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, 2021

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

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. ☐

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, 2021 was approximately $108.8 million.

As of March 7, 2022, the registrant had 24,626,004 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 2022 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, 2021, are incorporated by reference into Part III of this Annual Report on Form 10-K.

TABLE OF CONTENTS

		Page
	PART I	
Item 1.	Business	3
Item 1A.	Risk Factors	16
Item 1B.	Unresolved Staff Comments	45
Item 2.	Properties	45
Item 3.	Legal Proceedings	45
Item 4.	Mine Safety Disclosures	45
	PART II	
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	46
Item 6.	Selected Financial Data	46
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	47
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	52
Item 8.	Financial Statements and Supplementary Data	53
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	84
Item 9A.	Controls and Procedures	84
Item 9B.	Other Information	84
	PART III	
Item 10.	Directors, Executive Officers and Corporate Governance	85
Item 11.	Executive Compensation	85
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	85
Item 13.	Certain Relationships and Related Transactions, and Director Independence	85
Item 14.	Principal Accountant Fees and Services	85
	PART IV	
Item 15.	Exhibits, Financial Statement Schedules	86
	Signatures	89

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;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act;
- 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," 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

Overview

We are a pharmaceutical company focused on developing, acquiring, and commercializing innovative pharmaceutical products that fulfill an unmet patient need. Since the formation of our company in 2017, we have used our expertise in business development, regulatory, and product development to assemble a diversified portfolio of eleven products and product candidates. Six of our products have been approved by the U.S. Food & Drug Administration ("FDA") and commercially launched, and an additional four product candidates have been submitted to the FDA. We plan to continue growing our business through the acquisition of additional late-stage, high-value product candidates.

Product Portfolio

Our product portfolio is comprised of three categories: Orphan Drugs, Hospital Products, and Royalty Products.

Orphan Drugs

Our orphan drug product category is focused on commercializing products that treat the unmet needs of patients suffering from rare diseases. As defined by the FDA, orphan drugs typically address diseases that impact fewer than 200,000 patients in the United States. Given these small patient populations, products are typically promoted with small, targeted sales forces and distributed through high-touch specialty pharmacies that provide comprehensive services to patients or caregivers. We expect to continue to grow our orphan drug product category. Some of our orphan drug products include:

Alkindi Sprinkle® (hydrocortisone granules) - 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 for the treatment of AI designed for use in children. 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. In November 2021, we entered into a co-promotion agreement with Tolmar Pharmaceuticals, Inc. ("Tolmar") to use their 60+ person salesforce to promote Alkindi Sprinkle. Tolmar's sales force will promote Alkindi Sprinkle to pediatric endocrinology healthcare professionals and Tolmar will receive a royalty on net sales growth above the product's baseline sales level at the time of the transaction. Eton retains ownership of the product and will maintain responsibility for all non-sales force related commercial activities. We believe there are approximately 10,000 children currently suffering from AI in the United States. Alkindi Sprinkle is protected by four issued patents that extend to 2034. In January 2021, we announced the acquisition of Canadian rights to Alkindi Sprinkle and we expect to pursue regulatory approval of the product in Canada in the near future.

Carglumic Acid tablets - Our Carglumic Acid product is the first and only 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 marketing rights to the product in October 2021 and launched the product in December 2021. We promote the product with our internal sales force. The product was awarded Competitive Generic Therapy (CGT) designation by the FDA, which provides us with 180 days of generic exclusivity. We believe that the Carbaglu® market is more than $50 million annually and our goal is to capture 25% to 35% of the market.

Dehydrated Alcohol Injection. Our dehydrated alcohol injection product candidate for the treatment of methanol poisoning was submitted to the FDA and was granted Orphan Drug Exclusivity in late 2020. In May 2021, we received a Complete Response Letter ("CRL") from the FDA. We believe all of the items raised by the CRL are addressable, and we plan to submit our response to the FDA in the near future. We believe the dehydrated alcohol injection market is more than $50 million annually.

Zeneo® Hydrocortisone Autoinjector. Our Zeneo hydrocortisone autoinjector product candidate is a proprietary needle-free autoinjector under development for the treatment of adrenal crisis. We acquired the product candidate from Crossject in June 2021. Currently patients suffering from adrenal crisis typically use Solu-Cortef, a lyophilized hydrocortisone injection kit that must be reconstituted prior to delivery. The current market for Solu-Cortef is more than $75 million annually based on IQVIA data. We believe our needle-free autoinjector will be preferred by patients. We expect to submit a New Drug Application ("NDA") for the product in 2023, which could allow for FDA approval in 2024.

Hospital Products

Our hospital products category consists of injectable products that are used in the hospital setting. These include:

Biorphen® (phenylephrine HCl). Biorphen is the first and only FDA-approved formulation of ready-to-use phenylephrine injection. Biorphen is indicated for the treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia. We acquired U.S. marketing rights to the product in February 2019. The product was approved in October 2019 and launched in December 2019. We estimate the current addressable market for ready-to-use phenylephrine to be more than twenty million units of Biorphen annually. Biorphen primarily competes with FDA-approved formulations of concentrated phenylephrine injection, which must be diluted prior to administration to patients, and with unapproved formulations of ready-to-use phenylephrine sold by 503B compounding pharmacies. Eton owns the Biorphen NDA, but the product is currently promoted by Xellia Pharmaceuticals' ("Xellia") hospital sales force under a co-promotion agreement. Eton pays Xellia a commission on sales of the product in certain channels. Eton retains the right to exit the co-promotion agreement under certain conditions. We are actively working on converting this product from its current ampule container to a vial. We expect to launch the vial presentation in 2022, which is expected to drastically increase the adoption of the product.

Rezipres® (ephedrine HCl)**.** Rezipres is an innovative ready-to-use formulation of a molecule that is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia. Our product will compete against Emerphed® and non-FDA approved ready-to-use products from compounding facilities. Rezipres® provides a ready-to-use strength that can be immediately administered to patients, eliminating the need for calculations and additional dilution steps. Our product is also preservative free and does not contain any sulfites. This product was launched in March 2022. We have partnered with XGen Pharmaceuticals DJB ("XGen") for commercialization of the product. XGen's sales force is responsible for promoting the product to hospitals. We are actively working on converting the product from its current ampule container to a vial. We expect to launch the vial presentation in 2022.

Cysteine Injection. Our cysteine injection product candidate is a generic form of EXELA Pharma Sciences' Elcys® product for which we have submitted an Abbreviated New Drug Application ("ANDA") to the FDA. We are actively engaged in the Paragraph IV litigation associated with the innovator company's patent. Given our first-to-file status, we expect to be entitled to 180 days of generic exclusivity if we are successful in challenging the patent. The trial is expected to begin in March of 2022. We believe the current market for Cysteine injection is more than $50 million annually.

Royalty Products

Our royalty products category is comprised of products that Eton does not commercialize. In most cases, these are products that Eton initiated development of, or licensed at an early stage, and advanced development to an FDA submission before selling the product rights to a third party. These products are now owned and commercialized partners that pay Eton milestones and royalties on commercial sales. Our royalty products category strategy allows us to monetize our vast experience and talent in business development, regulatory activities, and product development to generate high returns on our financial investments without being restricted by commercial organization limitations and it does not require significant ongoing overhead support costs. We currently have four royalty products: Alway Preservative Free, which is owned and marketed by Bausch Health, and our three neurology oral liquid products, EPRONTIA™, Zonisamide oral suspension and Lamotrigine oral suspension, which are owned and marketed by Azurity Pharmaceuticals ("Azurity").

Alaway® Preservative Free (ketotifen fumarate)**.** Alaway Preservative Free is the first and only preservative-free ophthalmic product approved for the treatment of allergic conjunctivitis. The preservative-free formulation is designed to deliver an improved comfort profile to patients compared to currently available ketotifen ophthalmic products that contain preservatives. The product is sold via the over-the-counter channel. Currently, the market for ketotifen ophthalmic products is estimated to be more than $75 million annually based on data from IRI and IQVIA. We sold the product rights to Bausch Health in February 2019. Bausch Health is responsible for commercialization of the product which was launched in February 2021. We received a $1.5 million milestone payment in conjunction with the launch of the product and receive a twelve percent royalty on the product's net sales.

Neurology Oral Liquids. Starting in 2018, we assembled a portfolio of three neurology oral liquid products through in-licensing and internal development. All three products are molecules that are widely used in oral solid forms to treat epilepsy, but were not FDA-approved in liquid formulations. We believe the formulations will be beneficial to patients suffering from dysphagia, which is prevalent among pediatric and geriatric patients. In addition, the liquid formulations offer precision dosing, which can provide patients and caregivers with accurate doses that are lower than or in between the limited strength doses available from oral solid products. We sold these three products to Azurity in February 2021. Under terms of the agreement, Azurity has paid us $17 million and will pay up to $25 million in additional milestone payments plus a single digit royalty on net sales of the products. Azurity has taken over ownership of the products and is responsible for all development, regulatory, and commercial activities. The three neurology oral liquid products are:

EPRONTIA™ (topiramate oral solution). EPRONTIA® is the only FDA-approved liquid formulation of topiramate. The product is approved for three indications, including: monotherapy for treatment of partial-onset or primary general tonic-clonic seizures in patients two years of age and older; adjunctive therapy for treatment of partial-onset seizures, including seizures associated with Lennox-Gastaut syndrome in patients two year of age and older; and as a preventive treatment of migraine in patients 12 years of age and older. The product was approved in November 2021 and launched by Azurity in December 2021. The current market for topiramate in oral form is more than $800 million annually according to IQVIA.

Zonisamide Oral Suspension. The product is an innovative liquid formulation of zonisamide under FDA review for the treatment of partial seizures in patients with epilepsy. The product application was originally assigned a PDUFA date of May 29, 2021 and the FDA issued a Complete Response Letter because it was unable to inspect the manufacturing site due to COVID-related travel restrictions. The FDA inspected the facility in January 2022, and we believe the application could be approved in the near future. The current market for zonisamide in oral form is more than $65 million annually according to IQVIA.

Lamotrigine for Oral Suspension. The product is an innovative liquid formulation of lamotrigine under FDA review for the treatment of partial on-set seizures, primary generalized tonic-clonic seizures, and seizures of Lennox-Gastaut syndrome in patients two year of age and older. The product has been issued a patent, which is now owned by Azurity. The product's NDA application received a Complete Response Letter in March 2020 and the FDA requested changes to the Dosage and Administration section of the product's Prescribing Information to simplify the dosing information for intended users. The FDA requested a human factors validation study with the revised labeling to demonstrate that the intended users can prepare and administer the oral suspension safely and effectively. Our development partner completed the study and submitted the report to the FDA in November 2021. The application has been assigned a PDUFA date of May 30, 2022. The current market for lamotrigine in oral form is more than $600 million annually according to IQVIA.

