with applicable laws and any established legal privilege, Seller shall between the Signing Date and Closing Date give Purchaser and its authorized representatives (including independent public accountants and attorneys) reasonable access, during regular business hours and upon reasonable advance notice to Ipsen, to the Business Information, books, records, technical information and personnel to the extent Related to the Business, as reasonably required by Purchaser and available to Ipsen solely for purposes of furthering the Transaction or integration planning related thereto. All requests for information made pursuant to this Section 5.1 shall be directed to Lori Badura, Vice President, Global Partnering, Neuro & Rare Disease (lori.badura@ipsen.com) and Marine Beurdeley Senior Director, Global Partnering, Neuro & Rare Disease (marine.beurdeley@ipsen.com) in writing by Purchaser. All information made available pursuant to this Section shall be governed by the terms of the Confidentiality Agreement. Notwithstanding the foregoing, nothing contained in this Agreement shall give Purchaser, directly or indirectly, the right to direct Seller's or any of its Seller Affiliates' operations prior to the Closing Date. In addition, subject to any applicable antitrust laws, promptly following the Signing Date, Seller and Purchaser shall mutually agree on a communication plan to notify employees, suppliers, MA holders, collaboration partners and distributors, in each case, Related to the Business and/or related to the Transaction, of the Transactions contemplated hereunder, before the Closing Date, and Purchaser agrees that, during the period between the Signing Date and the Closing Date, it is not authorized to, and shall not, and shall not permit any of its Affiliates or representatives to contact any employee, supplier, collaboration partner, distributor of the Increlex Product or Related to the Business except in accordance with such communication plan.

5.2 **Reasonable Efforts**.

(a) Promptly after the Closing [information redacted]: (i) Seller shall file, or cause to be filed, with the FDA the Seller FDA Letters and provide a copy of the as-filed Seller FDA Letters to Purchaser and (ii) Purchaser shall file, or cause to be filed, with the FDA the Purchaser FDA Letters and provide a copy of the as-filed Purchaser FDA Letters to Seller. Seller and its Affiliates shall assist the Purchaser to the extent necessary by furnishing all necessary documents to implement the transfer, free of any charge (except as provided in the Transitional Services Agreement).

(b) Seller and Purchaser shall make all filings and submissions required by law to coordinate the transfer of all MAAs and Governmental Authorizations on a country-by-country basis for the countries listed in **Schedule 2.1(a)(vii)**, and cooperate in connection with any investigation of, and respond to, any requests from the relevant Regulatory Authority Related to the Business to effect the Transaction contemplated hereby and promptly file any additional information requested as soon as practicable after receipt of such request. Each of the Parties shall, and will cause its Affiliates to, cooperate and use its Commercially Reasonable Efforts to secure transfer of each of the Governmental Authorizations and MAAs. Purchaser shall take, and ensure that its Affiliates and any designated Third Party takes, all actions as are required to be taken by a transferee of MAAs and Governmental Approvals, such as the registration of a pharmaceutical establishment in the relevant countries of the European Union with the relevant VAT and Economic Operators Registration and Identification ("**EORI**") numbers in a country of the European Union, and with the appointment of qualified persons to have all MAA and Governmental Approvals transferred to Purchaser or its designee timely after the Closing Date, but no later than [information redacted].

(c) After the Closing Date, on a country-by-country basis for each country in the Territory, pending the transfer of the Governmental Authorizations and MAAs in such country, Seller or its relevant Affiliates will:

(i) continue to distribute or sell, until the Handover Date, the currently marketed Increlex Product in such country where the Increlex Product was commercialized prior to the Closing Date, in the same manner as it was conducted by Ipsen and/or its Affiliates [information redacted] prior to Closing Date pursuant to, and in accordance with, the Transitional Services Agreement;

(ii) hold, until the Handover Date, each Governmental Authorization and MAA in such country for the account, risk and benefit of the Purchaser and act in accordance with past practice and the instructions of the Purchaser in respect of each such Governmental Authorization and MAA;

(iii) maintain in force, until the Handover Date, each Governmental Authorization and MAA in such country, and not voluntarily amend, cancel, withdraw or surrender any such Governmental Authorization or MAA unless (1) required to do so by applicable law or any Governmental Authority or (2) with the Purchaser's prior written consent;

(iv) if prior to the Handover Date, certain tender contracts that may have been entered into by Ipsen or its designated Affiliate with pharmaceutical public procurement agencies in specific countries of the Territory (e.g., Italy) cannot be terminated or transferred to Purchaser due to the specificity around the tendering system that may exist in such countries despite the Governmental Authorizations being transferred to Purchaser (such countries, "**Tender Contract Countries**"), the Parties agree that they will engage in good faith discussions to enter into an agreement pursuant to which Purchaser will designate Ipsen as its distributor for the importation and sale of the Increlex Product to such pharmaceutical public procurement agencies until such tender contracts are effectively transferred to Purchaser or until Purchaser enters into a tender contract with such agencies.

(d) As of the Closing Date, Purchaser has no intention to cease or discontinue the commercialization of the Increlex Product. Purchaser acknowledges the importance of supplying the Increlex Product in the countries where the MAA is granted in a manner sufficient to meet patients' demand, particularly given that there is no alternative treatment.

5.3 **Transferred Intellectual Property**.

Purchaser shall be responsible to prepare and, if permitted under the relevant laws and regulations, file or cause to be filed all assignment documents and complete all formalities that are required in order to record the transfer of the Transferred Intellectual Property, if so required. If required by applicable laws, Purchaser shall provide standard form assignment documents by country, at Purchaser's expense. The Purchaser shall pay or (as applicable) bear the cost of all expenses incurred after the Closing Date in connection thereto. Seller shall be responsible to obtain, at its own cost, the notarization, authentication, or legalization of the signatures of Seller's representatives on all assignment documents pursuant to this **Section 5.3** (Transferred Intellectual Property).

As long as Seller or any of its Affiliates or designees is registered as the owner of any Transferred Intellectual Property, Seller shall, at its own cost, reasonably assist (and procure that its Affiliates or designees reasonably assist) Purchaser in the registration of assignment of Transferred Intellectual Property with all competent Governmental Authorities. In particular, Seller shall promptly and in any event within [information redacted] after any written request by the Purchaser execute (and procure that its Affiliates or designees execute) such agreements, deeds, declarations, transfers, conveyances, standard form assignments and other documents, as may be reasonably required pursuant to applicable local law, to achieve the registration of assignment of all Transferred Intellectual Property.

In the event that any of the Transferred Intellectual Property comes up for renewal before the applications of the changes in ownership have been filed by Purchaser or is Affiliates, Seller shall carry out the necessary formalities to file the renewal of such Transferred Intellectual Property.

Notwithstanding any provision to the contrary herein, Ipsen and its Affiliates hereby grant and agree to grant to Purchaser an irrevocable, perpetual, worldwide, non-exclusive, royalty-free, fully paid license, sublicensable through multiple tiers, under all Patent Rights and Know-How necessary for, or used in, the manufacture, use, sale, or other exploitation of the Increlex Product, which license Purchaser may practice to manufacture, use, sell, and otherwise exploit the Increlex Product.

5.4 **Consents Pertaining to the Transferred Assets**.

Subject to **Section 5.2(c)(iv)**, from the Signing Date and [information redacted] after the Closing Date, Seller shall use all Commercially Reasonable Efforts (which shall not require it or any of its Affiliates to take any action that would be materially adverse to the business retained by Seller and/or its Affiliates) to obtain any consent of, or waiver by, any Third Parties or Governmental Authorities necessary for the transfer of the Transferred Assets (the "**Consents**"). Purchaser shall, and shall cause its Affiliates to, cooperate with Seller to obtain the Consents.

Notwithstanding the other provisions of this Agreement, if any Transferred Asset is necessary or useful to be retained by Seller or its Affiliates to facilitate the provision by Seller or its Affiliates of services under the Transitional Services Agreement, then, at Purchaser's election, the transfer of such Transferred Asset shall be delayed until such other date as may be agreed by Purchaser.

In each instance in which an attempted transfer or assignment of a Transferred Asset would be ineffective or would adversely affect the ability of Seller or (as the case may be) its Affiliate to convey on a pass-through basis the interest in the relevant Assigned Contract to Purchaser, Seller shall use, or shall cause the corresponding Affiliate to use, all Commercially Reasonable Efforts to assist Purchaser, [information redacted], in entering into any such alternative arrangement and agreement with the Third Party or with another third party as may be appropriate (including subcontracting, if permitted) in order to allow Purchaser to realize, receive and enjoy substantially similar rights and benefits as if Purchaser had been a party to such Assigned Contract in lieu of Seller or its Affiliates. With respect to the foregoing, Seller shall, or shall cause its Affiliates to, promptly pay to Purchaser, when received, all income, proceeds and other monies received by Seller or any of its subsidiaries with respect to any non-assignable Transferred Asset (except during the provision by Seller or its Affiliates of services under the Transitional Services Agreement). In such instance, as long as such assignment or alternative arrangement or agreement remains effective, Seller shall, at its cost, procure that it or its relevant Affiliates continue to perform all provisions of any Assigned Contract for which Consent has failed to be obtained at Purchaser's direction. Until the transfer of the relevant Transferred Asset is completed, all decisions relating to such Transferred Asset shall be made by Purchaser.

5.5 **Termination of Certain Agreements**.

Seller, or its relevant Affiliate, shall provide termination notices in form and substance reasonably acceptable to Purchaser in respect of the contracts listed on **Schedule 5.5** (the "**Terminating Contracts**") within the time-periods set forth in **Schedule 5.5**.

5.6 **Public Announcements**.

Subject to: (a) the provisions of **Section 5.9(a)** (Confidentiality) and (b) each Party's disclosure obligations imposed by law (including any obligations under any securities law before the *Autorité des marchés financiers*), during the period from the Signing Date until the Closing, Purchaser and Seller shall, and shall cause their respective Affiliates to, cooperate with the other Party in the development and distribution of all public information disclosures and announcements, including announcements and notices to Third Parties, relating to this Agreement and the Ancillary Agreements.

Promptly following the Closing, Seller shall provide written notice to each Business Customer in such form and substance as approved in writing in advance by the Purchaser, notifying such Business Customer of the sale of the Business to Purchaser. Such notice shall, among other things, direct the Business Customer to order Increlex Product from the Purchaser following the Handover Date and provide the contact information for the Purchaser. In countries of the Territory where Seller, its Affiliates or its designee continue to distribute or sell, until the Handover Date, the Increlex Product pursuant to the Transitional Services Agreement, the Parties shall cooperate with each other to establish a communication plan and agree on an appropriate schedule for the delivery of such notice.

5.7 **Pre-Closing Conduct of Business**.

