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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO

Commission File Number 001-38738

ETON PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**37-1858472**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
21925 W. Field Parkway, Suite 235 Deer Park, IL	**60010-7208**
(Address of principal executive offices)	**(Zip Code)**

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

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

Title of each class	**Name of each exchange on which registered**
Common Stock, $0.001 par value	**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 [X]

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 [X]

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 [X] 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 [X] NO [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

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	[X]	Small reporting company	[X]
		Emerging growth company	[X]

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. [X]

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

The registrant did not have a public float on the last business day of its most recently completed second fiscal quarter because there was no public market for the registrant's common equity as of such date.

As of March 15, 2019, the registrant had 17,627,928 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 2019 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, 2018, are incorporated by reference into Part III of this Annual Report on Form 10-K.

TABLE OF CONTENTS

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 future financial and operating results;
- our intentions, expectations and beliefs regarding anticipated growth, market penetration and trends in our business;
- the timing and success of our plan of commercialization;
- our ability to successfully develop and clinically test our product candidates;
- our ability to submit for FDA approval of our product candidates through the 505(b)(2) regulatory pathway;
- our ability to obtain FDA approval for any of our product candidates;
- our ability to comply with all U.S. and foreign regulations concerning the development, manufacture and sale of our product candidates;
- the adequacy of the net proceeds from our initial public offering;
- the effects of market conditions on our stock price and operating results;
- our ability to maintain, protect and enhance our intellectual property;
- the effects of increased competition in our market and our ability to compete effectively;
- costs associated with initiating and defending intellectual property infringement and other claims;
- the attraction and retention of qualified employees and key personnel;
- 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 report. 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 were formed in April 2017 as a specialty pharmaceutical company focused on developing and commercializing innovative pharmaceutical products utilizing the FDA's 505(b)(2) regulatory pathway. Our business model is to develop proprietary innovative products that fulfill an unmet patient need. Since our formation, we have focused our efforts on the development of our initial product candidates, engaging in preliminary discussions with the FDA concerning the regulatory pathway for certain additional product candidates, registration filings of our initial product candidates and the licensing of late-stage product candidates.

We have established a diversified pipeline of product candidates in various stages of development. Our corporate strategy is to pursue what we perceive to be low-risk 505(b)(2) product candidates where existing published literature, historical clinical trials, or physician usage has established safety or efficacy of the molecule, thereby reducing the incremental clinical burden required for us to bring the product to patients. We intend to focus on product candidates that we believe will offer innovative and proprietary functional advantages to currently available alternatives, as well as product candidates that are currently unapproved.

We typically pursue product candidates that require a single small Phase 3 trial, a bio-equivalence trial, or literature-based filings. Prior to initiating significant development activities on a product candidate, we intend to meet with the FDA to establish a defined clinical and regulatory path to approval.

Market Opportunity

We believe there is a large market opportunity for developing drugs that offer improvements to currently approved treatments and address unmet patient needs. We pursue product opportunities where patient demand is not being met by current FDA-approved pharmaceutical products. This may include products that are being supplied on an unapproved basis, products that are currently being compounded, products that are approved and sold internationally but not available in the United States, or approved products where we believe we can provide a lower-cost alternative to an existing high-priced branded product. While we may opportunistically pursue 505(b)(2) opportunities across all dosage forms, we are primarily focused on liquid products, including injectables, oral liquids and ophthalmics.

505(b)(2) Pathway. The 505(b)(2) pathway is intended for molecules that have been previously approved by the FDA or have already been proven to be safe and effective. A 505(b)(2) product typically reformulates the known molecule in a new strength or dosage form. 505(b)(2) products have the advantage of potentially significantly lower development costs and shorter development timelines versus traditional new molecular entities. We expect to utilize the 505(b)(2) pathway for all of our current product candidates, except for EM-100, for which we are utilizing the 505(j) pathway.

A 505(b)(2) NDA is an application that contains full reports of investigations of safety and effectiveness, but where at least some of the information required for approval comes from studies not conducted by or for the applicant. This alternate regulatory pathway enables the applicant to rely, in part, on the FDA's findings of safety and efficacy for an existing product, or published literature, in support of its application. A 505(b)(2) product candidate might rely on the clinical studies or literature of a previously FDA-approved drug, or rely on the literature and physician usage of an FDA-unapproved, or DESI, drug. The clinical requirements for a 505(b)(2) drug candidate can vary widely from product to product and may include new clinical trials, bioequivalence trials, limited safety and efficacy trials, or full Phase 1 through 3 trials. Unless the FDA has released a guidance document, the clinical requirement for a new product candidate is typically not known until the drug sponsor has a Pre-IND meeting with the FDA. We believe there is a significant opportunity to pursue liquid or other alternative formulations of off-patent drugs using the 505(b)(2) regulatory pathway.

We are utilizing the 505(j) pathway for obtaining FDA approval for our EM-100 product candidate. The 505(j) pathway is used for product candidates that are therapeutically equivalent to an approved product and 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.

DESI Program. Upon its enactment in 1938, the FDCA required new drugs to demonstrate that they were safe before they could be marketed. In 1962, the FDCA was amended to require that new drugs demonstrate that they were effective as well as safe. Following the 1962 amendments to the FDCA, the FDA adopted a program called the Drug Efficacy Study Implementation, or DESI, to review the efficacy of drugs approved between 1938 and 1962, and the drugs approved between 1938 and 1962 are commonly referred to as DESI drugs. DESI drugs were allowed to remain on the market until they were re-reviewed as long as they weren't substantially changed. The DESI program removed many products that were deemed to not be effective, but there was no comprehensive list of drugs approved and marketed at the time and not all drugs were re-reviewed. As a result, many DESI products remained marketed without a formal approval for effectiveness. Based on the FDA's published guidance document, we would expect the currently marketed product to exit the market within one year of our product's approval. We believe there is a significant opportunity to obtain FDA approval of unapproved DESI drugs.

Goals and Strengths

Our goal is to become a leading specialty pharmaceutical company through the introduction of innovative medicines that are affordable and available to all patients. We believe our competitive strengths include our:

- unique knowledge of the industry, including our ability to identify product opportunities;
- management's regulatory and development experience, particularly within the 505(b)(2) pathway;
- our portfolio of attractive assets that we believe will enable us to compete effectively in the market;
- management's experience in business development, M&A, licensing activities and broad industry connections;
- differentiated business model as compared to generic and branded specialty pharmaceutical drug companies, utilizing the 505(b)(2) pathway; and
- patent rights, know-how, exclusive API and manufacturing relationships.

Strategy

We intend to grow our business through opportunistic development and licensing of 505(b)(2) products. Our primary criteria for product candidates are:

- Low regulatory risk: We focus on molecules where there is significant existing clinical data or literature to show that the product is safe and effective, creating a higher probability of clinical and regulatory success. Our product candidates do not typically require extensive clinical trials.
- Low commercial risk: We select product candidates where patient demand is apparent, providing a high-degree of confidence in commercial success. We pursue products that are currently compounded, sold as unapproved products, or where we are providing a lower-cost alternative to high-price branded products with strong existing demand. Our candidates are typically well-known molecules that require minimal sales force promotion, so we able to pursue opportunities across various therapeutic areas.