Eton Pharmaceuticals
Products Summary

Product	Eton Category	Indication	FDA Status
Carglumic Acid Tablets	Orphan Drug	NAGS deficiency	Commercial
ALKINDI SPRINKLE®	Orphan Drug	Adrenal Insufficiency	Commercial
Biorphen®	Hospital Product	Hypotension	Commercial
Rezipres®	Hospital Product	Hypotension	Commercial
Alaway® Preservative Free	Royalty Product	Allergic Conjunctivitis	Commercial
EPRONTIA™	Royalty Product	Epilepsy / Migraine	Commercial
Dehydrated Alcohol Injection	Orphan Drug	Methanol Poisoning	Filed
Zonisamide Oral Susp	Royalty Product	Epilepsy	Filed
Lamotrigine for Susp	Royalty Product	Epilepsy	Filed
Cysteine Injection	Hospital Product	Parenteral Nutrition	Filed
ALKINDI SPRINKLE (Canada)	Orphan Drug	Adrenal Insufficiency	Submission Expected in 2022
ZENEO® Hydrocortisone	Orphan Drug	Adrenal Crisis	Submission Expected in 2023

Goals and Strengths

Our goal is to become a leading profitable pharmaceutical company that brings innovative treatments to patients. 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 avoid participating in broker led transactions of auction processes.

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

Sales and Marketing

We currently own or have economic interests in six commercial products. We typically commercialize our orphan products under our own label with our internal infrastructure and sales force, however, we may at times supplement our efforts with a co-promotion arrangement as we have with Tolmar Pharmaceuticals on Alkindi Sprinkle. In our orphan product category, we currently commercialize Alkindi Sprinkle and Carglumic Acid in the United States. These products are distributed to patients via a specialty pharmacy, which supports customer service and reimbursement activities.

In our hospital category, we have entered into short-term co-promotion agreements for the ampule format of both Biorphen and Rezipres. We retain ownership of the products and have no commercial arrangements relating to the vial formats of both products. For each future product launch we will assess if it is more advantageous to promote internally with our own sales force or partner with a company with an existing hospital sales force.

In our royalty product category, the products are commercialized by our partners. Bausch Health is responsible for all sale and marketing activities related to Alaway Preservative Free, and Azurity is responsible for all sales and marketing activities related to Eprontia, zonisamide oral suspension, and lamotrigine suspension. In all cases we receive a royalty on net sales of the products

In January 2020 we signed a co-promotion agreement with Xellia for the promotion of Biorphen. Under terms of the agreement, Xellia's U.S.-based hospital sales force will promote Biorphen in certain customer channels in exchange for a commission based on net sales realized at certain customer accounts. Eton owns the Biorphen NDA and the product is sold under Eton's brand name. The agreement has a five-year term, but allows Eton to exit under various scenarios, including a change of control, and after 2021 if Biorphen net sales from Xellia designated accounts do not exceed $29.4 million in 2021, or $42.0 million in 2022 and the following years. In July 2021 we signed a co-promotion agreement with XGen whereby XGen's salesforce will promote Rezipres for a three-year term, in exchange for a profit share on the Rezipres product. In November 2021 we signed a co-promotion agreement with Tolmar whereby Tolmar will promote Alkindi Sprinkle® through its 60+ person salesforce in exchange for a royalty on net sales.

Research and Development

We currently have seven employees that support our product research and development activities. In addition, we utilize external sources for various product development activities, including the resources of our product development partners for certain product candidates, and also through the use of contract laboratory services on a fee for service model.

Manufacturing and Suppliers

We rely on third-party contract manufacturing organizations ("CMOs") to manufacture our products. All our 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 ("cGMP"), 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 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 four issued patents that extend to 2034. We intend to seek patent protection on our internally developed products as circumstances warrant.

Our development partners for zonisamide and topiramate have filed patent applications on those products and our development partner for lamotrigine was granted a patent by the United States Patent and Trademark Office for the product's unique formulation. We expect the lamotrigine patent to be Orange Book listed after product approval. These patents were assigned to Azurity in February 2021.

Government Regulations and Funding

Pharmaceutical companies are subject to extensive regulation by foreign, federal, state and local agencies, such as the FDA, and various European regulatory authorities. The manufacture, distribution, marketing and sale of pharmaceutical products are subject to government regulation in the United States and various foreign countries. 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 cGMP 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, 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 illegal 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.

These regulatory requirements impact our operations and differ from one country to another, so that securing the applicable regulatory approvals of one country does not imply the approval of another country. The approval procedures involve high costs and are manpower intensive, usually extend over many years and require highly skilled and professional resources.

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;
- completion of required chemistry, manufacturing and controls testing;
- the submission to the FDA of an investigational new drug, or IND, the application for 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;
- submission and approval of an NDA; and
- agreement with FDA of the language on the package insert.

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 normally 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 small populations of sick patients to look for initial signs of efficacy in treating the targeted disease or condition and to continue to assess safety. Phase 3 clinical trials are usually multi-center, double-blind controlled trials in larger numbers of subjects at various sites to assess as fully as possible both the safety and effectiveness of the drug.

Clinical trials must be conducted in accordance with the FDA's 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 institutional review board ("IRB") generally must approve the clinical trial design and patient informed consent at study sites that the IRB oversees and also 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 check points 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 cGMP. To comply with cGMP 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.

Assuming 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 the Prescription Drug User Fee Act ("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 an 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 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 a number of post-approval regulatory requirements. We would be required to report, among other things, certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling for any of our products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP, 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, and such data will take time and are costly to generate, and the delay associated with generating these 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 or 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 the applicant 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 is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or Orange Book. Specifically, the applicant must certify that: (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, or 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

For products distributed in the United States, we will also be 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 and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or 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;

- The Physician Payments Sunshine Act which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services ("CMS") information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; 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 a number of legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval pharmaceutical products, 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.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, (collectively, 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. 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. The Tax Cuts and Jobs Act of 2017 (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." The Bipartisan Budget Act of 2018, among other things, amended the Health Care Reform, effective January 1, 2019, 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 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. While the ruling has no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Health Care Reform will impact the Health Care Reform Law.

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 and an increase in the statute of limitations period for the government to recover overpayments to providers from three to five years.

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, in President Biden's 2022 State of the Union Speech, President Biden again called for Congress to take action to combat high prices of prescription drugs. In 2019, the Health and Human Services ("HHS") Office of Inspector General proposed modifications to the U.S. 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.

Employees

We currently have 17 full-time employees, seven of whom are engaged in research and development activities, six are engaged in sales/marketing operations and four of whom are engaged in general corporate and strategy roles. We periodically utilize outside consultants on an as-needed basis, including medical consultants and product telesales services.

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 issues press releases, file reports with the SEC or post certain other information to our website. Information contained on or accessible through our website is not a part of this Annual Report on Form 10-K or our other filings with the SEC.

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

Risk Factor 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 16 of this Annual Report, including, but not limited to, the following:

- We are a specialty pharmaceutical company with a limited operating history, and it is difficult for potential investors to evaluate our business.
- Our business is adversely affected by the ongoing coronavirus pandemic and the impact could be material.
- 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.
- 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 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.
- 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.
- 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.

- Our future growth may depend, in part, on our ability to penetrate international markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

- 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.

- Our Chief Executive Officer holds ownership interest in some of the third parties we have entered into agreements with. The terms and fee arrangements of these agreements, we believe, approximate the terms and fee arrangements of an agreement that would have been obtained in an arm's length and unaffiliated transaction. Nonetheless, this may expose us to claims of interested transactions and other fiduciary suits.

- 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 are a specialty pharmaceutical company with a limited operating history, and it is difficult for potential investors to evaluate our business.

We are a specialty pharmaceutical company founded in April 2017 and have only recently commenced revenue-producing operations and our historical operations have primarily consisted of the preliminary formulation, testing and development of our various product candidates. Our limited operating history makes it difficult for potential investors to evaluate our initial product candidates or our prospective operations. As an early-stage company, we are subject to all the risks inherent in the initial organization, financing, expenditures, complications and delays in a new business. Further, biopharmaceutical product development is a highly speculative undertaking, involves a substantial degree of risk and is a capital-intensive business. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of product development and commercialization, especially clinical-stage biopharmaceutical companies such as ours. As a company with a limited operating history, we may be unable to:

- successfully implement or execute our current business plan, or develop a business plan that is sound;
- successfully complete clinical trials and obtain regulatory approval for the marketing of our additional product candidates;
- successfully contract for the manufacture of our clinical drug products and establish a commercial drug supply;
- secure market exclusivity or adequate intellectual property protection for our product candidates;
- attract and retain an experienced management and advisory team; or
- raise sufficient funds in the capital markets to effectuate our business plan, including clinical development, regulatory approval and ongoing commercialization for our product candidates.

There can be no assurance that our efforts will be successful or that we will ultimately be able to attain profitability. If we cannot successfully execute any one of the foregoing, our business may not succeed.

Our business is adversely affected by the ongoing coronavirus pandemic and the impact could be material.

Public health outbreaks, epidemics or pandemics have had, and could in the future have, an adverse impact on our operations and financial condition. The continuing pandemic caused by the novel strain of coronavirus (COVID-19) has caused many countries, including the United States, to declare national emergencies and implement preventive measures such as travel bans and shelter-in-place or total lock-down orders, some of which have eased. The continuation or re-implementation of these bans and orders remains uncertain. In some cases, these bans and orders have influenced certain aspects of our business. For example, we began commercializing our Biorphen product in December 2019 and Alkindi Sprinkle product in December 2020; however, we have encountered difficulty in creating significant market pull-through demand for our products in 2020 and 2021 as our in-person sales calls to key personnel at hospitals and surgical centers and introductory product presentation seminars were limited as a result of the COVID-19 pandemic. We are working on other promotional efforts to drive further adoption in the market, but we may see our product sales and marketing efforts continue to be adversely affected by the pandemic in 2022 and beyond. COVID-19 may also affect our ability to complete recruitment and data analysis for our clinical trials and our ability to conduct research and development of our complement programs in our planned timeframe. The extent to which COVID-19 impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration and severity of the outbreak, and the actions that may be required to contain COVID-19 or treat its impact. In particular, as a result of the COVID-19 pandemic, we may experience disruptions that could severely impact our business, preclinical studies, drug manufacturing and clinical trials including:

- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;

- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;

- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines; and

- interruption of, or delays in promoting our products in-person, at conferences and at hospitals due to limitations on travel and in-person gatherings imposed or recommended by federal or state governments.

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.

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 causes 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 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.

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. System failures, accidents or security breaches could cause interruptions in our operations, and could 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.