Prior to the Closing, Seller shall, and shall cause its Affiliates to, conduct the Business in the ordinary course of business consistent with past practice, and shall not engage in any of the following actions, except as Purchaser shall otherwise consent in writing (which consent shall not be unreasonably delayed):

(a) transfer, sell, license or otherwise dispose of any Transferred Assets (including the Inventory), except for sales, leases, licenses or other dispositions of: (i) Inventory, (ii) obsolete assets and (iii) pursuant to contracts with Third Parties in effect as of the date of this Agreement, in each case of (i)-(iii), in the ordinary course of business in a manner consistent with past practices;

(b) incur any liens or encumbrances on any Transferred Assets (including the Inventory), other than with respect to the Business, in the ordinary course of business in a manner consistent with past practices;

(c) grant any license or sublicense of any rights under or with respect to any Transferred Intellectual Property;

(d) waive, release, assign, settle or compromise any claim, litigation or arbitration Related to the Business;

(e) voluntarily terminate or amend any Assigned Contract or any portion of a Shared Contract Related to the Business;

(f) enter into any new contract, agreement or commitment that would be an Assigned Contract; *provided* that, notwithstanding any provision to the contrary in this Agreement or the Ancillary Agreements:

(i) Seller or its Affiliates may after the date of this Agreement and with Purchaser's prior written consent, renew any contract, agreement or commitment pertaining to the Transferred Assets (including the Inventory) or the Business on terms that are consistent with their current terms, and

(ii) any such new or renewed agreements shall be deemed to be included on the Exhibits to this Agreement as an Assigned Contract;

(g) (i) apply any new terms and conditions of sale (including, discount or rebate policy or other commercial gesture) with a view to offering discounts or rebates higher than those disclosed in the Data Room or substantial changes to trade terms as disclosed in the Data Room or (ii) take any action or measure that materially increases the volume of account receivables (including the delay of acceptance of orders of the Increlex Product from, or shipment of the Increlex Product to, Third Party customers);

(h) (i) make any material change in the advertising, terms of sale, collection, or payment practices of the Business that are outside the ordinary course of business, (ii) enter into any material business practices, programs or long term allowances not previously used in the ordinary course of business, or (iii) engage in the practice of "channel stuffing" or any program, activity or other action (including any rebate, discount, chargeback or refund policy or practice), that would reasonably be expected to result, directly or indirectly, in purchases of the Increlex Product that are materially in excess of normal customer purchasing patterns;

(i) request the withdrawal of, or fail to renew or maintain, any Governmental Authorization or MAA in the Territory;

(j) incur any capital expenditures with respect to the Increlex Product; and

(k) agree, in writing or otherwise, to take any of the foregoing actions.

5.8 **Transaction Expenses**

Except as otherwise provided in this Agreement or the Ancillary Agreements, each of Seller and Purchaser shall bear its own costs and expenses (including brokerage fees, if any, legal fees and expenses) incurred in connection with this Transaction; *provided* that Purchaser shall be responsible for any costs, expenses and fees related to the transfer or assignment of any of the Transferred Intellectual Property or the assignment of any Assigned Contracts, if any.

5.9 **Confidentiality**

(a) The terms of the Confidentiality Agreement are incorporated into this Agreement by reference and shall continue in full force and effect until the Closing, at which time the Confidentiality Agreement shall terminate. If, for any reason, the Closing does not occur, the Confidentiality Agreement shall nonetheless continue in full force and effect in accordance with its terms.

(b) Purchaser acknowledges and agrees that any information made available to Purchaser by either Seller or any officer, director, employee, agent, representative, accountant or counsel thereof prior to the Closing shall be subject to the terms and conditions of the Confidentiality Agreement.

(c) The Parties acknowledge that the confidentiality obligations set forth herein shall not extend to information, knowledge and data that is publicly available or becomes publicly available through no act or omission of the Party owing a duty of confidentiality, or becomes available on a non-confidential basis from a source other than the Party owing a duty of confidentiality, so long as such source is not known by such Party to be bound by a confidentiality agreement with or other obligations of secrecy to the other Party.

5.10 **Certain Payments or Instruments Received from Third Parties**

To the extent that, after the Closing Date: (a) Purchaser or any of its Affiliates receives any payment or instrument that is for the account of Seller according to the terms of this Agreement or any Ancillary Agreement or relates to any business or business segment of Ipsen other than the Business, Purchaser shall, at Seller's cost, promptly deliver such amount or instrument to the extent related to such other business or business segment to Seller or (b) Seller or any of their respective Affiliates receives any payment that is for the account of Purchaser according to the terms of this Agreement or any Ancillary Agreement or relates to the Business, Seller shall promptly deliver such amount or instrument to the extent Related to the Business to Purchaser. All amounts due and payable under this **Section 5.10** (Certain Payments or Instruments Received from Third Parties) shall be due and payable by the applicable Party by wire transfer of immediately available funds to the account designated in writing by the relevant Party. Notwithstanding the foregoing, each Party hereby undertakes to use its Commercially Reasonable Efforts to direct or forward all bills, invoices or like instruments to the appropriate Party.

5.11 **Insurance Matters**

Purchaser acknowledges and agrees that coverage of the Transferred Assets and Assumed Liabilities under Seller Insurance Policies shall cease as of the Closing Date and the Transferred Assets and the Assumed Liabilities will be deleted in all respects as insureds (or additional insureds, as the case may be) under all Seller Insurance Policies.

5.12 **Notification of any Bankruptcy Proceedings.**

From the Signing Date until the Closing, each of Seller and Purchaser shall immediately notify the other party regarding the institution of any proceeding by or against it under any bankruptcy, insolvency, assignment or arrangement for the benefit of creditors or similar law.

5.13 **Maintenance of Books and Records**

After the Closing, Purchaser shall preserve or cause to be preserved, [information redacted], all pre-Closing Date records to the extent Related to the Business, possessed or to be possessed by Purchaser or its Affiliates as of the Closing. After the Closing Date and up until [information redacted], upon any reasonable request from Seller or its representatives for the filing of Tax Returns or the satisfaction of contractual or legal obligations to Third Parties (such as litigation, securities law disclosures), Purchaser shall provide to Seller or its respective representatives reasonable access to such records during normal business hours, and permit Seller or its representatives to make copies of such records solely to the extent required for the foregoing purposes, at Seller's cost and expense.

5.14 **Delivery of Information**

Seller shall on the Closing Date deliver to Purchaser to a destination designated by Purchaser, all Business Information required for Purchaser to conduct the Business in substantially the same manner as conducted by Seller [information redacted] prior to the Closing. Seller and its Affiliate shall also provide to Purchaser copies of, and hereby grant Purchaser and its Affiliates a non-exclusive, royalty-free, fully paid-up license to use, any Excluded Information to the extent necessary or useful to develop, manufacture, commercialize or otherwise exploit the Increlex Product in the Territory.

5.15 **Austrian Foreign Investment Clearance**

(a) Purchaser:

(i) acknowledges the importance for Seller that the Austrian Foreign Investment Clearance be obtained as soon as possible and represents and warrants to the Seller that, in respect of the Austrian Foreign Investment Clearance, it is not aware of any reason that may prevent or substantially delay the consummation of the Transaction; and

(ii) shall use Commercially Reasonable Efforts to obtain the Austrian Foreign Investment Clearance promptly after the Signing Date.

(b) The Parties shall (and shall cause their respective Affiliates to):

(i) as soon as reasonably possible after the Signing Date, at Purchaser's cost and expense, make all necessary filings with any competent Governmental Authority for the Austrian Foreign Investment Clearance in order to obtain the Austrian Foreign Investment Clearance, and confirm to the other Party in writing promptly after having made such filing;

(ii) use Commercially Reasonable Efforts to obtain, and not take any actions (including entering into any transaction, agreement or other arrangement) that might reasonably be expected to make it more difficult to or result in any material delay in obtaining, the Austrian Foreign Investment Clearance;

(iii) not withdraw any filings made in respect of the Austrian Foreign Investment Clearance without notifying the other Party;

(iv) keep the other Party regularly informed of the process of the Austrian Foreign Investment Clearance and in particular, promptly inform the other Party if it becomes aware of anything that could result in the Austrian Foreign Investment Clearances being delayed or denied; and

(v) give notice to the other Party of the receipt of any Austrian Foreign Investment Clearance within two (2) Business Days of becoming aware of the same (including a copy of the Austrian Foreign Investment Clearance).

(c) In the event the Austrian Foreign Investment Clearance is denied or is not granted by the competent Governmental Authority prior to the Long-Stop Date or at a date when all the conditions to Closings set forth in **Section 7** (other than the Austrian Foreign Investment Clearance) have been satisfied or waived by each of Purchaser and Seller, the Parties agree that the transfer of rights under this Agreement related to Austria shall be postponed and the Closing shall occur (subject to the satisfaction or waiver by each of Purchaser and Seller, at or prior to the Closing, of all the conditions to Closings set forth in **Section 7** (Conditions to Closing)) with no reduction of the Upfront Payment, Closing Inventory Payment or Deferred Payment. Subsequently, the Parties shall use Commercially Reasonable Efforts to obtain the Austrian Foreign Investment Clearance in order to have the rights related to Austria transferred to Purchaser prior to the Extended Long-Stop Date, and the Parties shall promptly execute any necessary documentation (including such as to enable Purchaser to file a new Austrian Foreign Investment Clearance, if so required) and perform any acts to effectuate such transfer, at no additional payment to be owed or due by Purchaser to Seller. Purchaser and Seller each agree that it shall (and shall cause its Affiliates to): (i) refrain from taking any actions (including entering into any transaction, agreement or other arrangement) that would be reasonably expected to make it more difficult to obtain the Austrian Foreign Investment Clearance or result in any material delay in obtaining such clearance, (ii) use Commercially Reasonable Efforts to avoid any suspension of the time periods of the Austrian Foreign Investment Clearance, (iii) not withdraw any filings made in respect of Austrian Foreign Investment Clearance without the prior written consent of the other Party and (iv) take reasonable actions required under applicable laws to obtain the required Austrian Foreign Investment Clearance prior to the Closing. In the meantime, the portion of the Transitional Services Agreement related to Austria shall be performed by the Parties in all respects, and the Parties will, if need be, enter into any agreement that may be required for Purchaser to supply Seller with the Increlex Product to be sold within Austria and for Seller to provide the required distribution and medical information services, with the understanding that: (i) the net consideration due to Seller for all such services will amount to the Commission as defined in the Transitional Services Agreement and (ii) Seller shall transfer monthly to Purchaser the amount of Net Sales made in Austria, *less* the amount of the supply price that Seller would have paid to Purchaser for the purchase of the Increlex Product to be distributed by Seller in Austria which amount of the supply price of the Increlex Product shall be at the amount set forth in **Schedule 1.1.29**, in such given calendar month.

5.16 **Rebates, Chargebacks, and Price Reporting Cooperation**

The Parties shall cooperate on rebates, chargebacks and price reporting matters, in accordance with **Schedule 5.16**.

5.17 **Other Payments**

(a) Genentech Payment Obligation. Subject to the truth and accuracy of the representation and warranty set forth in **Section 3.6(c)**, Purchaser will be solely and exclusively responsible for, and make payment (at no additional cost to Ipsen) of, all payments including Intellectual Property prosecution and enforcement payments, that are required to be paid under the Increlex License Agreements, in respect of the period commencing on the Closing Date.

(b) Currency. All payments to be made by, or on behalf of, Purchaser under this Agreement shall be made in US Dollars (USD), except with respect to the Remaining Inventory Value, which payment shall be made in Euros (€).