- Short development timelines: We believe that the product candidates internally developed by us typically have a path to approval of approximately 36 months from the time of product initiation. For product opportunities acquired or licensed by us, we primarily focus on opportunities where the NDA has been submitted, or is near submission, and the product candidate could be less than 18 months away from the commercial market.

- Relatively low cost: We prefer to develop numerous lower-cost projects, rather than a single high-cost candidate. We do not believe that development costs are necessarily correlated with the earnings potential of products.

- Protection from competition. We endeavor to acquire rights to or internally develop products that may receive Orange-book listed patents or FDA-granted exclusivity. We have also entered into exclusive agreements with manufacturing partners and API suppliers on most of our products.

We intend to aggressively pursue value-creating business development opportunities, including the licensing or acquisition of individual development-stage or commercial products, as well as the acquisition of companies or subsidiaries of operating companies. Our management team has a track record of successfully growing businesses through value-creating business development activities and has completed numerous transactions during their careers. At any particular time, we are typically evaluating multiple acquisition or licensing opportunities of various sizes. We believe management's business development experience and broad industry contacts provide us with a competitive advantage.

Products

We have assembled a diversified pipeline of high-value drug candidates in various stages of development. Four of our products have been submitted to the FDA.

We source products both internally, by contracting with third-parties for development of our internal candidates on a fee-for-service basis, and externally, through the licensing or acquisition of existing development or commercial products. For products that we have licensed or acquired from third parties, we typically are required to pay a combination of licensing fees, milestone payments, and/or profit share/royalty payments to our partner.

We expect to continue growing our pipeline of product candidates through business development activities, and we are in active discussions with the FDA on additional products that may be added to our pipeline if we elect to proceed with the opportunity after the outcome of our pre-IND meeting with the FDA.

Innovative Formula Products

For our innovative formula products, we have developed improved versions of already FDA-approved products. We believe our unique formulas will provide a significant benefit to patients or practitioners, in the form of improved safety, efficacy, or more affordable costs. Our innovative formula products include:

EM-100. EM-100 is an ophthalmic solution indicated for the treatment of allergic conjunctivitis. EM-100 is a unique preservative-free formulation of ketotifen. Ketotifen is an FDA-approved molecule that is widely used and sold via the over-the-counter channel. Ketotifen is an antihistamine for the eye that treats allergic symptoms. It is also a mast cell stabilizer that minimizes allergic reactions by reducing the release of natural substances that cause an allergic reaction. Side effects associated with ketotifen use include eye dryness, headache, and runny nose. All currently FDA-approved ketotifen ophthalmic products contain the preservative benzalkonium chloride, which has been shown to cause irritation and negatively impact long-term eye health. We believe our unique preservative-free formulation will successfully treat allergic conjunctivitis and, at the same time, provide an increased comfort profile to patients.

As of the date of this Annual Report, there are no FDA approved preservative-free ophthalmic products available for the treatment of allergic conjunctivitis. We are not aware of any other companies working on preservative-free versions of ketotifen, or any other allergic conjunctivitis treatment, so we expect EM-100 to be the first preservative-free product in its class.

Our development partner previously submitted an ANDA for EM-100 and in response to a complete response letter, or CRL, from the FDA we ran a bioequivalence trial in April 2018. The 65-patient clinical trial successfully showed statistically significant non-inferiority to ZADITOR (ketotifen fumarate ophthalmic solution 0.035%) and statistically significant superiority to the placebo with no adverse events reported. We responded to the CRL in September 2018. We are utilizing the 505(j) pathway for FDA approval of EM-100. The 505(j) pathway is typically utilized for generic drug candidates. We do not anticipate utilizing the 505(j) pathway for any other of our current product candidates.

On February 18, 2019, we entered into an Asset Purchase Agreement with Bausch Health Ireland Limited ("Bausch") for Bausch to sell EM-100 in the United States, including any such product that incorporates or utilizes our intellectual property rights with respect to EM-100.

ET-202. In February 2019 we acquired rights to ET-202. ET-202 is an injectable product candidate to be used in the hospital setting. ET-202 is an innovative ready-to-use formula of an existing injectable product that we believe to be one of the highest volume compounded products in the hospital setting. The existing FDA-approved product is only available in a concentrated strength that must be diluted prior to administration to patients. Hospitals currently purchase non-FDA approved ready-to-use products from compounding facilities, or manually dilute the products in-house. Our product candidate has been developed in a ready-to-use strength that can be immediately administered in patients, eliminating the need for additional dilution steps. We believe that if approved, ET-202 will offer significant benefits to hospitals over the current compounded products, including: longer shelf-life, elimination of compounding errors, greater sterility assurance, and more consistent supply. Our product development partner submitted an NDA for ET-202 in December 2018. The NDA has been accepted for review by the FDA, and was assigned a PDUFA target action date in October 2019.

ET-103. ET-103 is a unique oral liquid formulation of levothyroxine for the treatment of hypothyroidism. Hypothyroidism, also called underactive thyroid or low thyroid, is a disorder of the endocrine system in which the thyroid gland does not produce enough thyroid hormone. Levothyroxine is a synthetic form of thyroxine, an endogenous hormone secreted by the thyroid gland, which is converted to its active metabolite, L-triiodothyronine. Thyroxine and L-triiodothyronine bind to thyroid receptor proteins in the cell nucleus and cause metabolic effects through the control of DNA transcription and protein synthesis.

Currently, levothyroxine is delivered primarily in tablet and capsule form. Levothyroxine is one of the most frequently prescribed medications in the United States with sales of greater than $2.6 billion and more than 5.7 billion tablets and capsules sold annually. It is estimated that 15% of Americans over the age of 55 take levothyroxine daily. Side effects reported with oral use of levothyroxine include fatigue, weight loss, heat intolerance, fever and excessive sweating. We believe ET-103 will offer a significant benefit to the subset of levothyroxine patients that have challenges swallowing or need more flexible dosing. As a result, we expect ET-103 to capture a small percentage of the overall levothyroxine tablet and capsule market.

We plan to submit a 505(b)(2) NDA application referencing Synthroid®, the leading levothyroxine product in the market. We held a Pre-IND meeting with the FDA in September 2018, and the agency agreed with our proposal to conduct a bridging study between ET-103 and Synthroid as the principal means of proving safety and efficacy. We have initiated the study and, if successful, plan to submit an NDA in 2019.

ET-203. In February 2019 we signed a licensing agreement for ET-203. ET-203 is an injectable product candidate to be used in the hospital setting. ET-203 is an innovative ready-to-use formula of an existing injectable product that we believe to be one of the highest volume compounded products in the hospital setting. The existing FDA-approved product is only available in concentrated strengths that must be diluted prior to administration to patients. Hospitals currently purchase non-FDA approved ready-to-use products from compounding facilities, or manually dilute the products in-house. Our product candidate has been developed in a ready-to-use strength that can be immediately administered in patients, eliminating the need for additional dilution steps. We believe that if approved, ET-203 will offer significant benefits to hospitals over the current compounded products, including: longer shelf-life, elimination of compounding errors, greater sterility assurance, and more consistent supply. An NDA for ET-203 is expected to be submitted in 2019.

ET-104. In January 2019 we signed a licensing agreement for ET-104, an innovative oral liquid product candidate targeting a neurological indication. ET-104's active ingredient is approved and marketed in an oral solid formulation, but the active ingredient is not approved by the FDA in liquid form. Currently, patients requiring liquid formulations of the active ingredient are reliant on compounded products. ET-104 is expected to address this significant unmet patient need. Our development partner filed a patent application on its unique formula in March 2019. We and our development partner expect to complete a bioequivalence trial and, if successful, expect to submit an NDA with the FDA by the end of 2019.