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 have various product candidates under review with the FDA and are in the early stages of clinical development with a number of new product candidates, and have not yet generated significant revenues from our approved drug products. We plan on submitting our clinical trial protocols and receiving approvals from the FDA and international regulatory authorities before we commence any clinical trials. 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 substantially 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 of 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 Federal Food, Drug and Cosmetic Act ("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;
- 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 Federal Food, Drug and Cosmetic Act ("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 have 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 candidate, 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 prevalence and severity of any adverse effects;
- 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 Risk Evaluation and Mitigation Strategy ("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 Good Clinical Practices regulations ("cGCPs") 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 cGMP 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.

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, 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 is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Health Care Reform will impact the ACA and 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.

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. 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.

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 active pharmaceutical ingredient ("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 cGMPs for manufacture of both active drug substances and finished drug products. These cGMP 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 cGMPs 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 Biorphen or any of our product candidates, 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 cGCPs, 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 cGCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable cGCPs, 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 cGCPs. In addition, our clinical trials must be conducted with products produced under cGMP 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 cGMP 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, cGMP 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 candidate.

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

Our ability to successfully market Biorphen and our product candidates will depend in part on the coverage and level of reimbursement that government health administration authorities, private health coverage insurers and other organizations provide for the cost of our products and related treatments. Countries in which any of our product candidates are sold through reimbursement schemes under national health insurance programs frequently require that manufacturers and sellers of pharmaceutical products obtain governmental approval of initial prices and any subsequent price increases. In certain countries, including the United States, government-funded and private medical care plans can exert significant indirect pressure on prices. Increasingly, third-party payors attempt to contain health care costs in ways that are likely to impact our development of products, including:

- failing to approve or challenging the prices charged for health care products;
- introducing reimportation schemes from lower priced jurisdictions;
- limiting both coverage and the amount of reimbursement for new therapeutic products;
- denying or limiting coverage for products that are approved by the regulatory agencies but are considered to be experimental or investigational by third-party payors; and
- refusing to provide coverage when an approved product is used in a way that has not received regulatory marketing approval.

We may not be able to sell Biorphen or our product candidates profitably if adequate prices are not approved or coverage and reimbursement is unavailable or limited in scope.

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 laws and regulations governing data privacy and the protection of personal information. These laws and regulations 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 addition, in 2018 California adopted a new privacy law that became effective on January 1, 2020, which borrows heavily from the GDPR. The GDPR and similar data privacy laws of other jurisdictions place significant responsibilities on us and create potential liability in relation to personal data that we or our third-party service providers process, including in clinical trials conducted in the United States and the European Union. In addition, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the European Union and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

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 will depend, 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. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowable or enforceable in our patents. Patent and patent applications relating to our product candidates and related technologies may be challenged, invalidated or circumvented by third parties and might not protect us against competitors with similar products or technologies.

The degree of future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights, permit us to gain or keep our competitive advantage, or provide us with any competitive advantage at all. For example, others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to any of our product candidates, or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed by us, or that we will not be involved in interference, opposition or invalidity proceedings before U.S. or foreign patent offices.

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 U.S. Patent and Trademark Office (“U.S. PTO”), 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.

In the future, we may rely on know-how and trade secrets to protect technology, especially in cases when we believe patent protection is not appropriate or obtainable. However, know-how and trade secrets are difficult to protect. While we 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. Typically, research collaborators and scientific advisors have rights to publish data and information in which we may have rights. 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. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts are sometimes less willing to protect trade secrets than patents. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

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. 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.

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 U.S. PTO. 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 U.S. PTO proceedings compared to the evidentiary standard in U.S. federal court, a third party could potentially provide evidence in a U.S. PTO proceeding sufficient for the U.S. PTO 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 U.S. PTO 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 U.S. PTO, 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 may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates or any future product candidate. There may be certain 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 U.S. PTO, we would have to prove that the claims are unpatentable by a preponderance of the evidence. There is no assurance that a jury and/or court would find in our favor on questions of infringement, validity or enforceability.

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

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

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

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

Risks Related to Owning Our Common Stock

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

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

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 (including the $22.5 million raised in our October 2020 offering of common stock). 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;
- 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 an "emerging growth company" under the JOBS Act of 2012 and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"), and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley Act");
- reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements;
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments; and
- extended transition periods available for complying with new or revised accounting standards.

We have chosen to "opt out" of the extended transition periods available for complying with new or revised accounting standards, but we intend to take advantage of all of the other benefits available under the JOBS Act, including the exemptions discussed above. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will remain an "emerging growth company" for up to five years from the end of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement filed under the Securities Act, which will be December 31, 2023. We will lose that status sooner, however, if our revenues exceed $1.07 billion, if we issue more than $1 billion in non-convertible debt in a three-year period or if the market value of our common stock that is held by non-affiliates exceeds $700 million as of any June 30.

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 consolidated 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 is 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.

Our status as an "emerging growth company" under the JOBS Act may make it more difficult to raise capital as and when we need it.

Because of the exemptions from various reporting requirements provided to us as an "emerging growth company," we may be less attractive to investors and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our reporting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected.

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.

Our federal net operating losses ("NOLs") generated in taxable years ending prior to 2018 could expire unused. Under the Tax Act, federal NOLs incurred in taxable years ending after December 31, 2017, may be carried forward indefinitely, but the deductibility of federal NOLs generated in tax years beginning before December 31, 2017, is limited. It is uncertain if and to what extent various states will conform to the Tax Act. 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 7, 2022, we had 24,626,004 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, as well as by our former parent company, Harrow Health, Inc., may limit our stockholders' ability to influence corporate matters.

Our directors and executive officers beneficially own approximately 5.2% of our common stock. Additionally, Harrow Health, Inc. ("Harrow"), our former parent company, holds approximately 8.0% of our outstanding common stock as of March 7, 2022. 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, and particularly by Harrow, 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 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 on March 31, 2023.

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, 2021, the last trading date in 2021, was $4.29 per share.

Record Holders

As of March 7, 2022, we had 9 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 7, 2022 was $3.72.

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.

Recent Sales of Unregistered Securities

Not applicable.

Item 6. Selected Financial Data

Not applicable.

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 a unique pharmaceutical company focused on developing, acquiring, and commercializing innovative pharmaceutical products that fulfill an unmet patient need. Since the formation of our company in 2017, we have used our expertise in business development, regulatory, and product development to assemble a diversified portfolio of eleven products. Six of our products have been approved by the FDA and commercially launched. We plan to continue growing our business through the acquisition of additional late-stage, high-value product candidates.

Results of Operations

To date, we have realized revenues from the sale of our neurology products portfolio to Azurity in 2021, a licensing arrangement on our EM-100 product that was sold to Bausch Health and also the launch of our Biorphen®, Alkindi Sprinkle®, and Carglumic Acid products in December 2019, December 2020, and December 2021, respectively. We anticipate successfully growing our sales for these products and commercializing additional product candidates in 2022 and beyond.

Year Ended December 31, 2021 Compared to Year Ended December 31, 2020

Net revenues of $21.8 million in 2021 included $19.0 million of milestones, including $17.0 million from Azurity on three neurology products sold to them at the beginning of the year. Revenues were nominal in 2020 for Biorphen and reflected the launch of Alkindi Sprinkle® late in mid-December.

Our 2021 gross profit of $19.2 million was up significantly as the prior year negative gross profit level was adversely impacted by Biorphen price discounts and a reserve charge to cost of sales for certain slow-moving Biorphen inventory that we do not believe we will be able to sell before its expiry date.

For the years ended December 31, 2021 and 2020, we incurred $6.2 million and $14.1 million of research and development ("R&D") expenses, respectively, and $14.5 million and $12.8 million of general and administrative ("G&A") expenses, respectively. The $7.9 million decrease in R&D was driven by significant milestone payments on a number of our products in development that did not recur in 2021. The $1.7 million increase in G&A expenses was primarily due to personnel additions and increased professional/consulting spending to support our growing business. We incurred a net loss of $2.0 million and $28.0 million for the years ended December 31, 2021 and 2020, respectively.

General and Administrative Expenses

G&A expenses consist primarily of employee compensation expenses, selling and adverting/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 – particularly with respect to sales and marketing for additional personnel and promotional expenses.

Research and Development Expenses

We currently have seven 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 in addition to development partner milestone payments. We closed our R&D facility in May 2021.

Year Ended December 31, 2020 Compared to Year Ended December 31, 2019

Net revenues for 2020 reflected limited benefit from Alkindi Sprinkle which launched in mid-December. In addition, revenue was negatively impacted by a price discount for Biorphen in 2020 related to the shelf stock at our wholesale customers. Our 2020 gross profit was also adversely impacted by a reserve charge to cost of sales for certain slow-moving Biorphen inventory that we do not believe we will be able to sell before its expiry date. Revenue and gross profit in 2019 reflected the initial launch for Biorphen and a $0.5 million milestone payment for our sale of EM-100 to Bausch Health.

For the years ended December 31, 2020 and 2019, we incurred $14.1 million and $11.6 million of research and development ("R&D") expenses, respectively, and $12.8 million and $7.6 million of general and administrative ("G&A") expenses, respectively. The increase in R&D expense was primarily due to $4.8 million of licensing and development fees for Alkindi Sprinkle in 2020 offset by reduced spending for Topiramate and Lamotrigine. The $5.2 million increase in G&A expenses was primarily due to personnel additions and increased sales/marketing spending to support product launches. In addition, we incurred significant legal expenses associated with our patent challenge against Exela Pharma Sciences for the Cysteine product that we have in development. We incurred a net loss of $28.0 million and $18.3 million for the years ended December 31, 2020 and 2019, respectively.

General and Administrative Expenses

G&A expenses consisted primarily of employee compensation expenses, selling and adverting/promotional expenses, legal and professional fees, business insurance and travel expenses. Our G&A expenses increased to support our business growth – particularly with respect to sales and marketing for additional personnel and promotional expenses.

Research and Development Expenses

As of December 31, 2020, we had six employees that supported our overall product development and we had facility and operating costs for a laboratory to support product development which we subsequently closed in May 2021.

Liquidity and Capital Resources

As of December 31, 2021, we had total assets of $27.5 million, cash and cash equivalents of $14.4 million and working capital of $19.0 million. We had previously capitalized our operations from the June 2017 private placement of approximately $20.1 million of Series A preferred stock which converted into shares of our common stock concurrent with our IPO in November 2018 and also the IPO which provided us with net proceeds of $22.0 million. In addition, we entered into a Credit Agreement with SWK Holdings in November 2019 whereby we drew a $5.0 million loan amount at closing and an additional $2.0 million in August 2020. In March and April 2020, we received net proceeds of approximately $7.8 million from the sale of shares of our common stock, and in October 2020, we received net proceeds of approximately $21.0 million from a public offering of our common stock at an offering price of $7.00 per share. We believe that our existing funding, revenues from our approved products and milestone payments expected to be paid in 2022 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, 2021, 2020 and 2019 (amounts are in thousands):

	Year ended December 31, 2021	Year ended December 31, 2020	Year ended December 31, 2019
Net cash used in operating activities	$ (4,721)	$ (22,346)	$ (18,026)
Net cash used in investing activities	(2,559)	(50)	(1,846)
Net cash flows provided by financing activities	391	31,625	5,203
Net change in cash and cash equivalents	$ (6,889)	$ 9,229	$ (14,669)

The decrease in cash used in operating activities is primarily a result of lower operating losses, driven by higher revenue. Investing activities in 2021 consist primarily of licensing fees for Carglumic Acid, partially offset by the proceeds from the sale of equipment from our laboratory facility which we closed in May 2021. The financing activity primarily consists of the October 2020 follow-on common stock offering and the November 2019 Credit Agreement borrowing from SWK Holdings.