(c) FDA Program Fee. Promptly following the Closing [information redacted], Purchaser shall notify the FDA and make all necessary filings with the FDA to seek, and shall use Commercially Reasonable Efforts to secure, an exemption and refund of the Prescription Drug User Program Fee ("**Program Fee**") set forth in **Schedule 5.17** for which payment was made by Seller or its Affiliates prior to the Signing Date. Purchaser shall keep Seller informed of the process by providing a copy of all material filings made with the FDA in connection thereto. In the event that Purchaser obtains the exemption and refund, Purchaser shall promptly, [information redacted], remit the refund of the Program Fee to Seller.

5.18 **Non-Compete Undertakings**

(a) For a period commencing on the Closing Date and ending on the second (2nd) anniversary date of the Closing Date, except as provided for in this Agreement or in an Ancillary Agreement, Seller shall, or shall cause its relevant Affiliates not to, directly or indirectly, in the countries of the Territory, engage in any development and commercialization activities of products: (i) for the treatment of, or approved or marketed in the indication of, growth failure in children with severe primary IGF-1 deficiency or for the treatment of patients with growth hormone deficiency who developed neutralizing GH antibodies (collectively "**Competing Indications**") or (ii) that have mecasermin hormone IGF-1 as an active ingredient (each of (i) and (ii), "**Competing Product**"). For clarity, Seller and/or its Affiliates shall have the right to conduct manufacturing activities of Competing Products or in Competing Indications.

(b) The undertaking set forth in the **sub-paragraph (a)** above shall not be deemed to prohibit or restrict any of Seller or its Affiliates from acquiring, holding or otherwise investing in a controlling ownership interest in any Third Party entity that conducts commercial activities in Competing Indications or in Competing Product.

(c) Seller acknowledges that the consideration for the undertakings contained in this **Section 5.18** (Non-Compete Undertakings) is included in the Upfront Payment.

5.19 **Transitional Services Agreement and Transfer of Remaining Inventory**

(a) The Purchaser acknowledges that in countries of the Territory where the MAA and associated Governmental Approvals Related to the Business have not yet been transferred to Purchaser as of the Closing Date, the distribution and sale of the Increlex Product as operated by Seller, its Seller Affiliates or their designated Third Party prior to the Closing Date, will continue to be conducted by Seller, its Affiliates and/or their Third Party designee during a certain transition period after the Closing Date ("**Transition Phase**"). The legal ownership of, and title to, the Remaining Inventory shall remain with Seller or its Seller Affiliates and shall be transferred to Purchaser on the Remaining Inventory Transfer Date, together with the transfer of the manufacturing and supply agreements listed at **Schedule 1.1.4(A)(ii)**.

(b) The distribution and sale of the Increlex Product by Seller, its Affiliates and/or their Third Party designee during the Transition Phase will be governed by the Transitional Services Agreement.

(c) On the Remaining Inventory Transfer Date, Seller shall, and shall cause its Affiliates to, sell, convey, transfer, assign and deliver to Purchaser, and Purchaser shall purchase and assume from Seller and its Affiliates, all of Seller's and its Affiliates' right, title and interest, in and to all of the Owned Inventory of Seller and its Affiliates, comprising the finished goods of Increlex Product labeled under the Ipsen Brands and the bulk naked vials of the Increlex Product, existing as of the Remaining Inventory Transfer Date ("**Remaining Inventory**"), free and clear of all Liens (other than Assumed Liabilities and liens created by or through Purchaser or any of its Affiliates).

(d) Within [information redacted] after the Remaining Inventory Transfer Date, Seller shall, or shall cause to be prepared and delivered to Purchaser, a statement (the "**Remaining Inventory Statement**") setting forth in reasonable detail an itemized list of all Remaining Inventory in each country of the Territory, by category of Inventory and the corresponding Inventory Value at a price per vial set forth in **Schedule 1.1.29** (the "**Remaining Inventory Value**"), which will serve as a calculation for the Remaining Inventory Value Payment of **Section 2.2(c).** If either Party conducts a physical inspection of the Inventory for the purpose of preparing the Remaining Inventory Statement, such Party shall allow the other Party to have a representative present for such physical inspection.

(e) Upon Seller's request, Seller (or its Seller Affiliates) and Purchaser (or its designated Affiliate) shall execute the necessary agreements to implement and perfect the transfer of the legal ownership of the Increlex Product from Seller (or its Seller Affiliates) to Purchaser (or its designated Affiliate) as of the Handover Date. Such agreements shall include any required transfer, conveyances, notarial deeds and other documents required under applicable local laws ("**Local Asset Sale Agreement**"). The Local Asset Sale Agreement shall be negotiated and entered into between the Parties in good faith. Purchaser shall not incur any additional purchase price at the Handover Date (apart from the Remaining Inventory Value Payment, and Commissions and any other costs and expenses to the extent any are payable to Seller or its Affiliates under the Transitional Services Agreement). In the event that under applicable local laws, a portion of the Purchase Price must be allocated to the relevant country under the Local Asset Sale Agreement, the Parties shall agree on the allocation price within the Local Asset Sale Agreement. If such allocated price is required to be paid at the time of the transfer of the legal ownership of the Increlex Product, the Parties agree that such portion of the Purchase Price shall be restituted by Seller to Purchaser followed by an immediate payment by Purchaser following such restitution of such relevant portion of the Purchase Price by the relevant Seller Affiliate.

5.20 **Use of Ipsen Brands**

It is expressly agreed that Purchaser is not purchasing, acquiring or otherwise obtaining any right, title or interest in the name "Ipsen" or any trademarks, trade names, corporate names, service marks, internet domain name, identifying logos or other indication containing the words "Ipsen," whether used alone or in combination with other words ("**Ipsen Brands**"), except as otherwise expressly set forth herein. Purchaser agrees that, upon and following the Closing Date, it shall use Commercially Reasonable Efforts to cease using any Ipsen Brands in connection with the Increlex Product and the Transferred Assets as soon as reasonably practicable [information redacted]. Notwithstanding the foregoing, Seller, on behalf of itself and its Affiliates, hereby grants Purchaser and its Affiliates, from the Closing Date, a worldwide royalty free sublicensable license to use the Ipsen Brands consistent with the manner they were used [information redacted] prior to the Closing Date by Seller and Seller Affiliates solely for the sole purpose of exhausting the Inventory of the Increlex Product bearing the Ipsen Brands, provided such use of the Ipsen Brands is permitted under local regulatory requirements and applicable laws.

5.21 **Ongoing Patient Registry**

Promptly following the Closing Date, Seller shall, and shall cause its relevant Affiliates to: (a) transfer (or cause to be transferred) the Increlex Global Registry which is being conducted by or on behalf of Seller or its Affiliates to Purchaser or its Affiliates, and (b) provide or cause to be provided, all requisite notices to any Third Parties, including Governmental Authorities participating in or exercising oversight over such Increlex Global Registry, in each case subject to any ethical considerations with respect to patients in any such study in effect as of the Signing Date. To the extent required by applicable law, Seller shall prepare and submit to the applicable Regulatory Authorities a study report that complies with all applicable requirements of the FDA, the EMA and applicable ICH guidelines and provide a copy of each such study report to Purchaser reasonably prior to the submission thereof to the applicable Regulatory Authorities.

5.22 **Data Processing**

The Parties agree to comply with all applicable data protection laws and regulations as amended from time to time, in particular the EU Regulation 2016/679 on the protection of natural persons about the processing of personal data and on the free movement of such data (the "**GDPR**"). The Parties' respective obligations are set out in the Data Processing Addendum attached hereto as **Schedule 5.22**, which the Parties acknowledge forms an integral part of the Agreement.

6. TAX MATTERS

6.1 **Transfer Taxes.**

All Transfer Taxes shall be borne by Purchaser. Purchaser and Seller shall cooperate to timely prepare and file any Tax Returns relating to such Transfer Taxes, including any claim for exemption or exclusion from the imposition of any Transfer Taxes. With respect to any such Transfer Tax, Tax Returns required to be filed by Seller or any of its Affiliates, Purchaser shall pay to Seller, [information redacted] before the due date for payment of such Transfer Taxes, [information redacted] of the amount of Transfer Taxes.

6.2 **Tax Cooperation.**

Subject to Section 5.13, Purchaser and Seller agree to furnish or cause their respective Affiliates to furnish, to each other, upon request, as promptly as practicable, such information and assistance relating to the Transferred Assets or the Business as is reasonably necessary for the filing of all Tax Returns and other Tax filings, the preparation for any audit by any Tax Authority and the defense of any claim or proceeding relating to Taxes of the Transferred Assets or the Business. No Party shall be required to deliver or otherwise provide cooperation, documentation or information with respect to Taxes that is not related to the Transferred Assets or the operation of the Business or that such Party considers in good faith to be proprietary, including any documentation or information relating to any consolidated, combined or unitary Tax Return of the Parties or any of their respective Affiliates, or any other Tax Return of the Parties or any of their respective Affiliates to the extent not related to the Transferred Assets or the Business.

6.3 **VAT and Other Similar Taxes**

All state, local or foreign or other excise, sales, use, value added, transfer, stamp, documentary, filing, recordation and other similar Taxes and fees that may be imposed or assessed as a result of the Transactions, together with any interest, additions or penalties with respect thereto and any interest in respect of such additions or penalties, shall be borne by the party determined by any applicable law.

6.4 **Withholding Taxes**

(a) Notwithstanding anything to the contrary contained herein, Purchaser and any other withholding agent shall be entitled to deduct or withhold, or cause to be deducted and withheld, any amounts required to be deducted and withheld under the Internal Revenue Code of 1986, as amended, or any other Tax law, from the Purchase Price or other amounts payable hereunder to Ipsen. To the extent that amounts are so withheld, such amounts will be treated for all purposes of this Agreement as having been paid to the Seller or such other Person in respect of whom such withholding was made.

(b) No later than [information redacted] prior to the Closing Date, Seller shall deliver to Purchaser a properly completed, validly executed, true and correct Internal Revenue Service Form W-9.

6.5 **Other Taxes**

Seller shall reimburse all Taxes paid by Purchaser after the Closing Date pertaining to any Excluded Asset or Excluded Liability.

7. CONDITIONS TO CLOSING

7.1 **Conditions to Each Party's Obligation**

The obligation of the Parties to effect the Closing is subject to the satisfaction or waiver by each of Purchaser and Seller, at or prior to the Closing, of the following condition:

(a) There shall not be in effect any law or Governmental Order permanently restraining, enjoining or otherwise prohibiting or preventing the consummation of the Transactions.

7.2 **Conditions to Ipsen's Obligation as Seller**

The obligation of Seller to effect the Closing is subject to the satisfaction (or waiver by Ipsen), at or prior to the Closing, of each of the following conditions:

(a) Representations and Warranties. The representations and warranties of Purchaser as Purchaser set forth in **Section 4** (Representations & Warranties of Purchaser) shall be true and correct as of the date of this Agreement and as of the Closing Date as though made on and as of such date and time (except to the extent that any such representation and warranty expressly speaks as of an earlier date, in which case such representation and warranty shall be true and correct as of such earlier date).

(b) Covenants. Each of the covenants and agreements of Purchaser contained in this Agreement that are to be performed at or prior to the Closing shall have been duly performed in all material respects.

(c) Transitional Services Agreement. Purchaser shall have executed and delivered the Transitional Services Agreement.