ET-101. ET-101 is an innovative oral liquid product for a neurological indication. The active ingredient in ET-101 is FDA-approved in an oral solid dosage form and there are several approved products in the market in oral solid dosage form. ET-101 is not approved in oral liquid form. The exact mechanism of action of the active ingredient is unknown. Based on a pre-IND meeting with the FDA, we expect to conduct a bioequivalence trial for ET-101 as the principal means of proving safety and efficacy. We anticipate submitting a patent application on our unique formulation and expect to submit an NDA for ET-101 in 2020.

ET-102. ET-102 is an innovative oral liquid product for a neurological indication. The active ingredient in ET-102 is FDA-approved in an oral solid dosage form, but not approved in an oral liquid form. The precise mechanism of action of ET-102 is not fully known but it is believed to be capable of inhibiting both monosynaptic and polysynaptic reflexes at the spinal level. Based on a pre-IND meeting with the FDA, we expect to conduct a bioequivalence trial for ET-102 as the principal means of proving safety and efficacy. We expect to submit an NDA for ET-102 in 2020.

CT-100. CT-100 is our patent-pending synthetic corticotropin therapeutic candidate for the treatment of rheumatoid arthritis. Our CT-100 product candidate mimics the amino acid chain of H.P. Acthar Gel. Our patent-pending technology stabilizes a known unstable molecule of the approved drug. It is well documented that natural corticotropin is an unstable molecule and that its instability leads to reduced potency over time or at higher temperatures. We believe that our synthetic corticotropin is stable and retains its potency far longer that H.P. Acthar Gel. Our synthetic corticotropin is a 39-chain amino acid peptide synthetic adrenocorticotrophic hormone, non-gelatin and preservative-free. CT-100 is an injectable product candidate that could be administered in both the hospital and home settings.

We have held two written response meetings with the FDA regarding CT-100 and we are currently working with a clinical research organization ("CRO") to analyze the cost and protocol for CT-100's clinical program based on the FDA's feedback. Due to the long projected development timeline and significant clinical cost required to bring CT-100, we believe CT-100 does not fit our current business strategy. We plan to out-license the product to a company that can advance the product's development, allowing us to retain economic exposure to CT-100's potential commercial sales without requiring any additional investment in this product candidate's development.

DESI Conversion Products

Our portfolio also includes DESI conversion product candidates for which we are seeking formal FDA approval for molecules where the U.S market is currently relying on a DESI product. We will seek to convert the market from the current DESI products to our formally approved products. DESI products, also known as "grandfathered" or "unapproved" products, are products that were marketed prior to 1962 when the FDA began requiring proof of efficacy, in addition to safety, in order to gain approval. The FDA has allowed DESI products to remain on the market until someone receives formal FDA approval for the molecule. We will pursue a formal approval via the 505(b)(2) NDA pathway for our products. Based on the FDA's published guidance document, we would expect the currently marketed unapproved product to exit the market within one year of our product's approval.

Currently, the combined IQVIA sales of the DESI products we are referencing is greater than $40 million. With more consistent supply and promotion of our product candidates, we believe our market opportunity is larger than the historic sales levels. Our DESI conversion products include:

DS-300. DS-300 is an injectable product intended for use as an additive to meet the nutritional requirements of neonates requiring total parenteral nutrition. The product is administered in the hospital setting to patients that are unable to naturally produce sufficient levels of needed nutrients. DS-300's active ingredient is naturally occurring in the body and has been administered to patients as a supplement for decades with no reports of any meaningful adverse events besides occasional infusion site reactions.

Based on a Pre-IND meeting with the FDA, DS-300's NDA was submitted as a literature-based filing as the principal means of proving safety and efficacy. The NDA references 24 studies published in well-respected medical publications, tracking more than 700 patients. The product's NDA was filed with the FDA in January 2018. DS-300 has been granted Fast Track Designation by the FDA and is being reviewed by the FDA as a Rolling Review, meaning we are allowed to submit sections of our NDA as they are completed rather than waiting for completion of the entire NDA. All sections of the NDA have been submitted. However, the original manufacturing site is no longer available, so the product is being transferred to a different FDA-approved manufacturing site. We are not aware of any drug companies that have publicly disclosed their development of a product based on DS-300's active ingredient.

DS-200. DS-200 is an injectable nutrition product indicated for use as a supplement to intravenous solutions for total parenteral nutrition. The product is administered in the hospital setting to patients that are unable to naturally produce sufficient levels of needed nutrients and minerals. DS-200's active ingredient is naturally occurring in the body and has been administered to patients as a supplement for decades with no reports of any meaningful adverse events besides occasional infusion site reactions.

Based on a Pre-IND meeting with the FDA, DS-200 was submitted as a literature-based filing as the principal means of proving safety and efficacy. We referenced more than 15 published articles which showed safety and efficacy in studies involving more than 2,000 patients. DS-200 has been granted Fast Track Designation by the FDA, which we believe highlights the unmet need our product is aiming to address. DS-200's NDA was submitted in March 2019 as a Rolling Review. We are not aware of any drug companies that have publicly disclosed their development of a product based on DS-200's active ingredient.

DS-100. DS-100 is an injectable nerve block indicated for therapeutic neurolysis for the relief of intractable pain, generally defined as severe, constant pain that is not curable by any known means. We are currently in discussions with the FDA regarding the exact indication we will pursue and clinical requirements for DS-100, however as of the date of this Annual Report it is our intention to seek FDA approval of DS-100 for the indication as a general nerve block. We expect either a literature-based filing or a small clinical trial as the principal means of proving safety and efficacy. We believe the existing literature shows safety and efficacy in 10 published studies involving more than 850 patients. Reported side effects included mild hypotension, diarrhea, and nausea. We expect an NDA for DS-100 to be submitted in 2020. An injectable version of DS-100's active ingredient was previously FDA-approved for a different indication.

At any time, we typically have various products and product ideas in early-stage development. These may include products where we have not yet met with the FDA, or products for which we have met with the FDA and received agreement upon our clinical pathway, but we have yet to complete significant development activities.

Research and Development

Set forth below is our R&D spending for our current product candidates. We currently have nine employees that support our overall product development and we also have facility and operating costs for a laboratory that will support product development. We do not track internal costs by product for our employees and laboratory expenses and they are listed as indirect expenses in the table below (amounts are in thousands).

Product Candidate	Year ended December 31, 2018	Period from April 27,2017 (Inception) to December 31, 2017
CT-100	$ 74	$ 93
DS-100	—	750
DS-200	910	1,686
DS-300	1,251	402
EM-100	1,265	470
ET-101	131	—
ET-102	341	—
ET-103	353	—
Other products	127	132
Indirect expenses	1,175	397
Total	**$ 5,627**	**$ 3,930**

Sales and Marketing

We intend to market prescription products ourselves under our own label and we have initiated the process of establishing our internal sales infrastructure. We are in the process of registering for licenses to distribute pharmaceuticals in all required states and territories of the United States. We anticipate being fully registered with all states in advance of launching our initial product under our own label. We have engaged an experienced third-party logistics company specializing in pharmaceuticals to manage inventory, logistics, and sales reconciliation for our commercial products. We may selectively out-license or seek a marketing partner on a product by product basis for products where we find it financially or strategically advantageous.