Critical Accounting Policies

Our financial statements are prepared in accordance with 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

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 the contract is determined to be 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 or over time, and if over time this is based on the use of an output or input method. Any amounts received prior to revenue recognition will be recorded as deferred revenue. Amounts expected to be recognized as revenue within the twelve months following the balance sheet date will be classified as current portion of deferred revenue in our balance sheets. Amounts not expected to be recognized as revenue within the twelve months following the balance sheet date are classified as long-term deferred revenue, net of current portion.

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.

We sell Biorphen 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 of Biorphen represent performance obligations under each purchase order. We use a third-party logistics ("3PL") vendor to process and fulfill orders and have 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. We have no significant obligations to wholesalers to generate pull-through sales. In addition, we sell our Alkindi Sprinkle and Carglumic Acid products to one pharmacy distributor customer which provides order fulfillment and inventory storage/distribution services.

Selling prices initially billed to wholesalers are subject to discounts for prompt payment and subsequent chargebacks when the wholesalers sell Biorphen at negotiated discounted prices to members of certain group purchasing organizations ("GPOs") and government programs. In addition, we pay fees to wholesalers for their distribution services, inventory reporting and chargeback processing. We pay GPOs fees for administrative services and for access to GPO members and concluded the benefits received in exchange for these fees are not distinct from our sales of Biorphen, and accordingly we apply these amounts to reduce revenues. Wholesalers also have rights to return unsold product nearing or past the expiration date. Because of the shelf life of Biorphen and our lengthy return period, there may be a significant period of time between when the product is shipped and when we issue credits on returned product. For our Alkindi Sprinkle and Carglumic Acid products, we bill at the initial product list prices which are subject to offsets for patient co-pay assistance and potential state Medicaid reimbursements which are estimated and recorded as a reduction of net revenues at the date of sale/shipment.

We estimate the transaction price when we receive each purchase order, taking into account the expected reductions of the selling price initially billed to the wholesaler arising from all of the above factors. We have developed estimates for future returns and chargebacks of Biorphen and the impact of the other discounts and fees we pay. Our sales of Alkindi Sprinkle and Carglumic Acid to our distributor are not subject to returns. When estimating these adjustments to the transaction price, we reduce it sufficiently to be able to assert that it is probable that there will be no significant reversal of revenue when the ultimate adjustment amounts are known.

We recognize revenue from Biorphen product sales and related cost of sales upon product 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 us. 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, we do not believe they have a significant incentive to return the product to us. We store our Alkindi Sprinkle and Carglumic Acid inventory at our pharmacy distributor customer location and sales are recorded when stock is pulled and shipped to fulfill specific patient orders.

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 of accounts receivable. We monitor actual product returns, chargebacks, discounts and fees subsequent to the sale. If these amounts end up differing from our estimates, we will make adjustments to these allowances, which are applied to increase or reduce product sales revenue and earnings in the period of adjustment.

In addition, we anticipate we will receive revenues from product licensing agreements where we have contracted for milestone payments and royalties from products we have developed or for which we have acquired the rights to a product developed by a third party.

Stock-Based Compensation

We account 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").

We estimate the fair value of stock-based option awards to our 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 comparable companies' historical volatility along with a limited weighting included for our own 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.

Prior to our initial public offering in November 2018, the fair value of the shares of common stock underlying our stock-based awards was determined by our board of directors, with input from management. Because there had been no public market for our common stock prior to the IPO, our board of directors had determined the fair value of the common stock on the grant-date of the stock-based award by considering a number of objective and subjective factors, including enterprise valuations of our common stock performed by an unrelated third-party specialist, valuations of comparable companies, sales of our convertible preferred stock to unrelated third parties, operating and financial performance, the lack of liquidity of our capital stock, and general and industry-specific economic outlook. Following our IPO, we use the closing stock price on the date of grant for the fair value of the common stock.

Research and Development Expenses

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 our R&D operations. External contracted services include product development efforts including 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. We review and accrue R&D expenses based on services performed and rely upon estimates of those costs applicable to the stage of completion of each project. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from our 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.

Off Balance Sheet Transactions

We do not have any off-balance sheet transactions.

JOBS Act Transition Period

In April 2012, the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Subject to certain conditions, as an emerging growth company, we may rely on certain of these exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier to occur of (1) the last day of the fiscal year (a) December 31, 2023, which is the end of the fiscal year following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenues of at least $1.07 billion or (c) in which we are deemed to be a "large accelerated filer" under the rules of the SEC, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

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, 2021, 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 due to the extremely low 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 (PCAOB ID: 170)	54
Balance Sheets	55
Statements of Operations	56
Statements of Stockholders' Equity	57
Statements of Cash Flows	58
Notes to Financial Statements	59

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 sheets of Eton Pharmaceuticals, Inc. (the "Company") as of December 31, 2021 and 2020, the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, 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.

Critical Audit Matter

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

Product Sales Deductions

Critical Audit Matter Description

As described in Note 3 to the financial statements under the caption "Revenue Recognition for Contracts with Customers," revenues from product sales are recognized net of reductions for estimated returns, chargebacks, distribution fees, prompt payment discounts, state Medicaid and GPO fees (collectively "sales deductions"), which are established at the time of sale.

Auditing the estimation of sales deductions was challenging because of the limited sales history of the Company's products and the subjectivity of certain assumptions required to estimate those amounts. In particular, management estimates potential chargebacks, which relate to price reductions below the estimated sales price that the wholesalers provide to certain customers, based on historical industry data for competitive products and adjusted for actual historical experience. In addition, management estimates its provision for product returns based on prior experience with similar product launches and considers other factors such as levels of inventory in the distribution channel, forecasted buying patterns, and product dating and expiration period. The product sales deductions are estimated based on current contractual and statutory requirements, market events and trends, and internal and external historical data.

How the Critical Audit Matter Was Addressed in the Audit

To test management's estimated product sales deductions, we obtained management's calculations for the respective estimates and performed the following procedures, among others. We tested management's estimation process for determining of product sales discounts accruals by developing an independent expectation of the estimated accrual rate, including a comparison of rates used in management's forecast to rates in the underlying contracts and performing a retrospective review of assumptions to actual activity. In addition, we assessed subsequent events to determine whether there was any new information that would require adjustment to the initial accruals, evaluated trends in actual sales and discount accrual balances, and compared cash receipts to product sales. We also examined terms and conditions for a sample of contracts with the Company's customers, tested a sample of credits issued and payments made throughout the year and agreed rates to underlying contract terms.

/s/ KMJ Corbin & Company LLP

We have served as the Company's auditor since 2018.

Irvine, California
March 16, 2022

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

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 14,406	$ 21,295
Accounts receivable, net	5,471	48
Inventories	550	1,242
Prepaid expenses and other current assets	3,177	2,116
Total current assets	**23,604**	**24,701**
Property and equipment, net	115	811
Intangible assets, net	3,621	575
Operating lease right-of-use assets, net	104	192
Other long-term assets, net	21	40
Total assets	**$ 27,465**	**$ 26,319**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,774	$ 2,344
PPP loan, current portion	—	280
Current portion of long-term debt	1,418	—
Accrued liabilities	1,366	1,170
Total current liabilities	**4,558**	**3,794**
Long-term debt, net of discount and including accrued fees	5,262	6,532
Long-term portion of PPP and EIDL loans	—	231
Operating lease liabilities, net of current portion	15	99
Total liabilities	**9,835**	**10,656**
Commitments and contingencies (Note 14)		
Stockholders' equity		
Common stock, $0.001 par value; 50,000,000 shares authorized; 24,626,004 and 24,312,808 shares issued and outstanding at December 31, 2021 and 2020, respectively	25	24
Additional paid-in capital	111,718	107,797
Accumulated deficit	(94,113)	(92,158)
Total stockholders' equity	**17,630**	**15,663**
Total liabilities and stockholders' equity	**$ 27,465**	**$ 26,319**

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, 2021	**December 31, 2020**	**December 31, 2019**
Revenues:			
Licensing revenue	$ 19,000	$ —	$ 500
Product sales and royalties, net	2,832	39	459
Total net revenues	**21,832**	**$ 39**	**959**
Cost of Sales:			
Licensing revenue	1,500	—	—
Product sales and royalties	1,123	286	453
Total cost of sales	2,623	286	453
Gross profit (loss)	**19,209**	**(247)**	**506**
Operating expenses:			
Research and development	6,235	14,104	11,555
General and administrative	14,469	12,760	7,552
Total operating expenses	**20,704**	**26,864**	**19,107**
Loss from operations	**(1,495)**	**(27,111)**	**(18,601)**
Other income (expense):			
Interest and other income (expense), net	(1,006)	(859)	281
Gain on PPP loan forgiveness	365	—	—
Gain on equipment sale	181	—	—
Loss before income tax expense	**(1,955)**	**(27,970)**	**(18,320)**
Income tax expense	—	—	—
Net loss	**$ (1,955)**	**$ (27,970)**	**$ (18,320)**
Net loss per share, basic and diluted	**$ (0.08)**	**$ (1.33)**	**$ (1.03)**
Weighted average number of common shares outstanding, basic and diluted	25,207	21,010	17,761

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	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balances at December 31, 2018	**17,607,928**	**$ 18**	**$ 72,153**	**$ (45,868)**	**$ 26,303**
Stock-based compensation	—	—	1,888	—	1,888
Stock option exercises	167,622	—	214	—	214
Common stock issued under employee stock purchase plan	44,885	—	239	—	239
Stock warrant exercises	57,051	—	—	—	—
Relative fair value of warrants to purchase common stock issued in connection with debt	—	—	226	—	226
Net loss	—	—	—	(18,320)	(18,320)
Balances at December 31, 2019	**17,877,486**	**$ 18**	**$ 74,720**	**$ (64,188)**	**$ 10,550**
Stock-based compensation	15,190	—	2,576	—	2,576
Stock option exercises	194,878	—	255	—	255
Employee stock purchase plan	25,780	—	112	—	112
Proceeds from sales of common stock, net of offering costs	5,820,000	6	28,776	—	28,782
Issuance of common stock for product candidate licensing rights	379,474	—	1,264	—	1,264
Relative fair value of warrants to purchase common stock issued in connection with debt	—	—	94	—	94
Net loss	—	—	—	(27,970)	(27,970)
Balances at December 31, 2020	**24,312,808**	**$ 24**	**$ 107,797**	**$ (92,158)**	**$ 15,663**
Stock-based compensation	—	—	3,381	—	3,381
Stock option exercises	144,233	1	338	—	339
Employee stock purchase plan	49,155	—	202	—	202
Common stock issued related to restricted stock units	25,000	—	—	—	—
Stock warrant exercises	94,808	—	—	—	—
Net loss	—	—	—	(1,955)	(1,955)
Balances at December 31, 2021	**24,626,004**	**$ 25**	**$ 111,718**	**$ (94,113)**	**$ 17,630**