7.3 **Conditions to Eton's Obligation as Purchaser**

The obligation of Purchaser to effect the Closing is subject to the satisfaction (or waiver by Purchaser), at or prior to the Closing, of each of the following conditions:

(a) Representations and Warranties. The representations and warranties of Ipsen as Seller set forth in **Section 3** (Representations & Warranties of Ipsen) shall be true and correct as of the date of this Agreement and as of the Closing Date as though made on and as of such date and time (except to the extent that any such representation and warranty expressly speaks as of an earlier date, in which case such representation and warranty shall be true and correct as of such earlier date).

(b) Covenants. Each of the covenants and agreements of Seller contained in this Agreement that are to be performed at or prior to the Closing shall have been duly performed in all material respects.

(c) Third Party Consent. All consents or waivers from any Third Parties or Governmental Authorities that are required to validly assign or transfer the Transferred Assets listed on **Schedule 7.3(c)** hereto, each in form and substance pre-approved by the Purchaser (each, a "**Closing Consents**"), shall have been obtained.

(d) FDA Letter. Seller shall have delivered to Purchaser, letters from Seller to the FDA transferring to Purchaser the rights to the MAAs and Governmental Authorizations issued by the FDA in substantially the form attached hereto as **Schedule 7.3(d)(i)** ("**Seller FDA Letters**"); provided that Purchaser shall have delivered to Seller, letters from Purchaser to the FDA assuming responsibility for the MAAs and Governmental Authorizations issued by the FDA in substantially the form attached hereto as **Schedule 7.3(d)(ii)** ("**Purchaser FDA Letters**").

(e) Transitional Services Agreement. Seller shall have executed and delivered the Transitional Services Agreement.

8. TERMINATION

8.1 **Termination**

(A) This Agreement may be terminated at any time prior to the Closing Date:

(a) by written agreement of Seller and Purchaser;

(b) by Purchaser, by giving written notice to Seller, if the Closing does not take place on or prior to the Long-Stop Date;

(c) by Purchaser, by giving written notice to Seller, if any Governmental Authorization or MAA for the Increlex Product with the FDA, the EMA or the European Commission is revoked, suspended, limited or withdrawn;

(d) by Purchaser, if there has been a breach of any representation, warranty, covenant or agreement made by Ipsen in this Agreement, or any such representation and warranty shall have become untrue after the date of this Agreement, such that the conditions set forth in **Sections 7.3(a)** or **7.3(b)** (Conditions to Purchaser's Obligation as Purchaser) would not be satisfied and such breach or condition is not curable or, if curable, is not cured prior to the earlier of: (i) thirty (30) days after written notice thereof is given by Purchaser to Ipsen and (ii) one (1) Business Day prior to the Long-Stop Date; *provided, however,* that Purchaser is not then in material breach of its obligations under this Agreement; and

(e) by Ipsen, if there has been a breach of any representation, warranty, covenant or agreement made by Purchaser in this Agreement, or any such representation and warranty shall have become untrue after the date of this Agreement, such that the conditions set forth in **Sections 7.2(a)** or **7.2(b)** (Condition's to Ipsen's Obligation as Seller) would not be satisfied and such breach or condition is not curable or, if curable, is not cured prior to the earlier of: [information redacted] and [information redacted]; *provided, however*, that Ipsen is not then in breach of its obligations under this Agreement.

(B) Austria shall be withdrawn from this Agreement (such withdrawal not affecting the payment of the Purchase Price) if the Austrian Foreign Investment Clearance is denied by a competent Government Authority, or not obtained, prior to the Extended Long-Stop Date, unless such failure is due to a breach by the Party seeking to terminate the Agreement with respect to Austria, of any of the covenants, agreements or other undertakings set forth in this Agreement to be performed or observed by such Party.

8.2 **Effects of Termination**

If this Agreement is terminated pursuant to **Section 8.1** (Termination), all further obligations of the Parties under or pursuant to this Agreement shall terminate without further liability of any Party to the other except for the provisions of **Section 5.8** (Transaction Expenses), **Section 5.9** (Confidentiality), **Section 6** (Tax Matters), **Section 8** (Termination), and **Section 10** (Miscellaneous); *provided* that neither the termination of this Agreement nor anything in this **Section 8.2** (Effects of Termination) shall relieve any Party from liability for any fraud or intentional breach of this Agreement occurring before the termination hereof.

9. SURVIVAL; INDEMNIFICATION

9.1 **Survival of Representations and Warranties or Covenants**

9.1.1 Survival

(a) The representations or warranties in **Section 3** (Representations & Warranties of Ipsen) and **Section 4** (Representations & Warranties of Purchaser) of this Agreement shall survive for a period of sixteen (16) months after the Closing Date, except that: (i) claims in connection with Fundamental Warranties which shall survive the Closing for three (3) years, and (ii) claims in respect of breaches thereof pending on, or asserted prior to, the expiry date will continue to survive until such claims have been resolved.

(b) The covenants and agreements of Ipsen and Purchaser contained in this Agreement or any instrument delivered pursuant to this Agreement shall survive until satisfied in accordance with their terms.

Notwithstanding anything to the contrary contained in this Agreement, nothing shall limit any Party's ability to recover losses which result from or arise out of fraud or intentional breach of this Agreement by the other Party.

9.1.2 Limitations

(a) The indemnification obligations of Seller under **Section 9.1** (Survival of Representations and Warranties or Covenants) (other than on account of any fraud or the breach of any Fundamental Warranties) shall in no event exceed in the aggregate an amount equal to the Upfront Payment paid by Purchaser ("**Applicable Cap Amount**").

(b) Purchaser shall not be entitled to make a claim under **Section 9.1** (Survival of Representations and Warranties or Covenants) unless and until the aggregate amount of claims for damages of Purchaser under this Agreement exceeds an amount equal to one hundred seventy-five thousand US Dollars (US$175,000) ("**Basket Threshold**"), in which case Seller shall be obligated to indemnify Purchaser in the full amount; *provided* that the limitations in this clause (b) shall not apply with respect to fraud or breach of any Fundamental Warranties.

(c) No claim or series of related claims (based on the similar or identical triggering event) in respect of any individual event or occurrence, or in respect of events or occurrences arising out of substantially similar facts and circumstances, shall be taken into account for purposes of calculating the Basket Threshold referred to in **Section 9.1** (Survival of Representations and Warranties or Covenants) unless and until the damage claimed exceeds an amount equal to fifty thousand US Dollars (US$50,000), it being specified that if such amount is exceeded with respect to an individual claim or a series of related claims, the full amount of such damage with respect to such claim or series of related claims shall be taken into account for the purposes of determining whether the Basket Threshold has been reached; *provided* that the limitations in this clause (b) shall not apply with respect to fraud or breach of any Fundamental Warranties.

9.2 **Indemnification; Claim**

(a) Ipsen and its Affiliates shall indemnify Purchaser and its Affiliates, and its and their respective, officers, directors, employees, stockholders, agents and representatives against, and hold them harmless from and against, any Losses arising or resulting from any: (i) misrepresentation in, or breach of, any representations and warranties, covenants or agreements of Ipsen contained in this Agreement and (ii) any Liabilities to the extent arising out of or relating to: (A) the Transferred Assets prior to or on the Closing Date, whether or not such Liability arises or becomes known prior to, on or after the Closing Date or (B) any Excluded Asset or Excluded Liability.

(b) Purchaser and its Affiliates shall indemnify Ipsen and its Affiliates and its and their respective, officers, directors, employees, stockholders, agents and representatives against, and hold them harmless from and against, any losses arising or resulting from: (i) any misrepresentation in, or breach of, any representation and warranties, covenants or agreements of Purchaser contained in this Agreement or (ii) any Liabilities to the extent arising out of or relating to Assumed Liabilities to the extent arising after the Closing Date.

(c) The indemnified Party shall notify the indemnifying Party in writing (and in reasonable detail) of any claim, demand, or action (for purposes of this **Section 9.2** (Indemnification; Claim), a "**Claim**") asserted by a Third Party [information redacted]; *provided, however,* that failure to give such notification shall not affect the indemnification provided under this Agreement except to the extent the indemnifying Party shall have been actually and materially prejudiced as a result of such failure. Notwithstanding any provision herein to the contrary, with respect to any claim relating to breach of representations or warranties under **Section 3** (Representations & Warranties of Ipsen), such Claim must be made within the survival period set forth in **Section 9.1** (Survival of Representations and Warranties or Covenants), and if not made within such period, such claim shall be forever barred. If reasonably requested by the indemnifying Party, the indemnified Party shall deliver to the indemnifying Party, [information redacted], copies of all notices and documents (including court papers) received by the indemnified Party relating to a Third Party Claim.

(d) If a claim is made by a Third Party against an indemnified Party, the indemnifying Party shall be entitled to participate in the defense thereof as set forth in this **Section 9.2(d)** (Indemnification; Claim). The indemnifying Party shall have the right to elect (by written notice to the indemnified Party [information redacted]) to defend such Third Party Claim on behalf of the indemnified Party, at the indemnifying Party's sole cost and expense and with counsel reasonably satisfactory to the indemnified Party. The indemnifying Party shall not be entitled to assume control of a Third Party Claim and shall pay the reasonable fees and expenses of counsel retained by the indemnified Party if: (A) the Third Party claim relates to or arises in connection with any criminal proceeding, action, indictment or allegation or (B) the Third Party claim solely seeks injunctive or other equitable relief. If the indemnifying Party assumes such defense, then the indemnified Party shall have the right to participate in the defense thereof and to employ counsel, at its own expense, separate from the counsel employed by the indemnifying Party, it being understood that the indemnifying Party shall control such defense and the indemnified Party shall be given the opportunity to comment (which comments shall be taken into account to the extent reasonable) with respect to the conduct of the defense of such Third Party Claim. After the notice period, if the indemnifying Party has not assumed the defense of a particular claim or proceeding, the indemnifying Party shall be liable for the reasonable fees and expenses of counsel employed by the indemnified Party after the notice period and shall be bound by any determination made in a proceeding for which the indemnifying Party was not defending at the time of such determination, except where the indemnifying Party is not obligated to indemnify the indemnified Party under this Agreement in respect of such claim. If the indemnifying Party chooses to defend or prosecute a Third Party claim, then all indemnified Parties shall reasonably cooperate in the defense or prosecution thereof. Such cooperation shall include the retention and (upon the indemnifying Party's request) the provision, subject to a mutually agreeable confidentiality agreement, to the indemnifying Party of records and information that are reasonably relevant to such Third Party claim, and making employees and representatives reasonably available on a mutually convenient basis to provide additional information related to such Third Party Claim (except any confidential information covered by attorney-client privilege). The indemnified Party shall not admit any liability with respect to, or settle, compromise or discharge, such Third Party claim without the indemnifying Party's prior written consent (which consent shall not be unreasonably withheld or delayed) and the indemnifying Party shall not settle, compromise or discharge, such Third Party claim without the indemnified Party's prior written consent (which consent shall not be unreasonably withheld or delayed). The indemnified Party shall agree to any settlement, compromise or discharge of a Third Party claim that the indemnifying Party may recommend that by its terms: (i) obligates the indemnifying Party to pay the full amount of the Losses in connection with such Third Party claim, (ii) releases the indemnified Party completely in connection with such Third Party claim, (iii) does not impose any injunction or other equitable relief on the indemnified Party and (iv) does not require an admission of liability by the indemnified Party.