Manufacturing and Suppliers

We rely on third party contract manufacturing organizations, or 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 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.

Licensing Arrangements

We source certain products externally through the licensing or acquisition of existing development or commercial products. Among our current pipeline of product candidates, we have entered into licensing and profit-sharing arrangements for many of our product candidates, including:

EM-100. We acquired the exclusive rights to develop, manufacture and sell the EM-100 product in the United States pursuant to a Sales and Marketing Agreement dated August 11, 2017 between us and Eyemax LLC (“Eyemax”), an entity affiliated with our Chief Executive Officer (the “Sales Agreement”). On February 18, 2019, we entered into an Amended and Restated Agreement (the “Amended Agreement”) with Eyemax amending the Sales Agreement. Pursuant to the Amended Agreement, Eyemax sold us all of its right, title and interest in EM-100, including any such product that incorporates or utilizes Eyemax’s intellectual property rights. Pursuant to the Amended Agreement, we remain obligated to pay Eyemax two milestones: (i) one milestone payment for $250,000 upon regulatory approval in the territory by the FDA of the first single agent product and (ii) one milestone payment for $500,000 following the first commercial sale of the first single agent product in the territory. Following payment of the milestones, we are entitled to retain all of the non-royalty transaction revenues and royalties up to $2,000,000 (the “Recovery Amount”). After we have retained the full Recovery Amount, we are entitled to retain half of all royalty and non-royalty transaction revenue.

On February 18, 2019, we entered into an Asset Purchase Agreement with Bausch. Pursuant to the Asset Purchase Agreement, we sold all of our right, title and interest in EM-100 in the United States, including any such product that incorporates or utilizes our intellectual property rights with respect to EM-100. Pursuant to the Asset Purchase Agreement, Bausch paid us an upfront payment of $500,000 and Bausch is required to pay us commercial milestone payments of up to $2,500,000. Bausch is required to pay us a royalty in the low-double digit percentage range on net sales for a period of 10 years from the date of the first commercial sale of the first single agent EM-100 product in the United States. In the event that any product with the same sole active ingredient as EM-100 is launched in the United States by any person other than Bausch (or its affiliates) during the term of Bausch's royalty commitment, then the royalty rate will be reduced to a lower specified percentage. In the event that EM-100's market share in the territory falls below a certain percentage of the target market during the term of Bausch's royalty commitment, then the royalty rate will be further reduced to a lower specified percentage.

ET-103. We acquired the exclusive license to develop, manufacture and sell ET-103 in the United States pursuant to an Exclusive License and Supply Agreement dated August 3, 2018 between us and Liqmeds Worldwide Limited, an unaffiliated entity. Pursuant to the agreement, we will be responsible for, and shall own, all regulatory filings and approvals at our expense, provided that we shall have the right to recoup 35% of any regulatory filing fees from the initial profits from the sale of ET-103 and, provided further, the licensor shall be responsible for any bioequivalence study and shall be responsible for 60% of the costs of such study. An affiliate of the licensor shall manufacture the ET-103 and sell it to us at its cost. We paid the licensor $350,000 upon execution of the agreement and will pay the licensor $1,500,000 upon the FDA's acceptance of an NDA for review, $1,000,000 upon FDA approval, $1,500,000 upon issuance of patent covering ET-103 listed in the FDA's Orange Book and $500,000 in the event of product sales in excess of $10,000,000 in any calendar year. In addition, we are required to pay the licensor 35% of the net profit from product sales. The license agreement is for an initial term of ten years from the date of the first commercial sale of the product, subject to two-year renewals unless either party elects to terminate no less than 12 months prior to the then current term.

CT-100. We acquired from Harrow Health, Inc. ("Harrow", fka Imprimis Pharmaceuticals, Inc.) all of its rights to the CT-100 product and all related intellectual property and know-how and trade secrets specific to the product pursuant to an Asset Purchase and License Agreement dated May 9, 2017. Pursuant to the agreement, we also obtained from Harrow a non-exclusive license to certain know-how and trade secrets related, but not specific, to the CT-100 product. In addition, we licensed back to Harrow a non-exclusive, perpetual, non-transferable and royalty free license to use, manufacture and sell any product incorporating the intellectual property acquired from Harrow, other than products incorporating the synthetic corticotropin. The agreement requires us to pay Harrow a $50,000 milestone fee upon our initial patent issuance for the product and a six percent royalty fee on net sales of the product distributed and marketed by us or our licensees at such times as the product is covered by an issued patent, and a three percent royalty at all other times. The agreement also contains customary representations, warranties, covenants and indemnities by the parties.

DS-300. We acquired the exclusive rights to develop, manufacture and sell the DS-300 product in the United States pursuant to a Sales and Marketing Agreement dated November 17, 2017, as amended on August 29, 2018, with an unaffiliated third party. Pursuant to the agreement, the licensor is responsible for obtaining FDA approval, at its expense, and we are responsible for commercializing the product in the United States, at our expense. We are entitled to 100% of the first $500,000 of net profit from the sale of the DS-300, generally defined as gross profit less certain fees and costs incurred by us, and will pay the licensor 100% of the next $1 million of net profit. Thereafter, we will pay 50% of the net profit to the licensor and its designees for the term of the agreement. The agreement has a term of ten years from the date of the first commercial sale of the DS-300, subject to one five-year extension at our option. The licensor may terminate the agreement if we choose not to launch the DS-300, for commercial reasons only, within three months after FDA approval or if during the first calendar year following the first commercial sale of the DS-300 net sales of the product do not exceed $1 million. The agreement also contains customary representations, warranties, covenants and indemnities by the parties.

DS-200. We acquired the DS-200 product and all related intellectual property and government approvals pursuant to an Asset Purchase Agreement dated June 23, 2017 between us and Selenix LLC, an entity affiliated with our Chief Executive Officer. Pursuant to the agreement, we paid the seller $1.5 million and have agreed to pay $1.5 million upon submission of an NDA and $1 million upon FDA approval. We have also agreed to pay the seller 50% of the net profit from the sale of the product for the first ten years following the date of the agreement.

DS-100. We acquired the exclusive rights to develop, manufacture and sell the DS-100 product in the United States pursuant to an Exclusive Development and Supply Agreement dated July 9, 2017 between us and Andersen Pharma, LLC, an entity affiliated with our Chief Executive Officer. We also hold an option to purchase the DS-100 product and all related intellectual property and government approvals. Pursuant to the agreement, the licensor is responsible for obtaining FDA approval at its expense and manufacturing the product for sale to us at its cost, however we are responsible for the advancement of the FDA submission fees, which we have the right to recoup from the initial profits from product sales prior to any profit split. We are responsible for commercializing the product in the United States at our expense. We paid the licensor $750,000 upon execution of the agreement and will pay the licensor $750,000 upon successful completion of a registration batch of product, $750,000 upon submission of an NDA and $750,000 upon FDA approval. We will also pay the licensor 50% of the net profit from the sale of the product. The license agreement is for an initial term of five years from the first commercial sale of the product, subject to successive two-year renewals unless either party elects to terminate the agreement. The agreement also contains customary representations, warranties, covenants and indemnities by the parties.