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, 2021	**December 31, 2020**	**December 31, 2019**
Cash flows from operating activities			
Net loss	$ (1,955)	$ (27,970)	$ (18,320)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	3,381	2,576	1,888
Common stock issued for product candidate licensing rights	—	1,264	—
Depreciation and amortization	462	651	447
Debt discount amortization	148	121	16
Gain on forgiveness of PPP loan	(365)	—	—
Gain on sale of equipment	(181)	—	—
Changes in operating assets and liabilities:			
Accounts receivable	(5,423)	425	(473)
Inventories	692	(862)	(380)
Prepaid expenses and other assets	(1,026)	(20)	(1,361)
Accounts payable	(570)	1,769	(377)
Accrued liabilities	116	(300)	534
Net cash used in operating activities	**(4,721)**	**(22,346)**	**(18,026)**
Cash used in investing activities			
Proceeds from sale of equipment	700	—	—
Purchases of property and equipment	(9)	(50)	(1,096)
Purchase of product licensing rights	(3,250)	—	(750)
Net cash used in investing activities	**(2,559)**	**(50)**	**(1,846)**
Cash flows from financing activities			
Proceeds from issuance of long-term debt, net of issuance costs	—	1,965	4,750
Proceeds from sales of common stock, net of offering costs	—	28,782	—
Proceeds from PPP and EIDL loans	—	511	—
EIDL loan payoff	(150)	—	—
Proceeds from employee stock purchase plan and stock option exercises	541	367	453
Net cash provided by financing activities	**391**	**31,625**	**5,203**
Change in cash and cash equivalents	**(6,889)**	**9,229**	**(14,669)**
Cash and cash equivalents at beginning of year	21,295	12,066	26,735
Cash and cash equivalents at end of year	**$ 14,406**	$ 21,295	$ 12,066
Supplemental disclosures of cash flow information			
Cash paid for interest	$ 815	$ 797	$ —
Cash paid for income taxes	$ —	$ —	$ —
Supplemental disclosures of non-cash investing and financing activities:			
Relative fair value of common stock warrants issued in connection with debt	$ —	$ 94	$ 226
Right-of-use assets obtained in exchange for lease liabilities	$ —	$ 195	$ —

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

Note 1 — Company Overview

Eton Pharmaceuticals, Inc. ("Eton" or the "Company") was incorporated as a Delaware "C" corporation on April 27, 2017 and was initially set up as a wholly-owned subsidiary of Harrow Health, Inc. ("Harrow", fka Imprimis Pharmaceuticals, Inc.). In June 2017, the Company raised $20,055 in start-up capital through a private sale of preferred stock and a separate management team was then established for Eton with its corporate offices located in Deer Park, Illinois. In November 2018, the Company completed an initial public offering (the "IPO") and received net proceeds of $21,960, after deducting underwriting discounts and commissions and offering-related expenses. In November 2019, the Company entered into a credit agreement and received net proceeds of $4,750 and in August 2020 the Company received net proceeds of $1,965 under the credit agreement (see Note 5). In March and April 2020, Eton received net proceeds of $7,756 from the sale of shares of its common stock and in October 2020, the Company received net proceeds of $21,026 from a public offering for its shares at an offering price of $7.00 per share (see Note 6).

Eton is a specialty pharmaceutical company focused on developing, acquiring, and commercializing innovative products. Eton is primarily focused on hospital injectable and rare disease products. The Company seeks to improve the formula, delivery system, or safety of existing molecules in order to address unmet patient needs. Eton pursues what it perceives to be low-risk product candidates where existing published literature, historical clinical trials, or physician usage has established safety and/or efficacy of the molecule, thereby reducing the incremental clinical burden required for the Company to bring the product to patients.

The Company's Biorphen® product was approved by the FDA in October 2019 and sales commenced for this product at the end of 2019. Eton's EM-100 product was sold to Bausch Health and the product was approved by the FDA in September 2020. Bausch Health launched this product under the name of Alaway® Preservative Free in January 2021 and Eton receives royalties from the sale of the product. The Company acquired the licensing rights to Alkindi Sprinkle and this product was approved by the FDA in October 2020 and launched in December 2020. The Company entered into a co-promotion agreement with Tolmar Pharmaceuticals in November 2021 whereby Tolmar will promote Alkindi Sprinkle through its 60+ person salesforce in exchange for a royalty on net sales. In addition, the Company launched Carglumic Acid tablets in December 2021 as the first and only FDA-approved generic version of Carbaglu®.

Note 2 — Liquidity Considerations

As of December 31, 2021, the Company had an accumulated deficit of $94,113 and for the year ended December 31, 2021 the Company used net cash in operating activities of $4,721.

To date, the Company has generated revenues from six products and expects further growth in 2022 and beyond in accordance with additional market penetration from these products plus revenues from licensing and additional products where it anticipates FDA approval. The Company currently believes its existing cash and cash equivalents of $14,406 as of December 31, 2021 augmented by the $5,000 milestone payment received in January 2022 for the commercial launch of EPRONTIA™ (Topiramate oral solution) by Azurity Pharmaceuticals ("Azurity"), 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 accounting principles generally accepted in the United States of America ("GAAP").

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, provisions for uncollectible receivables, chargebacks and sales returns, valuation of inventories, useful lives of assets and the impairment of property and equipment, the accrual of research and development expenses and the valuation of common stock, stock options and warrants. 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.

Segment Information

The Company operates the business on the basis of a single reportable segment, which is the business of developing and commercializing prescription drug products. The Company's chief operating decision-maker is the Chief Executive Officer ("CEO"), who evaluates the Company as a single operating segment.

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. Cash equivalents consist of an interest-bearing checking account and a U.S. treasury bill. 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 doubtful accounts, cash discounts for prompt payment, distribution fees, chargebacks and returns and allowances. The total for these reserves amounted to $96 and $71 as of December 31, 2021 and 2020, 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 will record a write-down if an impairment is identified. Inventories at December 31, 2021 and 2020 consist solely of purchased finished goods. At December 31, 2021, inventories are shown net of a slow-moving reserve for its Biorphen product of $1,414 due to the risk of expiry before this entire stock of inventories is sold. There was an inventory reserve of $1,414 and $623 at December 31, 2021 and 2020, respectively.

Property and Equipment

Property and equipment are stated at cost. 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.

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 in accordance with Accounting Standards Codification ("ASC") 350 — Intangibles - Goodwill and Other. A $750 payment related to the approval of the Company's Biorphen product in 2019 has been capitalized and that cost is being amortized over five years. A $3,250 payment related to the approval of the Company's Carglumic Acid product in December 2021 has been capitalized and that cost is being amortized over ten years. The intangible assets, net on the Company's balance sheet reflected $379 and $175 of accumulated amortization as of December 31, 2021 and 2020, respectively. The Company recorded amortization expense of $204, $150 and $25 for the years ended December 31, 2021, 2020 and 2019, respectively, and will record amortization expense of $475 per year for these intangible assets for 2022 through 2023 and then $450 in 2024 when the Biorphen asset will be fully amortized. For 2025 through 2030, the Company will incur amortization expense of $325 and then $271 in 2031 when the Carglumic Acid asset will be fully amortized.

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, 2021, 2020 and 2019.

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 of 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, 2021 and 2020.

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. 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 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. 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 historical experience. Based upon the review of these factors, the Company recorded no allowance for doubtful accounts at December 31, 2021 or 2020. The accounts receivable balance at December 31, 2021 and 2020 and product sales revenue recognized during the year ended December 31, 2021 and 2020 consist of sales to and amounts due from AmerisourceBergen Corporation, Cardinal Health Services and McKesson Corporation for sales of the Company's Biorphen product. The December 31, 2021 accounts receivable balance and sales in 2021 also include a $5,000 milestone from Azurity, in accordance with the Eprontia™ (topiramate oral solution) product, amounts due from AnovoRx for sales of the Company's Alkindi Sprinkle product and its Carglumic Acid product, which launched in December 2021.

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 or over time, and if over time this is based on the use of an output or input method. Any amounts received prior to revenue recognition will be recorded as deferred revenue. Amounts expected to be recognized as revenue within the twelve months following the balance sheet date will be classified as current portion of deferred revenue in the Company's balance sheets. Amounts not expected to be recognized as revenue within the twelve months following the balance sheet date are classified as long-term deferred revenue, net of current portion.

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. To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

Significant Financing Component – In determining the transaction price, the Company 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 Biorphen 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 of Biorphen 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. In addition, the Company sells its Alkindi Sprinkle and Carglumic Acid product to one pharmacy distributor customer which provides order fulfilment and inventory storage/distribution services.

Selling prices initially billed to wholesalers are subject to discounts for prompt payment and subsequent chargebacks when the wholesalers sell Biorphen at negotiated discounted prices to members of certain group purchasing organizations ("GPOs") and government programs. In addition, the Company pays fees to wholesalers for their distribution services, inventory reporting and chargeback processing. The Company pays GPOs fees for administrative services and for access to GPO members and concluded the benefits received in exchange for these fees are not distinct from its sales of Biorphen, and accordingly it applies these amounts to reduce revenues. Wholesalers also have rights to return unsold product nearing or past the expiration date. Because of the shelf life of Biorphen and the Company's lengthy return period, there may be a significant period of time between when the product is shipped and when it issues credits on returned product. For its Alkindi Sprinkle and Carglumic Acid 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.

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 of Biorphen and the impact of the other discounts and fees it pays while Alkindi Sprinkle and Carglumic Acid sales to its distributor are not subject to returns. When estimating these adjustments to the transaction price, the Company reduces it sufficiently to be able to assert that it is probable that there will be no significant reversal of revenue when the ultimate adjustment amounts are known.

The Company recognizes revenue from Biorphen product sales and related cost of sales upon product 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. The Company stores its Alkindi Sprinkle and Carglumic Acid inventory at its pharmacy distributor customer location and sales are recorded when stock is pulled and shipped to fulfill specific patient orders.

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 of 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.

In addition, the Company anticipates it will receive revenues from product licensing agreements where it has contracted for milestone payments and royalties from products it has developed or for which it has acquired the rights to a product developed by a third party.

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 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 relies upon estimates of those costs applicable to the stage of completion of each project. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. 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.