(e) In the event any indemnified Party should have a claim against any indemnifying Party under **Section 9.2** (Indemnification; Claim) that does not involve a Third Party claim being asserted against or sought to be collected from such indemnified Party, the indemnified Party shall deliver notice of such claim with reasonable promptness to the indemnifying Party, [information redacted]. The failure by any indemnified Party to so notify the indemnifying Party shall not relieve the indemnifying Party from any indemnification obligation that it may have to such indemnified Party under **Section 9.2** (Indemnification; Claim), except to the extent that the indemnifying Party is actually and materially prejudiced by such failure. If the indemnifying Party disputes that it has an indemnification obligation with respect to such claim, the indemnifying Party shall deliver notice of such dispute with reasonable promptness [information redacted] and the indemnifying Party and the indemnified Party shall proceed in good faith to negotiate a resolution of such dispute for a period of [information redacted]. If the indemnified Party and the indemnifying Party have not resolved such dispute during such time period through good faith negotiations, such dispute shall be resolved by litigation in an appropriate court of competent jurisdiction or other mutually agreeable non-judicial dispute resolution mechanism.

10. MISCELLANEOUS

10.1 Notices

All demands, notices, communications and reports provided for in this Agreement shall be in writing and shall be either sent by email transmission with confirmation to the email address specified below or sent by reputable overnight courier service (delivery charges prepaid) to any Party at the address specified below, or at such address, to the attention of such other Person, and with such other copy, as the recipient Party has specified by prior written notice to the sending Party pursuant to the provisions of this **Section 10.1** (Notices):

If to Seller, to:

Ipsen Biopharmaceuticals, Inc.
One Main Street
Cambridge, MA 02142, U.S.A
Attention: François Garnier, EVP General Counsel
Email: francois.garnier@ipsen.com

With a copy to:

Ipsen Pharma S.A.S.
65 Quai Georges Gorse
Boulogne-Billancourt 92100, France
Attention: Naomi Binoche, VP Head of Strategic Alliance Management
Email: naomi.binoche@ipsen.com

If to Purchaser, to:

Eton Pharmaceuticals, Inc.
21925 W. Field Parkway, Suite 235
Deer Park, Illinois 60010-7278
Attention: Sean Brynjelsen
Email: sbrynjelsen@etonpharma.com

With a copy, which shall not constitute notice, to:

Ropes & Gray LLP
Prudential Tower, 800 Boylston Street
Boston, MA 02199-3600
Attention: Hannah England
Email: Hannah.England@ropesgray.com

10.2 **Consent to Amendments; Waivers**

No Party shall be deemed to have waived any provision of this Agreement or any Ancillary Agreement unless such waiver is in writing, and then such waiver shall be limited to the circumstances set forth in such written waiver. This Agreement shall not be amended, altered or qualified except by an instrument in writing signed by all the Parties hereto or thereto, as the case may be.

10.3 **Successors and Assigns**

This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors, legal representatives and permitted assigns. No Party to this Agreement may assign any of its rights or delegate any of its obligations under this Agreement, by operation of law or otherwise, without the prior written consent of the other Party hereto, and any attempted or purported assignment in violation of this **Section 10.3** (Successors and Assigns) shall be null and void; *provided* that: (a) any obligation of any Party to another Party under this Agreement, which obligation is performed, satisfied or fulfilled completely by an Affiliate of such first Party, shall be deemed to have been performed, satisfied or fulfilled by such Party and (b) Purchaser may, without the consent of Ipsen, assign any of its rights, interests and obligations under this Agreement to one or more Affiliates of Purchaser, which assignment, in either case, will not relieve Purchaser of any obligations hereunder.

10.4 **No Third-Party Beneficiaries**

This Agreement is for the sole benefit of the Parties and their permitted assigns, and nothing herein, express or implied, is intended to, or shall confer upon, any other person any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

10.5 **Entire Agreement**

This Agreement, including all Schedule and Exhibits thereto contains the entire agreement between the Parties with respect to the subject-matter and supersedes all prior agreement and understandings, oral or written with respect to such matters.

10.6 **Specific Performance**

The Parties agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached, that monetary damages may be inadequate and that a Party may have no adequate remedy at law. The Parties accordingly agree that the Parties hereto will be entitled to seek an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement in accordance with this Agreement, this being in addition to any other remedy to which such Party is entitled at law.

10.7 **Governing Law; Jurisdiction**

(a) Any questions, claims, disputes, remedies or actions arising from or related to this Agreement, and any relief or remedies sought by any Parties, shall be governed exclusively by the laws of the State of New York, without regard to the principles of conflicts of laws that might otherwise be applicable.

(b) Any dispute arising out of, or in connection with the interpretation or execution of this Agreement shall be resolved under the exclusive jurisdiction of the ICC Rules of Arbitration, then in effect, by an arbitral tribunal composed of three (3) arbitrators appointed in accordance with said Rules. The place of arbitration shall be [information redacted] and the language of the arbitration shall be English.

10.8 **Severability**. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or its severance herefrom, and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties.

10.9 **Equitable Relief**. The Parties agree that irreparable damage may occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that a Party shall be entitled to an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement in any Governmental Authority having jurisdiction, this being in addition to any other remedy to which it is entitled at law or in equity.

10.10 **Entire Agreement**. This Agreement, together with the Schedules and Exhibits expressly contemplated hereby and attached hereto, the Seller Disclosure Schedules, the Ancillary Agreements and the other agreements, certificates and documents delivered in connection herewith or therewith or otherwise in connection with the transactions contemplated hereby and thereby, contain the entire agreement between the Parties with respect to the transactions contemplated hereby or thereby and supersede all prior agreements, understandings, promises and representations, whether written or oral, between the Parties with respect to the subject matter hereof and thereof. In the event of any inconsistency between any such Schedules and Exhibits and this Agreement, the terms of this Agreement shall govern.

[Signature page follows]

In Witness Whereof, the Parties have executed or caused this Agreement to be executed as of the date first written above.

IPSEN BIOPHARMACEUTICALS, INC.

Name: François Garnier
Title: Executive Vice President, General Counsel and Chief Business Ethics Officer

ETON PHARMACEUTICALS, INC.

Name: Sean Brynjelsen
Title: Chief Executive Officer & Director

LICENCE AGREEMENT

Dated as of November 21, 2024 (the "Effective Date")

BY AND BETWEEN:

AMMTeK,
a limited company incorporated under the laws of France,
Paris Registrar, number 502 864 598,
whose registered office is 15 rue Armand Carrel, Paris 75019,

represented by its Chief Executive Officer, Paul Czernichow,

hereafter referred to as Ammtek,

on the first part,

AND:

Eton Pharmaceuticals, Inc.
a company incorporated under the laws of Illinois- United States,
registered office: 21925 W Field Pkwy #235, Deer Park, IL 60010, United States of America,
registration number 333-226774,

hereby represented by its Chief Executive Officer, Sean Brynjelsen,

hereafter referred to as Eton,

on the second part,

(disk DB-11700.97-Licence Agr-SAM--16.10.2024)

SUMMARY

WHEREAS:

1- Ammtek owns the proprietary rights and the European Marketing Authorization of a product that contains the API for use in the Field, whereas the product has been granted an Orphan Drug Status in the European Union and in the United States of America.

2- Both parties wish that Ammtek grants Eton an exclusive licence (the “Licence”) to market the Product in the Field, in the Territory.

3- Ammtek is currently conducting the Hyperglycaemia Study.

THEREBY:

SECTION I - DEFINITIONS:

1- Ammtek Trademark means Glibentek.

2- API means the Active Principal Ingredient, Glyburide.

3- An Adverse Drug Reaction and a Serious Adverse Drug Reaction have the meanings provided by the International Conference Harmonization definition.

4- The Affiliate of a company is any other company:

a- of whom more than fifty percent of the shareholding or of the voting rights are detained whether directly or indirectly by such company;

b- of whom more than fifty percent of the shareholding or of the voting rights are detained whether directly or indirectly by a company detaining whether directly or indirectly more than fifty percent of the shareholding or of the voting rights of such company;

c- who detains whether directly or indirectly more than fifty percent of the shareholding or of the voting rights of such company.

5- This Agreement means this Licence Agreement and its Attachment 1, Patent list.

6- Applicable Law means all federal, state, local, national and regional statutes, laws, rules, regulations and directives applicable to a particular activity hereunder, including drug development, manufacturing, performance of clinical trials, medical treatment and the processing and protection of personal and medical data, that may be in effect from time to time, including those promulgated by a Regulatory Authority in any jurisdiction and including without limitation cGMP and GCP (each as defined below); all data protection requirements; export control and economic sanctions regulations; anti-bribery and anti-corruption laws pertaining to interactions with government agents, officials and representatives; laws and regulations governing payments to healthcare providers; and any country’s or jurisdiction’s successor or replacement statutes, laws, rules, regulations and directives relating to the foregoing.

7- Competing Product means any product for use in the Field and the Territory.

8 - Confidential Information means any information, knowledge, Proprietary Rights, that are not in the public domain and that relate either to the API or to the Products or to any Party with the exception of any such information, knowledge and Proprietary Rights, that the Receiving Party has received or receives through its own work or from any third party not in breach of any obligation towards Ammtek;

a- Confidential Information ceases to be Confidential Information if and when it enters the public domain by no fault of any Receiving Party;

b- a Receiving Party means any Party with regard to the Confidential Information received from the Other Party;

c- a Disclosing Party means any Party with regard to the Confidential Information disclosed to the Other Party.

9- The Date of this Agreement means the date when this Agreement comes into force after all Parties have signed this Agreement.

10- The eCTD means the electronic Common Technical Document.

11- The EMA means the European Medicines Agency.

12- Eton Trademark means any Trademark used by Eton in connection with the Product other than the Ammtek Trademark.

13– The European Drug Production Site means the site in Europe currently owned by Unither and where the Product is currently manufactured.

14 The FDA means the Food and Drug Administration in the United States of America that has authority to grant the marketing authorization of a pharmaceutical product in the United States of America.

15- The Field means all indications relating to neonatal diabetes as may be further described by the FDA when granting the relevant Registration of the Product in the United States of America and does not include transient Hyperglycaemia of very low birth weight babies.

16- Hyperglycaemia Product means any product to be made from the API in accordance with the results of the Hyperglycaemia Study and indicated solely for transient hyperglycemia of very low birthweight babies.

17- Hyperglycaemia Study means the undergoing Ammtek phase II study assessing the efficacy of the API in controlling transient hyperglycemia of very low birthweight babies.

18- An Improvement means any improvement brought to the Product in the Field during the term of this Agreement including any new intake procedure.

19- J2F Pharma means J2F Pharma a company limited by shares, incorporated under the laws of France, Bordeaux Registrar 879 554 202, 93 Cr Journu Auber, 33300 Bordeaux.

20- The Product Know How means all knowledge, data and information including know-how, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, specifications, data, results, and other biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data (including batch records) and information, including Regulatory Documentation, study designs and protocols, reagents and biological methodology and sales and marketing material (including historic sales reports and data); in each case in written, electronic or any other form relating to or necessary or useful for the Product, the API and/or the Ammtek Proprietary Rights that are owned or controlled by Ammtek (including any affiliate, distributor, sublicensee or subcontractor of Ammtek) as of the Effective Date or at any time during the Term.