ET-104. We acquired the exclusive license to sell ET-104 in the United States pursuant to an Exclusive License and Supply Agreement dated January 23, 2019 between us and Liqmeds Worldwide Limited. Pursuant to the agreement, we will be responsible for regulatory and marketing activities. We paid the licensor $350,000 upon execution of the agreement and will pay the licensor additional milestones of up to $2.15 million based on the achievement of certain development and commercial milestones. In addition, we are required to pay the licensor 35% of the net profit from product sales. The agreement is for an initial term of 10 years from the date of the first commercial sale of the product, and we will retain sole ownership after expiration of the agreement.

ET-202. We acquired the exclusive license to market ET-202 pursuant to an Exclusive License and Supply Agreement dated February 8, 2019 between us and Sintetica SA (“Sintetica”). Pursuant to the terms of the agreement, we will be responsible for marketing activities and Sintetica will be responsible for development, manufacturing, and regulatory activities related to obtaining regulatory approval. We paid Sintetica a licensing payment of $2 million upon execution of the agreement and will pay an additional $750,000 upon FDA approval of the product candidate. Upon approval, Sintetica will supply ET-202 to us at its direct costs. We will retain 5% of net sales as a marketing fee. Sintetica will be entitled to receive the first $500,000 of product profits. All additional profit will be split 50% to us and 50% to Sintetica. The agreement has a 10-year term from first commercial sale of product.

ET-203. We acquired the exclusive license to market ET-203 pursuant to an Exclusive License and Supply Agreement dated February 8, 2019 between us and Sintetica. Pursuant to the terms of the agreement, we will be responsible for marketing activities and Sintetica will be responsible for development, manufacturing, and regulatory activities related to obtaining regulatory approval. We paid Sintetica a licensing payment of $1 million upon execution of the agreement and will pay an additional $750,000 upon FDA approval of the product candidate. Upon approval, Sintetica will supply ET-203 to us at its direct costs. We will retain 5% of net sales as a marketing fee. Sintetica will be entitled to receive the first $500,000 of product profits. All additional profit will be split 50% to us and 50% to Sintetica. The agreement has a 10-year term from first commercial sale of product.

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.

We own one patent application related to our CT-100 (Synthetic Corticotropin) product candidate. The patent application was submitted on June 13, 2017 and relates to a drug to treat multiple sclerosis, autoimmune diseases, and rheumatic disorders including infantile spasms, Addison’s disease, Nelson’s, Cushing’s and West syndromes. If granted, this application would have an approximate expiration of May 2037, in all jurisdictions where the cases are pending. The claimed subject matter in the patent application includes claims to compositions themselves and treatment methods using known compounds and formulations and dosage types.

Our development partner has filed a patent application for ET-104. We intend to seek patent protection on our internally developed products as circumstances warrant.

We have applied for trademark registration of the marks “Eton” and “Eton Pharmaceuticals” with the U.S. Patent and Trademark Office.

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 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 usually 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, or 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, or 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 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, or 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 complete response letter 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 complete response letter 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, or 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 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 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.

DESI Program

Upon its enactment in 1938, the FDCA required new drugs to demonstrate that they were safe before they could be marketed. In 1962, the FDCA was amended to require that new drugs demonstrate that they were effective as well as safe. Following the 1962 amendments to the FDCA, the FDA adopted a program called the Drug Efficacy Study Implementation, or DESI, to review the efficacy of drugs approved between 1938 and 1962, and the drugs approved between 1938 and 1962 are commonly referred to as DESI drugs. DESI drugs were allowed to remain on the market until they were re-reviewed as long as they weren't substantially changed. The DESI program removed many products that were deemed to not be effective, but there was no comprehensive list of drugs approved and marketed at the time and not all drugs were re-reviewed. As a result, many DESI products remained marketed without a formal approval for effectiveness.

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, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the Health Care Reform Law. Since January 2017, President Trump has 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 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." On January 22, 2018, 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 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". 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 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, 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 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 the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

Moreover, 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. Additionally, 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.

Employees

We currently have 15 full-time employees, nine of whom are engaged in research and development activities and six of whom are engaged in general corporate and strategy roles. We periodically utilize outside consultants on an as-needed basis, including medical consultants. We anticipate hiring additional employees in 2019.

Corporate and Other Information

We were incorporated under the laws of the state of Delaware in April 2017. We were initially a wholly-owned subsidiary of Harrow but are no longer a subsidiary of Harrow. 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.

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 not commenced revenue-producing operations. To date, our operations have consisted of the preliminary formulation, testing and development of our initial 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 development, 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 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 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.

We have a history of significant operating losses and anticipate continued operating losses for the foreseeable future.

From our inception in April 2017 through December 31, 2017 and for the year ended December 31, 2018, we incurred a net loss of $7.2 million and $12.7 million, respectively, and our operations used $4.7 million and $8.1 million of cash and cash equivalents, respectively. We expect to continue to incur substantial expenses without any corresponding revenues unless and until we are able to obtain regulatory approval and successfully commercialize a product candidate. We expect to incur significant expense to complete our clinical programs for our product candidates in the United States and elsewhere. We may never be able to obtain regulatory approval for the marketing of our product candidates in any indication in the United States or internationally. Even if we are able to commercialize our product candidates, there can be no assurance that we will generate significant revenues or ever achieve profitability.

We expect to have significant research, regulatory and development expenses as we advance our product candidates.

As a result, we expect to incur substantial losses for the foreseeable future. We are uncertain when or if we will be able to achieve or sustain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable may impair our ability to sustain operations and adversely affect our business and our ability to raise capital. If we are unable to generate positive cash flow within a reasonable period of time, we may be unable to further pursue our business plan or continue operations.

We could need additional financing to execute our business plan and fund operations, which additional financing may not be available on reasonable terms or at all.

As of December 31, 2018, we had total assets of $28.3 million and working capital of $25.5 million. We received $22.0 million in net proceeds from our initial public offering ("IPO") in November 2018, but could require additional funding at a future point in time. In the event we require additional capital, we will endeavor to seek additional funds through various financing sources, including the sale of our equity and debt securities, licensing fees for our technology and joint ventures with industry partners. In addition, we will consider alternatives to our current business plan that may enable to us to achieve revenue producing operations and meaningful commercial success with a smaller amount of capital. However, there can be no guarantees that such funds will be available on commercially reasonable terms, if at all. If such financing is not available on satisfactory terms, we may be unable to further pursue our business plan and we may be unable to continue operations.

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

As our development and commercialization plans and strategies develop, we will 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 we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. In addition, the loss of the services of our senior management would adversely impact our business prospects.

Our management team has expertise in many different aspects of drug development and commercialization. However, our ability to compete in the highly competitive pharmaceuticals industry depends in large part upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We will need to hire additional personnel as we further develop our product candidates. Competition for skilled personnel in our market is intense and competition for experienced scientists may limit our ability to hire and retain highly qualified personnel on acceptable terms. Despite our efforts to retain valuable employees, members of our management and scientific teams may terminate their employment with us on short notice. The loss of the services of any of our executive officers or other key employees, or our inability to hire targeted executives, could potentially harm our business, operating results or financial condition. In particular, we believe that the loss of the services of our chief executive officer would have a material adverse effect on our business.

Other pharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles, and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can develop and commercialize product candidates would be limited.