Earnings (Loss) Per Share

Basic net loss per common share is computed by dividing net loss attributable to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net 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 2021, 2020 or 2019 as the Company reported a net loss for the years ended December 31, 2021, 2020 and 2019 and including the effects of common stock equivalents in the diluted earnings per share calculation would have been anti-dilutive (see Note 9). Basic weighted average shares for the year ended December 31, 2021 include 600,000 vested warrants to purchase common shares. As the shares underlying these warrants can be purchased for little to no consideration ($0.01 per share exercise price), they are included in the computation of basic earnings per share.

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. The Company estimates the fair value of stock-based option awards using the Black-Scholes-Merton 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 comparable companies' historical volatility along with a limited weighting included for the Company's own volatility, which management believes represents the most accurate basis for estimating expected future volatility under the current conditions. The Company accounts for forfeitures as they occur. The Company uses the closing common stock price on the date of grant for the fair value of the common stock.

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, 2021 and 2020, 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, 2021 and 2020, there were no unrecognized tax benefits included in the balance sheets that would, if recognized, affect the effective tax rate. 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, 2021 or 2020, and has not recognized interest and penalties in the statements of operations for the years ended December 31, 2021, 2020 and 2019. As of December 31, 2021, 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 2021 are subject to examination by the federal and state tax authorities due to the carryforward of unutilized net operating losses ("NOLs").

Current accounting standards include guidance on the accounting for uncertainty in income taxes recognized in the financial statements. Such standards also prescribe a recognition threshold and measurement model for the financial statement recognition of a tax position taken, or expected to be taken, and provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company believes that the ultimate deductibility of all tax positions is highly certain, although there is uncertainty about the timing of such deductibility. As a result, no liability for uncertain tax positions was recorded as of December 31, 2021 or 2020.

Note 3 — Summary of Significant Accounting Policies (continued)

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.

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, PPP loan and long-term debt obligation. The carrying amounts of these financial instruments, except for the PPP loan and 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 PPP loan and long-term debt obligation approximate their respective fair values.

Impact of New Accounting Pronouncements

There were no new accounting pronouncements issued by the FASB during the current period that would apply to the Company and have a material impact on its financial position or results of operations.

(in thousands, except share and per share amounts)

Note 4 – Property and Equipment

Property and equipment consist of the following:

	December 31, 2021	December 31, 2020
Computer hardware and software	$ 157	$ 182
Furniture and fixtures	106	143
Equipment	132	994
Leasehold improvements	71	184
Construction in progress	—	—
	466	1,503
Less: accumulated depreciation and amortization	(351)	(692)
Property and equipment, net	$ 115	$ 811

Depreciation and amortization expense for the years ended December 31, 2021, 2020 and 2019 was $155, $347 and $283, respectively. The balances at December 31, 2021 reflect the sale of laboratory equipment in May 2021 which had a net book value of $519.

Note 5 – Debt

SWK Loan

On November 13, 2019, the Company entered into a credit agreement (the "SWK Credit Agreement") with SWK Holdings Corporation ("SWK") which provided for up to $10,000 in 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, excluding EM-100. In March 2020, in conjunction with the Company's Alkindi Sprinkle product licensing agreement (see Note 14) and the Company's March 2020 sale of additional shares of its common stock (see Note 6), the Company and SWK amended the SWK Credit Agreement. The amendment provided the Company with the option to immediately draw $2,000 and the ability to borrow an additional $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 on August 11, 2020. The term of the SWK Credit Agreement is for five years and borrowings bear interest at a rate of LIBOR 3-month plus 10.0%, subject to a stated LIBOR floor rate of 2.0%. A 2.0% unused credit limit fee is assessed during the first twelve months after the date of the SWK Credit Agreement and loan fees include a 5.0% exit fee based on the principal amounts drawn which is payable at the end of the term of the SWK Credit Agreement. The Company is required to maintain a minimum cash balance of $3,000, only pay interest on the debt until February 2022 and then pay 5.5% of the loan principal balance commencing on February 15, 2022 and then every three months thereafter until November 13, 2024 at which time the remaining principal balance is due. Borrowings under the SWK Credit Agreement are secured by the Company's assets. The SWK Credit Agreement contains customary default provisions and covenants which include limits on additional indebtedness. In March 2020, SWK provided a waiver for the Company to obtain loans with the Small Business Association. 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 change in connection with stock splits, dividends, reclassifications and other conditions.

The Company recorded interest expense of $1,042, $884 and $98 in 2021, 2020 and 2019, respectively, which included $148 $121 and $16, respectively, of debt discount amortization. The Company had accrued interest of $134 and $48 as of December 31, 2021 and 2020, respectively, which is included in accrued liabilities in the accompanying balance sheets.

(in thousands, except share and per share amounts)

Note 5 – Debt (continued)

The table below reflects the future annual payments for the SWK loan principal and interest as of December 31, 2021.

	Amount
2022	$ 2,202
2023	1,756
2024	5,300
Total payments	9,258
Less: amount representing interest	(2,258)
Loan payable, gross	7,000
Less: current portion of long-term debt	(1,418)
Less: unamortized discount	(320)
Long-term debt, net of unamortized discount	$ 5,262

PPP loan

On May 4, 2020, the Company received $361 in loan proceeds under the Paycheck Protection Program ("PPP") from the Small Business Administration ("SBA") through its banking relationship with Bank of America. On May 20, 2021, the Company received notice that the loan principal and cumulative interest of $4 was forgiven in full as permitted under the applicable SBA guidelines for PPP loans. The $365 gain on debt extinguishment is reflected in non-operating income for the year ended December 31, 2021.

EIDL loan

On July 21, 2020, the Company received $150 in loan proceeds under the Economic Injury Disaster Loan program ("EIDL") from the SBA. The Company paid off the full EIDL loan principal and its cumulative interest of $6 in July 2021.

Note 6 — Common Stock

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

In March and April 2020, the Company entered into securities purchase agreements with various investors and sold an aggregate of 2,600,000 shares of its common stock at a price of $3.00 per share and received $7,756 in net proceeds after deducting issuance costs associated with the sale.

In March 2020, the Company issued 379,474 shares of its common stock to Diurnal Limited ("Diurnal") as a milestone fee for acquiring the U.S. marketing rights to Alkindi Sprinkle®, an orphan drug product currently under review with the FDA (see Note 14). The shares were valued at $1,264 based on the Company's closing stock price on the date of issuance and this amount was recorded as a component of the Company's research and development expense and a corresponding increase to its additional paid-in-capital.

In October 2020, the Company issued 3,220,000 shares of its common stock in a public offering at an offering price of $7.00 per share and received net proceeds of $21,026.

For the years ended December 31, 2021 and 2020, the Company issued 144,233 and 194,878 shares, respectively, of its common stock resulting from stock option exercises under its 2018 Equity Incentive Plan (see Note 8). For the years ended December 31, 2021 and 2020, the Company issued 49,155 and 25,780 shares, respectively, under the Company's Employee Stock Purchase Program ("ESPP"). In April 2020, the Company issued 15,190 shares of its common stock as an RSA to a new employee. This RSA vested 25% every three months and was 100% vested in April 2021. In April 2021, the Company issued 25,000 shares of its common stock to a member of its board of directors upon his retirement from the board in connection with previously vested restricted stock units ("RSUs"). During 2021, there were 135,650 warrants exercised (all on a cashless basis) resulting in 94,808 shares of common stock being issued by the Company.

(in thousands, except share and per share amounts)

Note 7 — Common Stock Warrants

Listed below is a summary of warrants outstanding as of December 31, 2021:

Description of Warrants	No. of Shares	Exercise Price
Business Advisory Warrants – 2017	600,000	$ 0.01
Placement Agent Warrants – 2017 Preferred Stock Offering	471,446	$ 3.00
Placement Agent Warrants - IPO	414,000	$ 7.50
SWK Warrants – Debt (Tranche #1)	51,239	$ 5.86
SWK Warrants – Debt (Tranche #2)	18,141	$ 6.62
Total	**1,554,826**	**$ 3.18 (Avg)**

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.

A rollforward of the warrants outstanding is listed in the table below:

	No. of Shares
Balance as of the beginning of the year	1,690,476
Exercise of Placement Agent Warrants – 2017 Preferred Stock Offering	(135,650)
Balance as of the end of the year	**1,554,826**

There were 135,650 warrants exercised (all on a cashless basis) in 2021 resulting in 94,808 shares of common stock being issued by the Company. There were no warrant exercises is 2020. The intrinsic value of the warrants exercised in 2021 was $806.

Note 8 — 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 537,306 shares available for future issuance under the 2018 Plan as of December 31, 2021.

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, 2019, the share reserve was increased by 704,317 shares based on the 17,607,928 shares of common stock outstanding at December 31, 2018. On January 1, 2020, the share reserve was increased by 715,099 shares based on the 17,877,486 shares of common stock outstanding at December 31, 2019. On January 1, 2021, the share reserve was increased by 972,512 shares based on the 24,312,808 shares of common stock outstanding at December 31, 2020. 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.

(in thousands, except share and per share amounts)

Note 8 — Share-Based Payment Awards (continued)

In April 2020, the Company issued 15,190 shares of its common stock as an RSA to a new employee. This RSA vested 25% every three months and was 100% vested in April 2021.

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 generally have a ten-year life, except for options to purchase 50,000 shares of the Company's common stock granted to product consultants that expire within five years if the Company is not able to successfully file certain product submissions to the FDA prior to the five-year expiration date. Furthermore, these option awards to the Company's product consultants do 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.

For the years ended December 31, 2021, 2020, and 2019, the Company's total stock-based compensation expense was $3,381, $2,576 and $1,888, respectively. Of these amounts, $2,838, $2,295 and $1,574 was recorded in general and administrative expenses, respectively, and $543, $281 and $314 was recorded in R&D expenses, respectively.

A summary of stock option activity is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Options outstanding as of January 1, 2021	2,824,500	$ 4.05	8.3	$ 11,525
Issued	1,017,098	8.31		
Exercised	(144,233)	2.35		
Forfeited/Cancelled	(183,646)	6.63		
Options outstanding as of December 31, 2021	3,513,719	$ 5.22	7.9	$ 2,711
Options exercisable at December 31, 2021	2,096,630	$ 4.37	7.3	$ 2,257
Options vested and expected to vest at December 31, 2021	3,463,719	$ 5.27	7.9	$ 2,565

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 2021 was $682.

There were 144,233 shares issued for exercise of stock options during the year ended December 31, 2021 for proceeds of $339.

The assumptions used to calculate the fair value of options granted during the years ended December 31, 2021, 2020, and 2019 under the BSM were as follows:

	December 31, 2021	December 31, 2020	December 31, 2019
Expected dividends	—%	—%	—%
Expected volatility	70-80%	95%	90%
Risk-free interest rate	0.9-1.4%	0.4-0.7%	1.9-2.5%
Expected term	6.0 years	5.9 years	5.9 years
Weighted average fair value	$ 5.64	$ 3.06	$ 5.54

(in thousands, except share and per share amounts)

Note 8 — Share-Based Payment Awards (continued)

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 — Due to the Company's limited operating history and a lack of Company-specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. The Company has also applied some limited weighting to its own volatility.