21- The Licence has the meaning set forth in section II-1 hereafter.

22- The Licensed Patents means all Patents owned or controlled by Ammtek or its affiliates as of the Effective Date or at any time during the Term covering or otherwise relating to the Product, the API, methods of manufacture thereof or formulations therewith.

23- Marketing Authorization Holder means the Party holding the authorization to market the Product in all or part of the Territory.

24- Net Sales means the gross amounts invoiced or otherwise received for sales of the Product by Eton and/or its Affiliates and/or sublicensees, to Third Parties, less reasonable and customary deductions (the “Deductions“) paid or allowed in accordance with U.S. Generally Accepted Accounting Principles and in the ordinary course of business with respect to the sales of the Product, including:

- Cash discounts, quantity discounts, promotional discounts, stocking or other promotional allowances;
- Sales and excise taxes, customs and any other taxes, all the extent added to the sale price and paid and not refundable in accordance with Applicable Laws (but not including taxes assessed against the income derived from such sale);
- Freight, insurance, and other transportation charges to the extent added to the sale price and set forth separately as such in the total amount invoiced;
- Returns, recalls, and returned goods allowances;
- Retroactive corrections, including price adjustments (including those on customer inventories following price changes) and corrections for billing errors or shipping errors;
- Chargebacks, billbacks, rebates, administrative fees, any other allowances, actually granted or allowed to any person or entity, including group purchasing organizations, managed health care organizations and to governments, including their agencies, or to trade customers, in each case that are not Affiliates of Eton, and that are directly attributable to the sale of the Product;
- Redistribution center (RDC) fees, information service agreements (ISA) fees ;
- And the costs incurred by Eton (or any of its affiliates) in connection with patient support services and dispensing fees, including but not limited to, insurance benefits investigations, co-pay assistance, and provision of free or low cost drug to patients.

Sales among a Party and its Affiliates or sublicensees for purposes of resale shall be excluded from the computation of Net Sales; provided, however, that the ultimate subsequent resale to an end-user, distributor, or retail customer shall be included in Net Sales hereunder. Sales made in connection with the research, development or testing of a Product, for purposes of distribution as promotional samples, or for indigent or similar public support or compassionate use programs shall not, to the extent such sale is made for a price equal to or less than the reasonable, documented cost of supplying such Product, be included in Net Sales under this Agreement.

25- NDA means New Drug Application to be filed to the FDA in view of being granted a marketing authorization in the United States of America.

26- The Other Party means one of the Parties to this Agreement when making a difference with the other one.

27- A Party means any party to this Agreement.

28- Patents means (1) all national, regional and international patents and patent applications, including provisional patent applications and patent applications filed under the Paris Convention and Patent Cooperation Treaty (PCT), (2) all patent applications filed from such patents, patent applications or provisional applications, including divisionals, continuations, continuations-in-part, converted provisionals and continued prosecution applications, (3) any and all patents that have issued or in the future issue from the foregoing patent applications in subparts (1) and (2), including utility models, petty patents, reexaminations, reissues, and design patents and certificates of invention, and (4) any and all extensions or restorations of subparts (1), (2) or (3) by existing or future extension or restoration mechanisms, including, without limitation, patent term extension, supplementary protection certificate or pediatric extension.

29- The Product(s) means Glyburide in liquid doses of 0.6 mg/ml or 6mg/ml.

30- Proprietary Rights mean any intellectual property right as patents, know how, Trademarks, copyrights, software property and Confidential Information whether patentable or not and that belongs to either Party; Ammtek's Proprietary Rights include but are not limited to the Product eCTD submitted to the EMA for the filing of the Registration of the Product in the European Union and to all Ammtek's Proprietary Rights upon the API, the Product, the Licensed Patents, the Ammtek Trademark and the Product Know-How and Ammtek’s Confidential Information.

31- Registration means, with respect to a country or other jurisdiction, any and all technical, medical and scientific licenses, registrations, authorizations and approvals (including approvals of applications, supplements and amendments, pre- and post- approvals, pricing and third party reimbursement approvals, and labeling approvals) of any Regulatory Authority, necessary for the use, development, manufacture, and commercialization of a pharmaceutical product in a regulatory jurisdiction.

32 - Regulatory Authority means any applicable supra-national, federal, national, regional, state, provincial, or local governmental or regulatory authority, agency, department, bureau, commission, council, or other entities (e.g., the FDA or EMA) regulating or otherwise exercising authority with respect to activities contemplated in this Agreement.

33- Regulatory Documentation means all (1) Registrations and applications therefor, registrations, licenses, authorizations, and approvals, (2) material correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all regulatory drug lists, advertising and promotion documents, adverse event files, and complaint files, and (3) clinical data and data contained or relied upon in any of the foregoing, in each case ((1), (2), and (3)) relating to the Product.

34- Territory means the territory of the United States of America, its territories and possessions, Canada and Mexico.

35- Trademark means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo, business symbol or domain names, whether or not registered.

36- Unither means Unither Development Bordeaux, a company limited by shares, incorporated under the laws of France, Bordeaux Registrar 490 387 099.

37- Year, Quarter, Month and Day mean any Gregorian calendar year, quarter, month and day:

a- the Year of this Agreement means the Year of the Date of this Agreement and following Years are respectively referred to as the Second, Third, …..Year of Agreement up to and including the last Year of this Agreement;

b- the Year of Launch means the Year when the Product is launched in the Territory or in one of its countries according to context and the following Years are respectively referred to as the Second, Third, …..Year of Launch up to and including the last Year of this Agreement.

SECTION II – LICENCE:

1- Ammtek grants Eton who accepts it, (i) an exclusive, sublicensable license in the Field in the Territory licence under Ammtek's Proprietary Rights to research, develop, have developed, manufacture, have manufactured, use, register, have registered, market, have marketed, make, have made, offer for sale, have offered for sale, sell, have sold, distribute, have distributed, export and import or otherwise commercialize the Product, (ii) an exclusive license to the Ammtek Trademark in the Territory.

2- Eton or any of its Affiliates, sublicensees or subcontractors may use the Product Know How in support of the development or filing of any Registrations or applications therefor for the Product in the Field in the Territory. Ammtek hereby grants, and agrees to grant, a right of reference, with the right to grant further rights of reference, under the Registrations and any other Regulatory Documentation for the Product/API for purposes of development, registration, or commercialization of the Product in the Field in the Territory.

3- The Licences granted hereunder are exclusive and thereby, without limiting the generality of the forgoing:

a- Ammtek agrees not to grant any other licence similar to the Licence to any other party, i.e.: in relation to the API and/or the Products in the Territory and in the Field; Ammtek and its Affiliates shall not (either directly on its own or indirectly by enabling, assisting or granting rights to, with or through a Third Party) research, manufacture, develop, register or commercialize any Competing Product.

b- Eton agrees not to manufacture and/or market directly or indirectly the Products in whatever field outside the Territory. If Eton commercializes a Competing Product in the Territory, Eton shall pay to Ammtek a royalty on Net Sales of such Competing Product as per Section 7 hereof.

4 - Technology Transfer : Within five (5) working days after the Effective Date, Ammtek shall transfer all Product Know-How to Eton. As part of such technology transfer, Ammtek shall provide Eton with reasonable access, throughout the Term, to Ammtek personnel involved with the Product Know How for reasonable levels of collaboration and consultation to facilitate transfer of the Product Know-How at no cost to Eton. To the extent, during the Term, Ammtek develops or acquires any new Product Know How or if Eton identifies any Product Know How that was not previously transferred, Ammtek shall promptly transfer such Product Know How to Eton. Ammtek shall also make available to Eton a digital copy of all information provided in the data room.

SECTION III – IMPROVEMENTS:

A/ Ammtek's Improvement:

1- Any Improvement brought to the Product by Ammtek (including Ammtek’s Affiliates, sublicensees, subcontractors and distributors) and that Ammtek will choose to incorporate into the Product will become part of the Product and the Ammtek Proprietary Rights and subject to the provisions of this Agreement, subject to any third party's rights that may limit each Party's rights to such Ammtek's Improvement.

2- In as much as reasonably possible in Ammtek's reasonable opinion, Ammtek will provide at its costs for the proprietary protection of any Ammtek's Improvements whether by patent or otherwise.

B/ Eton's Improvement:

1- Any Improvement brought to the Product by Eton and that may be used in some ways without infringing Ammtek's Proprietary Rights will become part of Eton's Proprietary Rights and Eton may incorporate it into the Product and/or into the definition of the Product for the purpose of this Agreement. Such Product will remain subject to the royalty provisions set forth herein.

2- Any other inventions, data, know how or technology developed by or on behalf of Eton and that does not infringe any Ammtek’s Proprietary Rights shall belong solely to Eton.

SECTION IV – SUPPLY:

1- Eton will be responsible for its own supply of the API and Product and Ammtek will bear no responsibility thereof, save for introducing Eton to Unither for access by Eton to the European Drug Production Site.

2- For a period of eighteen (18) months following the Effective Date, Ammtek will provide Eton with reasonable transition support with respect the Product in relation to regulatory and clinical matters. Such support shall include Ammtek making its personnel available for reasonable levels of collaboration and consultation.

SECTION V – PROPRIETARY RIGHTS:

A/ Maintenance:

1- Ammtek shall diligently take all commercially reasonable steps required to maintain the Licensed Patents in full force and effect. Ammtek shall be responsible for the day-to-day activities associated with filing, prosecuting, extending and maintaining the Licensed Patents. Ammtek agrees to consult with and cooperate with Eton to promptly file, prosecute, extend and maintain the Licensed Patents in the Territory. All filing, prosecution, extensions and maintenance decisions with respect to the Patent Rights shall be made by Ammtek with the approval of Eton, such approval not to be unreasonably withheld Patent counsel shall at all times during the term of this Agreement keep Eton advised of the status of patent filings and upon request of either party shall provide copies of any papers relating to the filing, prosecution, extensions or maintenance of such Licensed Patents. During the term of this Agreement the parties shall cooperate in providing information to assist the patent counsel with the patent prosecution of the Licensed Patents. Ammtek shall promptly give notice to Eton of the grant, lapse, revocation, surrender, invalidation, or abandonment of any Licensed Patents for which Ammtek is responsible for the filing, prosecution and maintenance. If Ammtek fails to properly prosecute and maintain the Licensed Patents, Eton may do so at its cost and expense and deduct such costs and expenses from amounts owed to Ammtek.

2- In the event that Ammtek desires to discontinue maintenance or prosecution of the Licensed Patents, Ammtek shall first agree to assign such Patent Rights to Eton at no cost.

Ammtek shall pay all costs relating to the filing, prosecution and maintainance of the Licensed Patents, including, without limitation, costs of extensions, reissue, reexamination, interferences and oppositions, unless such Licensed Patents have been assigned by Ammtek to Eton.

The parties hereto shall cooperate with each other in obtaining patent term restoration or supplemental protection certificates or their equivalents in any country in the Territory where applicable to Licensed Patents. In the event that elections with respect to obtaining such patent term restoration, supplemental protection certificates or their equivalents are to be made, Eton shall have the right to make the election and Ammtek agrees to abide by such election.