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 clinical testing of our product candidates and will face an even greater risk if we commercialize any of our product candidates or any other future product. For example, we may be sued if 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 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 clinical testing and development. However, we will need additional product liability coverage at the time we commence commercial sale of our initial product. 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 products we develop. Although we will endeavor to obtain and maintain such insurance in coverage amounts 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.

Our business operations could suffer in the event of information technology systems' failures or security breaches.

While we believe that we have implemented adequate security measures within our internal information technology and networking systems, our information technology systems may be subject to security breaches, damages from computer viruses, natural disasters, terrorism and telecommunication failures. Any system failure or security breach could cause interruptions in our operations in addition to the possibility of losing proprietary information and trade secrets. To the extent that any disruption or security breach results in inappropriate disclosure of our confidential information, our competitive position may be adversely affected, and we may incur liability or additional costs to remedy the damages caused by these disruptions or security breaches.

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 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 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.

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.

Our Chief Executive Officer, Sean Brynjelsen, has a material ownership interest in several companies from which we have licensed or acquired product development and marketing rights. See, "Notes to Financial Statements — Related Party Transactions." We are required to pay these entities a combination of licensing fees, milestone payments and royalty payments. The transactional agreements also subject us to a loss of our rights to the product candidates in the event we breach any of our representations, warranties or covenants included in the agreements. While we believe the terms of the transactional agreements, including the licensing fees, milestone payments and royalty payments, approximate the terms and payments we could have obtained in an arms' length transaction with an unaffiliated party, these arrangements may present Mr. Brynjelsen with a conflict of interest in the event of dispute between the parties. Although we believe we have mechanisms in place to protect the interests of our stockholders, including a board of directors, a majority of which are independent and have no interest in these related parties, there can be no assurance that a conflict of interest will not arise or that any such conflict will not adversely impact the interests of our stockholders.

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

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

Our product candidates are in the early stages of clinical development, and we do not generate revenues from any FDA approved drug products. An abbreviated new drug application ("ANDA") was submitted for our EM-100 product candidate and NDAs have been submitted for three of our product candidates: one was submitted for DS-300 in January 2018, one was submitted for ET-202 in December 2018 and one was submitted for DS-200 in March 2019. 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 an approval 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 currently 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.

We hold one patent application for our CT-100 product candidate. 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.

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in early phases of pre-clinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates. The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We are not permitted to market our product candidates as prescription pharmaceutical products in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. In the United States, the FDA generally requires the completion of clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before an NDA is approved. Regulatory authorities in other jurisdictions impose similar requirements. We have submitted an ANDA for our EM-100 product candidate and an NDA to the FDA for our DS-300, ET-202 and DS-200 product candidates, however, there can be no assurance our NDAs will be approved by the FDA. If our development efforts for our product candidates, including regulatory approval, are not successful for their planned indications, or if adequate demand for our product candidates is not generated, our business will be materially adversely affected.

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 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.

We are a clinical stage company and as of the date of this Annual Report, one ANDA and three NDAs have been submitted for our product candidates and we have not received regulatory approval to market any product candidates in any jurisdiction. We have only limited experience in filing the applications necessary to gain regulatory approvals and expect to rely on consultants and third-party CROs with expertise in this area to assist us in this process. Securing regulatory approvals to market a product requires the submission of clinical and pharmacokinetic data, information about product manufacturing processes and inspection of facilities and supporting information to the appropriate regulatory authorities for each therapeutic indication to establish a product candidate's safety and efficacy for each indication. Our product candidates may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications.

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 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 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 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.

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, 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.

Even if we obtain marketing approval for any of our product candidates, we will be 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.

Even if we obtain regulatory approval for any of our product candidates for an indication, the FDA or foreign equivalent may still impose significant restrictions on their indicated uses or marketing 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 and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials, as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

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.

We currently have a limited sales and marketing organization. If we are unable to secure a sales and marketing partner or establish satisfactory sales and marketing capabilities, we may not successfully commercialize any of our product candidates.

We have limited sales and marketing personnel. In order to commercialize products that are approved for commercial sales, we must either collaborate with third parties that have such commercial infrastructure or develop our own sales and marketing infrastructure. If we are not successful entering into appropriate collaboration arrangements or recruiting sufficient sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty successfully commercializing our product candidates, which would adversely affect our business, operating results and financial condition.

We may not be able to enter into collaboration agreements on terms acceptable to us or at all. In addition, even if we enter into such relationships, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties. If we elect to establish a sales and marketing infrastructure, we may not realize a positive return on this investment. In addition, we will have to compete with established and well-funded pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize our product candidates without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or educate an adequate number of physicians as to the benefits of any our product candidates;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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, President Trump has 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, 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 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". 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 the Trump administration have each indicated that it 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.

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.

Our future profitability may depend, in part, on our ability to commercialize our product candidates in international markets for which we intend to rely on collaborations with third parties. If we commercialize any of our product candidates in international markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our product candidates in international markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing international regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;

- reduced protection of intellectual property rights in some foreign countries;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

International sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs, any of which may adversely affect our results of operations.

If we market any of our 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 will be completely dependent on third parties to manufacture our 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 future contract manufacturer caused by problems at suppliers could delay shipment of 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. 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. 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 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 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.

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.

Our Chief Executive Officer, Sean Brynjelsen, has a material ownership interest in several companies from which we have licensed or acquired product development and marketing rights. These include a 27% stake in Andersen Pharma, LLC (license for DS-100), 33% stake in Eyemax, LLC (license for EM-100) and 50% stake in Selenix, LLC (license for DS-200). We are required to pay these parties licensing fees, milestone payments and royalty payments. We believe the terms of the transactional agreements, including the licensing fees, milestone payments and royalty payments, approximate the terms and payments we could have obtained in an arms' length transaction with an unaffiliated party. Nonetheless, a stockholder may seek to challenge these agreements on grounds that they are not in the best interest of our company and our board breached its fiduciary duty by approving such agreements.

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 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 commence product sales and generate 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 have not conducted clinical trials for any of our product candidates, other than a bioequivalence trial for one product candidate, 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.

To date, we have not conducted any clinical trials other than a Phase 3 bioequivalence trial for our EM-100 product candidate. Our clinical trials may not be successful, and even if they are, the FDA may not approve our NDA for products that are successful in the trial, may not agree that the benefits outweigh its risks, or may raise new concerns regarding our clinical trial designs. The Phase 3 trial process is often long, complex, costly and uncertain, and delays or failure are common.

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 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 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. 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.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged global economic downturn could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. This is particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

The United Kingdom's referendum to leave the European Union or "Brexit," has and may continue to cause disruptions to capital and currency markets worldwide. The full impact of the Brexit decision, however, remains uncertain. A process of negotiation will determine the future terms of the United Kingdom's relationship with the European Union. During this period of negotiation, our results of operations and access to capital may be negatively affected by interest rate, exchange rate and other market and economic volatility, as well as regulatory and political uncertainty. Brexit may also have a detrimental effect on our suppliers and manufacturers, which would, in turn, adversely affect our financial condition.

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 is 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. We hold one patent application for our CT-100 product candidate and our development partner has filed a patent application for ET-104. 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.

Prior to our IPO, there was no public market for our common stock, and we cannot assure you that an active trading market for our shares will continue to develop or be sustained. As a result, it may be difficult for you to sell shares at an attractive price or at all.

Future capital raises may dilute our existing stockholders' ownership and/or have other adverse effects on our operations.