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.

A summary of activity for RSAs is as follows:

Restricted Stock Awards	**Number of shares**
Unvested as of January 1, 2021	7,595
Issued	—
Vested	(7,595)
Forfeited/Cancelled	—
Unvested as of December 31, 2021	—

The grant date fair value per share for the RSA issued in 2020 was $3.95. No RSAs were issued in 2021 or 2019. The fair value of the RSAs vested during the years ended December 31, 2021, 2020 and 2019 was $30, $30 and $66, respectively.

As of December 31, 2021, there was a total of $6,025 of unrecognized compensation costs related to non-vested stock option awards.

(in thousands, except share and per share amounts)

Note 8 — Share-Based Payment Awards (continued)

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 initial offering began on December 17, 2018 and ended on December 10, 2019. The initial offering consisted of two purchase periods, with the first purchase period ended on June 10, 2019 and the second purchase period ended on December 10, 2019. 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 $73, $71 and $112 in 2021, 2020 and 2019, respectively, related to the ESPP. The weighted average grant date fair value of share awards in 2021, 2020 and 2019 was $2.50, $2.32 and $2.56 per share, respectively. Employees contributed $205 and $115 to the ESPP during 2021 and 2020, respectively. Of these amounts, $22 and $18 at December 31, 2021 and 2020, respectively, is included in accrued liabilities in the accompanying balance sheets.

Note 9 — 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, unvested RSAs and RSUs, and warrants at December 31, 2021, 2020 and 2019 were 4,286,687, 3,371,489 and 3,590,465, 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, 2021	Year ended December 31, 2020	Year ended December 31, 2019
Net loss	$ (1,955)	$ (27,970)	$ (18,320)
Weighted average common shares outstanding (basic and diluted)	25,207,299	21,010,058	17,760,761
Net loss per common share (basic and diluted)	$ (0.08)	$ (1.33)	$ (1.03)

Note 10 — Related Party Transactions

Harrow

Harrow was issued 3,500,000 shares of the Company's common stock at the formation of the Company at the $0.001 par value per share price as the paid-in-capital contribution from Harrow. In April 2021, Harrow sold 1,518,000 shares of the Eton common stock it owned in an underwritten public offering. As of December 31, 2021, Harrow owned 1,982,000 shares of Eton's common shares which represents 8.0% of the Company's common shares outstanding. The Company and Harrow signed licensing agreements for two products developed by Harrow whereby Harrow assigned the product rights to the Company. In July 2018, the Company determined that one of the products was not viable for its portfolio of product opportunities and cancelled the licensing agreement whereby Harrow retains the product rights.

On May 6, 2019, the Company entered into an Asset Purchase Agreement (the "CT-100 Asset Purchase Agreement") with Harrow. Pursuant to the CT-100 Asset Purchase Agreement, the Company sold all of its right, title and interest in CT-100 to Harrow, including any such product that incorporates or utilizes its intellectual property rights (a "Product" or, collectively, "Products"). Pursuant to the CT-100 Asset Purchase Agreement, Harrow will make certain payments to the Company upon the achievement of certain development and commercial milestones. In addition, Harrow is required to pay the Company a royalty in the low-single digit percentage range worldwide on a country-by-country basis on net sales for a period of the longer of 15 years from the date of the first commercial sale of a product in a particular country or the time that a valid intellectual property claim on such Product remains in force in the applicable country. The CT-100 Asset Purchase Agreement also contains customary representations, warranties, covenants and indemnities by the parties. To date, there have not been any sales of the CT-100 product and therefore no earned royalties to the Company for this product.

Additionally, the Chief Executive Officer of Harrow was a member of the Company's board of directors until March 17, 2021 when he retired from service with the board. The Company issued 25,000 shares to the Harrow CEO in April 2021 after his retirement from the Company's board associated with RSU's that were previously fully vested.

In late March 2021, the Company closed its laboratory operation in Lake Zurich, Illinois and in May 2021 it reached an agreement for Imprimis Pharmaceuticals, a subsidiary of Harrow, to purchase its lab equipment for $700 which was $181 above the Company's net book value of the equipment.

Chief Executive Officer

The CEO has a partial interest in a company that the Company has partnered with for its EM-100 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. The Company also held a right of first refusal to obtain the exclusive license rights for geographic areas outside of the United States. Pursuant to the Eyemax Agreement, the Company was responsible for all costs of testing and FDA approval of the product, other than the FDA filing fee which was paid by Eyemax. The Company was also to be responsible for commercializing the product in the United States at its expense. The Company paid Eyemax $250 upon execution of the Eyemax Agreement, which was recorded as a component of R&D expense. 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 from the date of the Eyemax Agreement, subject to successive two-year renewals unless the Company elected to terminate the Eyemax Agreement. There were no amounts due under the terms of the Eyemax Agreement as of December 31, 2021 or 2020.

Note 10 — Related Party Transactions (continued)

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. Under the Amended Agreement, the Company assumed certain liabilities of Eyemax under its Exclusive Development & Supply Agreement with Excelvision SAS dated as of July 11, 2013, as amended (the "Excelvision Agreement"), with respect to certain territories and arising during certain time periods. 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. Following payment of the milestones, the Company is entitled to retain all of the non-royalty transaction revenues and royalties up to $2,000 (the "Recovery Amount"). After the Company has retained the full Recovery Amount, it is entitled to retain half of all royalty and non-royalty transaction revenue. The Company has realized $1,735 of the non-royalty and royalty revenue as of December 31, 2021. The Amended Agreement also contains customary representations, warranties, covenants and indemnities by the parties. 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 EM-100, which was approved by the FDA in September 2020, will be split between Eyemax and the Company. The royalty from Bausch Health is subject to reduction if a competitive product with the same active pharmaceutical ingredient is launched in the U.S. or if the EM-100 U.S market share falls below a specified target percentage. There were no amounts due Eyemax under the terms of the Amended Agreement as of December 31, 2021 or 2020.

(in thousands, except share and per share amounts)

Note 11 — 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.

On January 12, 2018, the Company signed an amended lease agreement to lease additional office space adjacent to its current corporate office space in Deer Park, Illinois. The amended lease was scheduled to expire at the end of March 2021. In October 2020, the Company renewed its office lease for a two-year period through March 31, 2023 and recorded $195 in ROU assets and $195 in operating lease liabilities associate with the lease extension. On March 7, 2018, the Company entered into a lease for laboratory space at a complex in Lake Zurich, Illinois. The lease commenced on March 7, 2018 and was scheduled to expire in February 2021. In November 2020, this laboratory lease was extended to June 2021 and was not extended after that date as the Company completed an evaluation its laboratory operations requirements and determined it would discontinue the laboratory activities and outsource its requirements.

The Company does not have any lease contracts that contain: (1) an option to extend that the Company is reasonably certain to exercise, (2) an option to terminate that the Company is reasonably certain to exercise, or (3) an option to extend (or not to terminate) in which exercise of the option is controlled by the lessor. Additionally, the Company does not have any leases with residual value guarantees or material restrictive covenants. Lease liabilities and their corresponding right-of-use assets have been recorded based on the present value of the future lease payments over the expected lease term. One of the Company's lease agreements contains provisions for escalating rent payments over the term of the lease.

The Company's leases do not contain readily determinable implicit discount rates, and therefore, the Company was required to use its incremental borrowing rate of 7.8% to discount the future lease payments based on information available at lease commencement. In October 2020, the new discount rate for the office lease extension was estimated at 5.4%. The incremental borrowing rate was estimated by determining the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

For the years ended December 31, 2021, 2020 and 2019, the Company recorded $113, $139, and $140, respectively, in rent expense.

The Company's operating lease cost as presented in the "Research and Development" and "General and Administrative" captions in the statements of operations was $9, $55 and $55 and $86, $84 and $85 for the years ended December 31, 2021, 2020 and 2019, respectively. Cash paid for amounts included in the measurement of operating lease liabilities was $83 and $131 for years ended December 31, 2021 and 2020, respectively. The ROU asset amortization for years ended December 31, 2021, 2020 and 2019 was $88, $129 and $121, respectively, and is reflected in depreciation and amortization in the Company's statements of cash flows. As of December 31, 2021, the weighted-average remaining lease term was 1.25 years, and the weighted-average discount rate was 5.4%.

The table below presents the lease-related assets and liabilities recorded on the balance sheet as of December 31, 2021:

Assets	**Classification**	
Operating lease right-of-use assets	Operating lease right-of-use assets, net	$ 104
Total leased assets		$ 104
Liabilities		
Operating lease liabilities, current	Accrued liabilities	$ 84
Operating lease liabilities, noncurrent	Operating lease liabilities, net of current portion	15
Total operating lease liabilities		$ 99

The Company's future annual lease commitments as of December 31, 2021 are as indicated below:

	Total	**2022**	**2023**	**Thereafter**
Undiscounted lease payments	**$ 102**	**$ 87**	**$ 15**	$ —
Less: Imputed interest	**(3)**			
Total lease liabilities	**$ 99**			

(in thousands, except share and per share amounts)

Note 12 – Income Taxes

The provision for income taxes for the Company consists of the following for the years ended December 31, 2021, 2020 and 2019:

	Year ended December 31, 2021	Year ended December 31, 2020	Year ended December 31, 2019
Current:			
Federal	$ —	$ —	$ —
State	—	—	—
Total current expense	—	—	—
Deferred:			
Federal	460	6,020	3,961
State	185	2,151	1,415
Change in valuation allowance	(645)	(8,171)	(5,376)
Total deferred expense	—	—	—
Total provision	**$ —**	**$ —**	**$ —**

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.

The significant components of the Company's deferred tax assets as of December 31, 2021 and 2020 are as follows:

	December 31, 2021	December 31, 2020
Net operating losses	$ 15,871	$ 16,250
Stock-based expenses	2,135	1,257
Accruals and other	542	396
Total deferred tax assets	18,548	17,903
Valuation allowance	(18,548)	(17,903)
Net deferred tax assets	$ —	$ —

Based on the uncertainty of future taxable income at this time management believes a 100% valuation reserve for the $18,548 and $17,903 deferred tax assets at December 31, 2021 and 2020, respectively, is appropriate.