B/ Infringement and claims for invalidity:

1- Infringement action:

Should any third party in the Territory and within the Field infringe any Party's Proprietary Rights in relation to the API and/or the Products, then:

a- Parties will inform one another of such infringement as soon as they know of it;

b- Eton shall have the first right, in its reasonable discretion and at its sole cost and expense and in consultation with Ammtek who will grant all necessary authorizations thereof to take all necessary legal action to terminate such infringement and for the infringing party to pay all relevant damages;

c- Ammtek may, at its sole cost and expense, join the legal action taken by Eton against the infringing party;

d- If Eton fails to take action as of paragraph 1-b hereabove, Ammtek may do so at its cost and expense.

2- Claim for invalidity:

Should any third party in the Territory claim that either Party's Proprietary Rights in relation to the API and/or the Products infringe any such third party's rights, then:

a- the Parties will inform one another of such claim as soon as they know of it;

b- Eton shall have the first right, in its reasonable discretion, to defend against such claim including by taking any legal action if necessary and Ammtek will grant Eton all necessary authorization to that extent;

c-- Ammtek may join the legal action taken by Eton at its sole cost and expense;

d- If Eton fails to take legal action as of paragraph 1-b hereabove, Ammtek may do so at its cost and expense.

3- Awards:

In case of any action as of subsection B-1 and 2 here-above, each Party will bear its cost thereof and any damage of any kind awarded by the jurisdiction and effectively paid by the infringing or claiming party will be allocated between the Parties:

a- at first to the reimbursement of all costs exposed by the Party(ies) having been involved in the relevant legal action, which reimbursement shall be in proportion to their respective costs if both Parties have been involved;

b- then to compensate both Parties' losses consequential to the infringement and/or the claim in the proportion of each Party's share in the Net Sales according to section VIII-3 hereafter.

4- Settlement:

No Party will amicably settle a dispute with any third party whether an infringing party or a claimant by acknowledging that any of the API, Products, Ammtek's Proprietary Rights, Eton's Proprietary Rights are invalid unless the Other Party previously agrees thereof in writing, such consent not to be unreasonably withheld, conditioned or delayed.

5- Assistance:

Each Party agrees to provide the Other Party with its reasonable necessary assistance in relation to such Other Party's obligations under this section.

C/ Trademarks:

The Ammtek Trademark is the property and will remain the exclusive property of Ammtek who grants Eton a fully paid up, perpetual, sublicensable Licence to use it for the Registration, manufacture and commercialization of the Product in the Field, in the Territory and Eton agrees to only use the Trademark(s) for the Registration, manufacture and marketing of the Product in the Field, in the Territory.

Any Eton Trademark shall be the sole property of Eton.

SECTION VI – USA: REGISTRATION – MARKETING:

1- Registration:

Eton will be the Marketing Authorization Holder of the Product. Eton shall have the sole right to seek, prepare, obtain, and maintain Registrations for the Product in the Field in the Territory. Eton shall be responsible, at its own expense, for the filing, payment of filing fees and all other associated costs and activities seeking Registration of the Product in the Field and Territory and Eton shall hold all Registrations for the Product in the Field and Territory.

Within thirty (30) days of Effective Date and receiving all necessary development and clinical data from Ammtek, Eton shall request a meeting with the FDA (''Additional FDA Meeting'') to clarify the regulatory pathway and the FDA's specific clinical and development requirements for Product.

2- Marketing:

1- Eton will use commercially reasonable efforts to commercialize Product in the Field in the Territory. Eton shall have the exclusive right and sole responsibility to commercialize, either itself or through one or more Affiliates, sublicensees or subcontractors, the Product in the Field in the Territory. Eton may do so, at its option, under the Ammtek Trademark and/or the Eton Trademark.

2- Eton shall have the sole right to invoice and book sales, establish all terms of sale (including pricing and discounts) and warehousing, and distribute the Product in the Field in the Territory and to perform or cause to be performed all related services. Eton shall handle all returns, recalls, or withdrawals, order processing, invoicing, collection, distribution, and inventory management with respect to the Product in the Field in the Territory.

3- Upon acceptance of the NDA of the Product in the Field for review by the FDA, Eton will provide Ammtek with a non-binding business plan stating the forecast for gross sales and Net Sales from the expected date of launch until the term of the Agreement, on a Year basis.

Such business plan will be updated by Eton each Year in January.

SECTION VII – CONSIDERATION:

1- Development costs:

1- In consideration for the development costs of the Product, already exposed by Ammtek, thirty (30) days after the receipt of minutes from Additional FDA Meeting, or thirty (30) days after the receipt of final FDA communication if additional communications are required (but subject to section XIV(3)(a)), Eton will pay Ammtek a non-refundable amount of USD$500,000 (five hundred thousand).

2- Upon receipt of each payment, Ammtek will issue the according invoice.

2- Further Payments:

1- Eton will pay Ammtek the following non-refundable payments (all amounts in USD):

a- $550 000 (five hundred and fifty thousand) upon the U.S. FDA's acceptance for review of Product's NDA;

b- $1 300 000 (one million three hundred thousand) upon NDA approval by the U.S FDA and commercial launch, as long as the NDA is approved with existing stability data collected out of Unither Bordeaux manufacturing site. If Eton is required to qualify a new manufacturing site to gain NDA approval, this milestone shall be reduced to the amount of $500 000 (five hundred thousand).

2- Upon accomplishment of each event, Ammtek will issue the according invoice and Eton shall pay within thirty (30) days.

3- Royalties:

1- In consideration for the Licence, Eton will pay Ammtek a Royalty of 14% of the Net Sales during the Term.

2- Payments will be due in relation to the Net Sales of each Quarter within forty-five Days from the end of each Quarter.

3- The Company will issue with each payment, a breakdown of the Net Sales for the relevant Quarter.

4- With regard to each payment and breakdown, the Laboratory will issue an invoice upon receipt thereof.

5- Upon completion of the Term, the licenses granted hereunder shall be fully paid up, perpetual and irrevocable.

4- Audit:

1- Once each Year, upon prior fourteen working Days notice, Ammtek may audit Eton's relevant accounting documentation to control the accuracy of all Royalty payments made during the past two Years:

a- such audit will continue for no more than eight (8) working days and will be conducted by no more than three (3) individuals;

b- Ammtek may be assisted by any relevant professional of its choice. All such professionals shall be subject to a confidentiality agreement and the information reviewed including all notes and extracts shall be the confidential information of Eton.

2- Any discrepancy revealed by the audit will be settled within ten working Days from the end of each audit.

3- The cost of the audit will be paid by Ammtek but reimbursed to Ammtek by Eton, should the audit reveal an undisputed discrepancy of over five percent to the prejudice of Ammtek.

SECTION VIII – PHARMACOVIGILANCE:

1- Parties will provide to one another by the end of each half Year and in as much as related to the API and/or the Product, all their mutual safety data from clinical trials, "Periodic Safety Update Reports", safety reports and adverse event reports, issued during each half Year.

2- The half Year period will be brought down to three working Days for any issue in relation to Serious Adverse Drug Events.

3- Parties agree for Ammtek or any appointee that it may appoint, to keep a consolidated safety data grouping the safety data of both Parties.

4- Should a major safety issue arise, whereby the API and/or the Product create a health danger, parties will immediately consult together and consult the relevant regulatory authorities in view of assessing such possible health danger and deciding in line with any decision or recommendation of such relevant regulatory authorities whether the API and/or the Product should be withdrawn from the Territory.

SECTION IX – COOPERATION:

1- The Parties agree to maintain regular communication as needed including a formal video or telephone meeting at least every (6) six months.

2- Parties will discuss items including:

a- any issue in relation to the development of the API and of the Products with regard to the Field;

b- any Improvement issue;

c- any pharmaco-vigilance issue;

d- update on commercial activities;

e- the Products' Trademarks.

3- Seven Days prior to each meeting, each Party will provide a summary of issues they wish to be addressed during such meeting.

4- Ammtek will promptly circulate the minutes of such meeting which will be deemed agreed subject to any remarks by Eton within a reasonable period of time.

SECTION X – WARRANTIES – LIABILITY – TOLERANCE:

A/ Warranties:

1- Each Party represents and warranties to the other Party:

a. that it will properly perform its obligations under this Agreement.
b. It is duly organized, validly existing, and in good standing under the Applicable Laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.
c. The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action, and do not violate (a) in any material respect, any agreement to which such Party is bound, (b) any requirement of any Applicable Law, or (c) any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to such Party.
d. This Agreement is a legal, valid, and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).
e. It is not under any obligation, contractual or otherwise, to any Person that conflicts in any material respect with the terms of this Agreement.
f. Each Party has all the necessary rights, title and interest to grant the licenses hereunder (and in the case of Ammtek, to the Licensed Patents, Ammtek Trademark and Product Know How).

g. Neither Party nor any of its Affiliates (a) has ever been debarred or subject to debarment or has received notice from the FDA of an intent to debar or has been convicted of a crime for which an entity or person could be debarred under 21 U.S.C. §335a; or (b) has ever been under indictment for a crime for which a Person or entity could be debarred under 21 U.S.C. §335a. If, during the Term, a Party has reason to believe that it or any of its employees, officers, independent contractors, consultants or agents rendering services relating to the Licensed Products: (a) is or will be debarred or convicted of a crime for which a Person or entity could be debarred under 21 U.S.C. §335a; or (b) is or will be under indictment for a crime for which a Person or entity could be debarred under 21 U.S.C. §335a, then such Party shall immediately notify the other Party of same in writing.

2- Eton represents and guarantees that each Product that it will market in the Territory will:

a- be of good marketing conditions and comply with the provisions of such Product's Registration;

b- be manufactured in full compliance with all applicable regulations.

3- Additional Representations and Warranties of Ammtek: Ammtek further represents and warrants to Eton, as of the Effective Date, as follows:

a the Licensed Patents include all Patents owned or controlled by Ammtek as of the Effective Date that are reasonably necessary or useful for the Product in the Field in the Territory;

b the Product Know How includes all know how, data, information and records necessary or useful for the Product in the Field in the Territory. Without limiting the generality of the foregoing, this included all historical data and records relating to the Product (including all clinical, pre-clinical, manufacturing, development and regulatory information and data) generated by or on behalf of Ammtek including that generated by Affiliates, partners, Etons and subcontractors and including all data and records of Nordic Pharma relating to the Product;

c- All Product Know How is accurate and, to the best of Ammtek's knowledge, has been generated in accordance with Applicable Laws and regulations including cGMP;

d- All clinical data relating to the Product has been obtained in accordance with Applicable Laws and regulations including all Applicable Laws relating to human subject protections;

e- To the best of Ammtek's knowledge, the Ammtek Proprietary Rights do not infringe or misappropriate the rights of any Third Party;

f- Ammtek has not received any written notice and has no reasonable basis to believe that the registration or commercialization of the Product in the Field in the Territory infringes upon or misappropriates any intellectual property right of any Third Party;

g- it has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in and to the Ammtek Proprietary Rights in the Field and in the Territory, and possesses all rights to enter into this Agreement and grant the rights and licenses granted hereunder;

h- Ammtek is not aware of any safety issues or hazards associated with the Product;

i- Ammtek is not aware of any pending of threatened litigation in relation to the Product or the Ammtek Proprietary Rights.