If we raise additional capital by issuing equity securities, our existing stockholders' percentage ownership will be reduced, and these stockholders may experience substantial dilution. 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 be volatile, and purchasers of our common stock could incur substantial losses.

Our stock price may 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, although we will lose that status sooner 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.

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.

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.

We will incur significant increased costs as a result of becoming a public company that reports to the Securities and Exchange Commission (the "SEC") and our management will be required to devote substantial time to meet compliance obligations.

As a newly public company reporting to the SEC, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to reporting requirements of the Securities Exchange Act of 1934 (the "Exchange Act"), and the reporting and governance provisions of the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Protection Act, as well as rules subsequently implemented by the SEC, that impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. There are significant corporate governance and reporting provisions in these laws that will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. Our management and other personnel will need to devote a substantial amount of time to these regulations. In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers.

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 after 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 currently performing a study to determine if we have triggered an "ownership change" limitation at the completion of our initial public offering in in November 2018. 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, shares eligible for future sale may adversely affect the market for our common stock.

All of our common shares are subject to lock-up agreements whereby the holder has agreed not to sell, transfer or pledge, or offering to do any of the same, directly or indirectly, any of our securities for a period of one year following the close of our IPO, except for the holders of common shares issued upon conversion of our preferred stock in connection with our IPO and the holders of 218,980 shares of our outstanding common stock who have agreed not to sell for 180 days following the close of our IPO. Notwithstanding the lock-up agreements, we have agreed to register for resale shares of common stock issued upon conversion of our preferred stock and shares of common stock underlying warrants. Furthermore, beginning in February 2019, certain of our stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act, subject to certain limitations. In general, pursuant to Rule 144, non-affiliate stockholders may sell freely after six months subject only to the current public information requirement (which disappears after one year). Beginning in May 2019, certain stockholders will be eligible to begin publicly selling their shares under Rule 144.

Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market 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.

We have broad discretion in the proceeds of our IPO.

Our management has considerable discretion in the application of the net proceeds from our recent IPO. We expect to use the proceeds from our IPO to fund clinical trials, product licensing opportunities and product development; to fund FDA filing fees; to fund laboratory expansion and for other general corporate purposes, including general and administrative expenses and working capital. However, our needs may change as our business and industry evolve and, as a result, the proceeds from our IPO may be used in a manner substantially different from our current expectations. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from our IPO in a manner that does not produce income or that loses value. The failure by our management to apply these funds effectively could result in financial losses that could harm our business, cause the price of our common stock to decline and delay the development of our product candidates.

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.

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.

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 11.5% of our common stock. Additionally, Harrow Health, Inc. ("Harrow"), our former parent company, holds approximately 19.9% of our outstanding common stock. Accordingly, these parties, together, can significantly influence, though not independently determine, the outcome of matters required to be submitted to our stockholders for approval, including decisions relating to the election of our board of directors and the outcome of any proposed merger or consolidation of our company. These interests may not be consistent with those of our other stockholders. In addition, the significant interest held by these parties, 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.

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, 2021.

We operate a 2,782 square foot research and development operation at a leased space located at 85 Oakwood Road, Lake Zurich, Illinois 60047. The lease for this facility expires on February 28, 2021 and may be extended for an additional two-year period.

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 has been listed on the Nasdaq Global Market under the symbol "ETON" since November 13, 2018. Prior to that date, there was no public trading market for our common stock. The closing price of our common stock on the Nasdaq Global Market on December 31, 2018, the last trading date in 2018, was $6.12 per share.

Record Holders

As of February 28, 2019, we had 243 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 February 28, 2019 was $7.94.

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

In November 2018, we entered into an underwriting agreement, relating to the public offering of 4,140,000 shares of common stock at a price to the public of $6.00 per share, less underwriting discounts and commissions. In November 2018, in connection with the underwriting agreement, we issued warrants exercisable for 414,000 shares of common stock at an exercise price of $7.50 per share to National Securities Corporation, a wholly owned subsidiary of National Holdings, Inc.

The issuance of these warrants was made in reliance on the exemption from registration contained in Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act") and/or Regulation D promulgated thereunder as private transactions not involving a public offering of securities.

Use of Proceeds

On November 9, 2018, our Registration Statement on Form S-1, as amended (File No. 333-226774) was declared effective in connection with our IPO, pursuant to which we sold 4,140,000 shares of our common stock, including the full exercise of the underwriter's option to purchase additional shares, at a price to the public of $6.00 per share. The IPO closed on November 13, 2018. We received net proceeds from the IPO of $22.0 million (after deducting the underwriter's discounts and commissions and additional offering related costs of $2.9 million). The sole underwriter was National Securities Corporation, a wholly owned subsidiary of National Holdings, Inc.

No expenses incurred by us in connection with our IPO were paid directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities, or (iii) any of our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service.

There has been no material change in the planned use of proceeds from our IPO from those disclosed in the final prospectus for our IPO dated as of November 9, 2018 and filed with the SEC on November 13, 2018 pursuant to Rule 424(b)(4).

Issuer Purchase of Equity 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 were formed in April 2017 as a specialty pharmaceutical company focused on developing and commercializing innovative pharmaceutical products utilizing the FDA's 505(b)(2) regulatory pathway. Our business model is to develop proprietary innovative products that fulfill an unmet patient need. Since our formation, we have focused our efforts on the development of our initial product candidates, engaging in preliminary discussions with the FDA concerning the regulatory pathway for certain additional product candidates, registration filings of our initial product candidates and the licensing of late-stage product candidates.

We have established a diversified pipeline of product candidates in various stages of development, four of which have been submitted to the FDA and are under review. We intend to focus on product candidates that are liquid in formulation, including injectables, oral liquids and ophthalmics, and qualify under the FDA's 505(b)(2) regulatory pathway.

Our corporate strategy is to pursue what we perceive 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 us to bring the product to patients. We intend to pursue product candidates that require a single small Phase 3 trial, a bio-equivalence trial, or literature-based filings. Prior to initiating significant development activities on a product candidate, we typically meet with the FDA to establish a defined clinical and regulatory path to approval.

We believe our product candidates can address situations where patient needs are not being met by current FDA-approved pharmaceutical products. This may include products that are being supplied on an unapproved basis, products that are currently being compounded, and products that are approved and widely used internationally but not approved in the United States.

Results of Operations

Since our inception, we have not generated any revenues and do not anticipate generating any revenues unless and until we successfully complete development and obtain regulatory approval for one of our product candidates.

For the periods ended December 31, 2018 and 2017, we incurred $5.6 million and $3.9 million of research and development ("R&D") expenses, respectively, and $4.7 million and $3.2 million of general and administrative ("G&A") expenses, respectively. The comparative period detail of our R&D expense is listed in the table below. The $1.5 million increase in G&A expenses was primarily due to the partial year start-up in late April 2017 as compared to a full year of operations in 2018 combined with personnel additions in the second half of 2018. Our compensation-related costs increased by $1.1 million plus costs for our board of directors increased by $0.4 million. In addition, the fair value of our warrant liability reflected in other expense increased by $2.5 million as a result of the increase in our stock price up to the date of our IPO. We incurred a net loss of $12.7 million and $7.2 million for the periods ended December 31, 2018 and 2017, respectively.