A reconciliation of the statutory federal tax rate to effective tax rate is shown below:

	Year ended December 31 2021	Year ended December 31, 2020	Year ended December 31, 2019
Benefit at statutory rate	(21.0)%	(21.0)%	(21.0)%
Permanent items (primarily warrants and stock compensation)	(2.5)	(0.5)	(0.6)
State tax benefit	(9.5)	(7.7)	(7.7)
Federal rate change	—	—	—
Other items	—	—	—
Establishment of valuation allowance	33.0	29.2	29.3
Income tax expense	—%	—%	—%

Note 12 – Income Taxes (continued)

The Company has a federal and state NOL carryforward of $55,675 as of December 31, 2021. Under the Tax Act, federal NOLs incurred in taxable years ending after December 31, 2017 in the amount of $50,023 may be carried forward indefinitely, but the deductibility of federal NOLs generated in tax years beginning before December 31, 2017 in the amount of $5,652 will expire in 2037. The state NOL carry forward will begin to expire in 2029.

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.

Note 13 - 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, 2021, 2020 and 2019, the Company made $154, $117 and $113, respectively, in matching contributions.

Note 14 — 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 Company acquired the exclusive rights to sell the Cysteine injection product in the United States pursuant to a sales and marketing agreement dated November 17, 2017 with an unaffiliated third party (the "Sales Agreement"). Pursuant to the Sales Agreement, the licensor is responsible for obtaining FDA approval, at its expense, and the Company is responsible for commercializing the product in the United States at its expense. The Company was to pay the third party 50% of the net profit from the sale of the product, however, in February 2020, it executed an amendment to the Sales and Marketing Agreement. Under the revised terms, the Company will be responsible for paragraph IV related litigation and will be entitled to 62.5% of product profit. The initial term is for the first 10 years following the first commercial sale of the product.

On February 8, 2019, the Company entered into an Exclusive Licensing and Supply Agreement (the "ET-202 License Agreement") with Sintetica SA ("Sintetica") for marketing rights in the United States to Biorphen® which is used for the treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia. The product was submitted to the FDA for review and subsequently received FDA approval on October 21, 2019. Pursuant to the terms of the ET-202 License Agreement, the Company is responsible for marketing activities and Sintetica is responsible for development, manufacturing, and the regulatory activities related to approval. The Company paid Sintetica a licensing payment of $2,000 upon execution of the ET-202 License Agreement and $750 upon the commencement of commercial product shipments. Sintetica supplies Biorphen to the Company at its direct costs and the Company retains 5% of net sales as a marketing fee. Sintetica is entitled to receive the first $500 of product profits. All additional profit will be split 50% to the Company and 50% to Sintetica. The ET-202 License Agreement has a ten-year term from the first commercial sale of Biorphen which occurred in November 2019. There was a gross loss for Biorphen for the years ended December 31, 2021 and 2020 due to slower than anticipated sales and a product price reduction through the Company's wholesale customers.

On February 8, 2019, the Company also entered into an Exclusive Licensing and Supply Agreement (the "ET-203 License Agreement") with Sintetica for marketing rights in the United States to ephedrine HCl (brand name Rezipres®), an injectable product candidate for use in the hospital setting. Pursuant to the terms of the ET-203 License Agreement, the Company will be responsible for marketing activities and Sintetica will be responsible for development, manufacturing, and regulatory activities related to obtaining regulatory approval. The Company paid Sintetica a licensing payment of $1,000 upon execution of the ET-203 License Agreement which was refunded to Eton in early 2020 due to the FDA not accepting the ET-203 file submission by Sintetica. The Rezipres product was successfully resubmitted in late 2020 and the Company paid a $600 milestone fee in July 2021 and will pay $750 upon the commercial sale of the product. Sintetica supplies Rezipres to the Company at its direct costs. The Company will retain 5% of net sales as a marketing fee. Sintetica will be entitled to receive the first $500 of product profits. All additional profit will be split 50% to the Company and 50% to Sintetica. The ET-203 License Agreement has a ten-year term from first commercial sale of product.

Note 14 — Commitments and Contingencies (continued)

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. The Company has recognized $17,000 in milestone revenues to date from these three products and may receive up to $25,000 in additional milestone revenues related to FDA product approvals and the future sales levels for the products.

During the years ended December 31, 2021, 2020 and 2019, 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. The Company subsequently filed the product with the FDA in October 2020 and paid a $1,438 filing fee. 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 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. LMW will be responsible for development and manufacturing of ET-104. The Company paid the licensor $350 upon execution of the Agreement and an additional $350 after receiving successful bioequivalence study results, and $325 upon the FDA's acceptance of the NDA for review and will pay $325 upon FDA approval of the NDA, $650 upon issuance of patent covering ET-104 listed in the FDA's Orange Book and $500 in the event that product sales in excess of $10,000 were achieved within a calendar year. In addition, the Company was required to pay the licensor 35% of the net profit from product sales. The Agreement was for an initial term of 10 years from the date of the first commercial sale of the product. The Company was to retain sole ownership of the NDA after expiration of the Agreement.

On June 12, 2019, the Company entered into an Exclusive Licensing and Supply Agreement (the "ET-105 License Agreement") with Aucta Pharmaceuticals, Inc. ("Aucta") for marketing rights in the United States to Lamotrigine, an oral suspension product candidate for use as an adjunct therapy for partial seizures, primary generalized tonic-clonic seizures, and generalized seizures of Lennox-Gastaut syndrome in patients two years of age and older. Pursuant to the terms of the ET-105 License Agreement, the Company was to be responsible for marketing activities and Aucta will be responsible for development, manufacturing, and regulatory activities related to obtaining regulatory approval. The Company paid Aucta a licensing payment of $2,000 in August 2019 upon receiving an acceptance for review letter from the FDA and will pay $2,450 upon FDA approval and commercial sales of the product candidate and another $1,000 upon issuance of an Orange-book listed patent. If Aucta successfully completes a Lamotrigine product line extension product, Eton will pay $1,500 upon FDA acceptance of the product filing, $1,500 upon FDA approval and commercial sales of the extension product candidate and $450 if the intellectual property for the extension product is transferred to Azurity. Aucta will be entitled to receive milestone payments from the Company of up to $3,000 based on commercial success of the product, including:

- $1,000 when net sales exceed $10 million in a calendar year
- $2,000 when net sales exceed $20 million in a calendar year

Azurity will assume royalty or profit share obligations owed to development partners as well as additional milestone payments based on sales volume targets.

Note 14 — Commitments and Contingencies (continued)

On March 27, 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. Alkindi Sprinkle's New Drug Application (NDA) was approved by the FDA on September 29, 2020 as a replacement therapy for pediatric adrenal insufficiency (AI), including congenital adrenal hyperplasia (CAH) in patients from birth to less than 17 years of age.

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 (see Note 6). The total amount of $4,764 was recorded as a component of research and development expense in the Company's statement of operations for the year ended December 31, 2020. The Company will also pay Diurnal $2,500 if the product obtains orphan drug exclusivity status from the FDA.

On June 15, 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 expects to submit the New Drug Application (NDA) to the FDA in 2023 and plans to request orphan drug designation. The Company paid Crossject $500 upon signing and could pay up to $4,500 in development milestones and up to $6,000 in commercial milestones, as well as a 10% royalty on net sales.

On October 28, 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 on October 12, 2021. The product is an AB-rated, substitutable generic version of Carbaglu®. The Company paid $3,250 upon signing and will retain 50% of future product profits with the balance being distributed to the licensor and manufacturer.

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, 2021 or 2020.

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 principal executive officer and our principal financial officer, to allow timely decisions regarding required disclosure.

The design of any disclosure controls and procedures also is based in part upon 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.

As of December 31, 2021, an evaluation was conducted under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, 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, 2021.

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 principal executive officer and principal financial officer, of the effectiveness of our internal control over financial reporting as of December 31, 2021, 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, 2021.

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, 2021 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

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 2021 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, 2021, 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:

Report of Independent Registered Public Accounting Firm
Balance Sheets as of December 31, 2021 and 2020
Statements of Operations for the years ended December 31, 2021, 2020 and 2019
Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2021, 2020 and 2019
Statements of Cash Flows for the years ended December 31, 2021, 2020 and 2019
Notes to the Financial Statements

(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	Warrant dated May 4, 2017 issued to Liquid Patent Advisors, LLC (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
4.3	Warrant dated June 26, 2017 issued to National Securities Corporation (incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
4.4	Form of Underwriter's Warrant (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
4.5	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).

Exhibit No.	Description
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†	Exclusive Development and Supply Agreement (DS-100) dated July 9, 2017 between Andersen Pharma, LLC and the Registrant (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.4	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)
10.5†	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).
10.6+	Eton Pharmaceuticals, Inc. 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.7+	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).
10.8+	Offer Letter Agreement by and between the Registrant and W. Wilson Troutman, dated as of June 27, 2017 (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.9	Exclusive License and Supply Agreement (ET-103) dated August 3, 2018 between the Registrant, Liqmeds Worldwide Limited and LM Manufacturing, Ltd. (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.10+	Eton Pharmaceuticals, Inc. 2018 Stock Incentive Plan (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.11+	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
10.12+	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).
10.13	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).
10.14.	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).
23.1	Consent of KMJ Corbin & Company LLP, Independent Registered Public Accounting Firm.
24.1	Power of Attorney. Reference is made to the signature page hereto.
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.
101	The following financial information from the Company's Annual Report on Form 10-K for the year ended December 31, 2020, formatted in Extensible Business Reporting Language (XBRL): (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.

† 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.

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 16, 2022

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

By: */s/ W. Wilson Troutman*
W. Wilson Troutman
Chief Financial Officer
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Sean Brynjelsen, his true and lawful attorney-in-fact and agent, each with full power of substitution and resubstitution, severally, for him and in his 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 16, 2022
/s/ W. Wilson Troutman W. Wilson Troutman	Chief Financial Officer, Treasurer and Secretary *(Principal Financial and Accounting Officer)*	March 16, 2022
/s/ Jennifer M. Adams Jennifer M. Adams	Director	March 16, 2022
/s/ Charles J. Casamento Charles J. Casamento	Director	March 16, 2022
/s/ Paul V. Maier Paul V. Maier	Director	March 16, 2022
/s/ Norbert G. Riedel, Ph.D. Norbert G. Riedel, Ph.D.	Director	March 16, 2022

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in Registration Statement Nos. 333-228493 and 333-230572 on Form S-8 and Registration Statement Nos. 333-235329 and 333-240252 on Form S-3 of our report dated March 16, 2022, relating to the financial statements of Eton Pharmaceuticals, Inc., appearing in this Annual Report on Form 10-K of Eton Pharmaceuticals, Inc. for the year ended December 31, 2021.

/s/ KMJ Corbin & Company LLP

Irvine, California
March 16, 2022

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 16, 2022

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, W. Wilson Troutman, 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 16, 2022

By: */s/ W. Wilson Troutman*
W. Wilson Troutman
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 W. Wilson Troutman, 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, 2021 (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 16th day of March, 2022.

/s/ Sean E. Brynjelsen	*/s/ W. Wilson Troutman*
Sean E. Brynjelsen President and Chief Executive Officer (*Principal Executive Officer*)	W. Wilson Troutman Chief Financial 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.