B/ Liability:

1- Indemnification by Eton. Eton shall at all times during the term of this Agreement and thereafter, indemnify, defend and hold Ammtek, its trustees, officers, employees and affiliates, from and against any and all claim, loss, damage, liability, injury, cost or expense, including without limitation expenses of litigation and reasonable attorneys' fees, in connection with any claims made or suits brought against Ammtek relating to this Agreement arising from the negligence, willful misconduct, violation of Applicable Laws or material breach of this Agreement by Eton, its Affiliates, subcontractors or agents; provided however that Eton shall not be obligated to provide indemnification hereunder to the extent that any such claim, loss, damage, liability, injury, cost or expense results from the negligence, willful misconduct, violation of Applicable Laws or material breach of this Agreement by Ammtek.

2- Indemnification by Ammtek. Ammtek shall at all times during the term of this Agreement and thereafter, indemnify, defend and hold Eton, its trustees, officers, employees and affiliates, from and against any and all claim, loss, damage, liability, injury, cost or expense, including without limitation expenses of litigation and reasonable attorneys' fees, in connection with any claims made or suits brought against Eton relating to this Agreement arising from the negligence, willful misconduct, violation of Applicable Laws or material breach of this Agreement by Ammtek, its Affiliates, subcontractors or agents ; provided however that Ammtek shall not be obligated to provide indemnification hereunder to the extent that any such claim, loss, damage, liability, injury, cost or expense results from the negligence, willful misconduct, violation of Applicable Laws or material breach of this Agreement by Eton.

Should a Party entitled to indemnification (the "Indemnitee") intend to claim indemnification under this section, such Indemnitee shall promptly notify the indemnifying Party (the "Indemnitor") in writing of any loss, claim, damage, liability or action in respect of which the Indemnitee intends to claim such indemnification. The Indemnitor shall be entitled to assume the defense thereof with counsel selected by the Indemnitor and approved by the Indemnitee, such approval not to be unreasonably withheld; *provided, however,* that if representation of the Indemnitee by such counsel first selected by the Indemnitor would be inappropriate due to a conflict of interest between such Indemnitee and any other party represented by such counsel, then the Indemnitor shall select other counsel for the defense of Indemnitee, with the fees and expenses to be paid by the Indemnitor, such other counsel to be approved by the Indemnitee and such approval not to be unreasonably withheld. The indemnity agreement in this section shall not apply to amounts paid in settlement of any loss, claim, damage, liability or action if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld unreasonably. The failure to deliver notice to the Indemnitor within a reasonable time after the commencement of any such action, if prejudicial to its ability to defend such action, shall relieve such Indemnitor of any liability to the Indemnitee under this section only to the extent of such prejudice, but the omission so to deliver notice to the Indemnitor will not relieve it of any liability that it may have to any Indemnitee otherwise than under this section. The Indemnities under this section shall survive any termination hereof. The Indemnitee and its employees and agents, shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action, claim or liability covered by this indemnification.

NOTWITHSTANDING ANYTHING IN THIS AGREEMENT OR OTHERWISE, NEITHER PARTY SHALL BE LIABLE TO THE OTHER WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT, WHETHER UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY, FOR ANY INCIDENTAL, INDIRECT, SPECIAL, EXEMPLARY, PUNITIVE, MULTIPLE, OR CONSEQUENTIAL DAMAGES *PROVIDED*, *HOWEVER*, THAT THE FOREGOING SHALL NOT APPLY TO OR LIMIT (A) DAMAGES AVAILABLE FOR ANY BREACH BY EITHER PARTY OF THE CONFIDENTIALITY OBLIGATIONS; (B) A PARTY'S INDEMNIFICATION OBLIGATIONS AS SET FORTH IN SECTION X-B FOR THIRD PARTY DAMAGES ACTUALLY AWARDED.

C/ Tolerance:

Any tolerance by either Party with regard to any breach by the Other Party of any of its obligations under this Agreement will not be deemed a waiver thereof and the non defaulting Party may seek compensation thereof at any time.

SECTION XI – INSURANCE:

1- During this Agreement, each Party will obtain and maintain at its own cost and expense an insurance coverage in relation to its obligations under this Agreement.

2- Eton's insurance coverage will be for a minimum amount of five million US Dollars.

SECTION XII– CONFIDENTIALITY:

The Receiving Party agrees to maintain the confidentiality of, and not to use except for the proper application of this Agreement, each Confidential Information of the Disclosing Party, for the whole duration of this Agreement and then for as long as such Confidential Information remains Confidential Information and then for five Years from entering the public domain if such entry is due to any fault of the Receiving Party.

SECTION XIII –ETONRIGHT OF FIRST REFUSAL FOR HYPERGLYCAEMIA PRODUCT:

1- Should Ammtek wish to license an Hyperglycaemia Product out in the Territory, it will give notice to Eton of a first offer therefore as follows.

2- Prior to Ammtek or its Affiliates' (1) commercializing an Hyperglycaemia Product, in the Territory, or (2) directly or indirectly entering into any license, grant of rights or other agreement with any third party for the commercialization of an Hyperglycaemia Product in or for the Territory, Ammtek will first offer such Hyperglycaemia Product to Eton on the same terms offered to any third party. In connection with such offer, Ammtek will provide to Eton all information in its possession regarding the Hyperglycaemia Product including the terms of any such third party offer. Eton shall then have forty-five (45) days to enter into an agreement with Ammtek for the Hyperglycaemia Product on terms comparable to such third party offer. Such forty-five (45) day period may be extended by mutual agreement.

3- Should no agreement be reached within three months from Ammtek's notice to Eton despite the Parties' good faith efforts, Ammtek will be free to license such Hyperglycaemia Product to such third party in the Territory subject to not granting such third-party better conditions than those offered to Eton, within twelve Months from the break-up of the Parties discussions.

4- If Ammtek licenses a Hyperglycaemia Product to a third party, third party must agree not to file, market, or sell, directly or indirectly the Product for the Field within the Territory.

SECTION XIV- DURATION:

1- This Agreement is agreed from the Date of this Agreement until the earliest of:

a- December 31st, 2034;

b- on a country-by-country basis, the launch of a generic product AB-rated to Product. In such event, the rights and licenses granted to Eton hereunder shall become fully paid up and perpetual.

2 This Agreement may be terminated by notice by either party at any time during the term of this Agreement if it is shown by credible evidence that the Other Party is in breach of its material obligations hereunder by causes and reasons within its control and has not cured such breach within ninety (90) days after written notice from the Other Party requesting cure of the breach. Such time period may be extended if the breaching Party is in the process of curing the breach but the breach has not yet been fully cured within ninety (90) days.

3- This Agreement may be terminated by Eton upon written notice to Ammtek:

a- Within thirty (30) days of the receipt of minutes from Additional FDA Meeting. In the event, in Eton's reasonable discretion, additional guidance or communication is required from the FDA in order to clarify the regulatory pathway and the FDA's specific clinical and development requirements for Product, Eton may terminate the Agreement within thirty (30) days after the receipt of such final FDA communication. If Eton terminates under this section XIV(3)(a), no payments shall be due under this Agreement, including without limitation, under section VII(1)(1).

b- prior to the Product being granted an NDA Approval and subject to a three Month notice period if any documented regulatory or pharmaceutical issue unforseeable at the Date of this Agreement makes it effectively unreasonable for Eton to pursue the NDA approval procedure although following such notice from Eton, such three month period may be terminated early by Ammtek should Ammtek enter into a licence agreement with any third party during such notice period, in relation to the Product, in the Field, in the Territory;

c- after the Product has been granted an NDA approval, subject to a twenty-four Month notice period and to Eton making the product available to patients during the notice period although such notice period may be terminated early by Ammtek should Ammtek enter into a licence agreement with any third party during such notice period, in relation to the Product, in the Field, in the Territory.

SECTION XV- CONSEQUENCES OF THE TERMINATION OF THIS AGREMENT:

1 - Upon the termination of this Agreement, Parties rights and obligations under this Agreement will come to an end. Upon termination or expiration other than as set forth in (2), below, Eton will keep all Registrations of the Product that it will then have in the Territory and may continue marketing the Product in the Territory against no consideration to Ammtek and all rights and licenses granted to Eton hereunder will become fully paid up and perpetual.

2- Upon termination of this Agreement by Eton pursuant to Section XV(3) (termination at will by Eton), all licenses shall terminate and Eton shall transfer the Registrations to Ammtek.

3- Expiration or termination of the Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Any expiration or early termination of this Agreement shall be without prejudice to the rights of either Party against the Other Party accrued or accruing under this Agreement prior to termination, including the obligation to pay royalties for Product sold prior to such termination.

4- For the sake of clarity, Parties agree that no payment by Eton to Ammtek will be refundable in any way as a consequence of the termination of this Agreement.

SECTION XVI - MISCELLANEOUS :

A/ Address:

1- Parties addresses are those marked at the head of this Agreement.

2- Each party will promptly give notice to the other party of any modification of its address(es).

B/ Notice:

Any notice under this Agreement will be served by registered letter with recorded delivery or by international courier with recorded delivery, will be deemed timely served if sent prior to the term of any time limitation and will come into force upon first presentation to the noticee's address.

C/ Nullity:

If any part of this Agreement is void under any Applicable Laws, the remaining part of this Agreement will remain in force.

D/ Inconsistency:

In case of any inconsistency between any provision of this Agreement, prevalence will be given in accordance with the general meaning of this Agreement.

E/ Force Majeure

Neither party shall be held liable or responsible to the other party nor be deemed to have defaulted under or breached the Agreement for failure or delay in fulfilling or performing any term of the Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the Party failing to perform or delayed in performing including, but not limited to, fire, floods, embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority or the other Party.

F/ Other provisions

This Agreement constitutes the entire Agreement between Ammtek and Eton with respect to the subject matter hereof, and supersedes all proposals, oral or written, purchase orders, confidentiality agreements and all other communications between the Parties with respect to such subject matter.

The terms and conditions of this Agreement may be amended only by a written instrument duly executed by both Parties.

Either Party may assign this Agreement at any time for any reason upon written notice to the Other Party. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective permitted successors and assigns.

It is expressly agreed that Ammtek and Eton shall be independent contractors with respect to this Agreement and that the relationship between the two Parties created by this Agreement shall not constitute a partnership, joint venture or agency. Neither Ammtek nor Eton shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior consent of the party to do so.

The waiver by either party hereto of any right hereunder or the failure to perform or of a breach by the other party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other party whether of a similar nature or otherwise.

SECTION XVII – APPLICABLE LAW:
This Agreement is acknowledged to have been made in and shall be construed, governed, interpreted and applied in accordance with the laws of Belgium, without giving effect to its conflict of laws provisions. The English speaking chamber of the Brussels Court of Law shall have exclusive jurisdiction over any litigation arising under this Agreement.

Date _____
Signed for and on behalf
of Ammtek
Paul Czernichow

Date _____
Signed for and on behalf
of Eton Pharmaceuticals, Inc.
Sean Brynjelsen

(disk DB-11700.97-Licence Agr-SAM--16.10.2024)

Attachment A

Licensed Patents

(disk DB-11700.97-Licence Agr-SAM--16.10.2024)

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 18, 2025

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 18, 2025

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, 2024 (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 18th day of March, 2025.

/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.