General and Administrative Expenses

G&A expenses consist primarily of employee compensation expenses, stock-based consulting service fees, legal and professional fees and travel expenses. We anticipate that our G&A expenses will significantly increase to support our business growth and the additional costs associated with being a public company.

Research and Development Expenses

Set forth below is our R&D spending for our current product candidates. We currently have nine employees that support our overall product development and we also have facility and operating costs for a laboratory that will support product development. We do not track internal costs by product for our employees and laboratory expenses and they are listed as indirect expenses in the table below (amounts are in thousands).

Product Candidate	Year ended December 31, 2018	Period from April 27, 2017 (Inception) to December 31, 2017
CT-100	$ 74	$ 93
DS-100	—	750
DS-200	910	1,686
DS-300	1,251	402
EM-100	1,265	470
ET-101	131	—
ET-102	341	—
ET-103	353	—
Other products	127	132
Indirect expenses	1,175	397
Total	$ 5,627	$ 3,930

Liquidity and Capital Resources

As of December 31, 2018, we had total assets of $28.3 million and working capital of $25.5 million. We had previously capitalized our operations primarily from the June 2017 private placement of approximately $20.1 million of Series A preferred stock, par value $0.001 (the "Series A Preferred"). Our Series A Preferred accumulated dividends at the rate of 6% per annum and those shares of stock plus all accrued but unpaid dividends automatically converted into shares of our common stock concurrent with our IPO in November 2018 at the conversion price of 50% of the IPO price. The IPO provided us with net proceeds of $22.0 million which we believe should be sufficient for at least the next twelve months of our operations including through securing regulatory approval and commencement of commercial sales for at least one product candidate. We do not anticipate requiring additional funding after that point, 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 periods ended December 31, 2018 and 2017 (amounts are in thousands):

	Year ended December 31, 2018	Period from April 27, 2017 (Inception) to December 31, 2017
Net cash used in operating activities	$ (8,145)	$ (4,718)
Cash used in investing activities	(236)	(130)
Cash flows provided by financing activities	21,960	18,004
Net increase in cash and cash equivalents	$ 13,579	$ 13,156

The increase in cash used in operating activities is primarily a result of higher operating losses due to our business expansion including additional personnel and increased product candidate development activity. Investing activities consist primarily of capital expenditures for setting up our headquarters office and the initial set-up for our laboratory facility. The financing activity primarily consists of the Series A Preferred private placement funding in June 2017 and the November 2018 IPO.

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 condensed 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.

Stock-Based Compensation

We account for stock-based compensation under the provisions of the Financial Accounting Standards Board (the “FASB”) Accounting Standards Codification (“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 for employees and directors and record expense over the related service periods, which are generally the vesting period of the equity awards. Awards for consultants are accounted for under ASC 505-50 - Equity Based Payments to Non-Employees. Compensation expense is recognized over the period during which services are rendered by such 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 employees and directors 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, which management believes represents the most accurate basis for estimating expected future volatility under the current conditions. We account for forfeitures as they occur.

Prior to the IPO, 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 in November 2018, 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.

Warrant Liability

We estimated the fair value of certain warrants at each reporting period using Level 3 inputs. The estimates in valuation models were based, in part, on subjective assumptions, including but not limited to stock price volatility, the expected life of the warrants, the risk-free interest rate and the exercise price of the warrants, and could differ materially in the future. Changes in the fair value of the warrant liability during the periods prior to the IPO were recorded as a component of other income (expense). We continued to adjust the fair value of the warrant liability at the end of each reporting period for changes in fair value until the earlier of the exercise or expiration of the applicable warrants or when the number of shares issuable upon exercise of these warrants became fixed which occurred with our IPO in November 2018.

Beneficial Conversion Feature

Prior to the IPO in November 2018, we classified our Series A Preferred as temporary equity due to a possible cash redemption feature in the event that an IPO or alternate financing was not available by December 31, 2018. At the IPO date, the Series A Preferred automatically converted into shares of our common stock. The conversion share calculation was based on the $3.00 initial issue price for the Series A Preferred plus any accrued but unpaid dividends and converted to our common stock using a stated divisor conversion price equal to 50% of the IPO price to the public which was $6.00 per share. In accordance with relevant accounting literature, since the stated terms of the conversion option did not permit us to compute the additional number of shares that we would need to issue upon conversion of the Series A Preferred when the contingent event would occur, we recorded the beneficial conversion amount as a deemed dividend at the date of the IPO in November 2018.

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.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. 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, 2018, our cash equivalents and investments are invested exclusively in money market funds. 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

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, 2018 and 2017, the related statements of operations, redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows for the year ended December 31, 2018 and the period from April 27, 2017 (inception) through December 31, 2017, 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, 2018 and 2017, and the results of its operations and its cash flows for the year ended December 31, 2018 and the period from April 27, 2017 (inception) through December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ KMJ Corbin & Company LLP

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

Costa Mesa, California
March 25, 2019

Eton Pharmaceuticals, Inc.

BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 26,735	$ 13,156
Prepaid expenses	767	136
Total current assets	27,502	13,292
Property and equipment, net	773	119
Other long-term assets, net	52	32
Total assets	$ 28,327	$ 13,443
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,421	$ 539
Accrued liabilities	603	254
Total current liabilities	2,024	793
Warrant liability	—	520
Total liabilities	2,024	1,313
Commitments and contingencies (Note 14)		
Redeemable convertible preferred stock – Series A		
$0.001 par value, 10,000,000 shares authorized as of December 31, 2018 and 2017; no shares and 6,685,082 shares issued and outstanding as of December 31, 2018 and 2017, respectively; aggregate liquidation preference of $0 and $20,698 as of December 31, 2018 and 2017, respectively	—	19,004
Stockholders' equity (deficit)		
Common stock, $0.001 par value; 50,000,000 shares authorized as of December 31, 2018 and 2017; 17,607,928 and 6,000,000 shares issued and outstanding at December 31, 2018 and 2017, respectively	18	6
Additional paid-in capital	72,153	1,759
Accumulated deficit	(45,868)	(8,639)
Total stockholders' equity (deficit)	26,303	(6,874)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 28,327	$ 13,443

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

Eton Pharmaceuticals, Inc.

STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	Year ended December 31, 2018	Period from April 27, 2017 (Inception) to December 31, 2017
Operating expenses:		
Research and development	$ 5,627	$ 3,930
General and administrative	4,694	3,220
Total operating expenses	10,321	7,150
Loss from operations	(10,321)	(7,150)
Other income (expense):		
Interest and other income, net	164	35
Change in fair value of warrant liability	(2,583)	(41)
Loss before income tax expense	(12,740)	(7,156)
Income tax expense	—	—
Net loss	(12,740)	(7,156)
Accrued dividends on redeemable convertible preferred stock	(1,048)	(643)
Deemed dividends for accretion of redeemable convertible preferred stock issuance costs	(1,694)	(840)
Deemed dividends for beneficial conversion feature of redeemable convertible preferred stock	(21,747)	—
Net loss attributable to common stockholders	$ (37,229)	$ (8,639)
Net loss per share attributable to common stockholders, basic and diluted	$ (5.80)	$ (2.50)
Weighted-average number of common shares outstanding, basic and diluted	6,418	3,453

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

Eton Pharmaceuticals, Inc.

STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share amounts)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balances at April 27, 2017 (Inception)	**—**	**$ —**	**—**	**$ —**	**$ —**	**$ —**	**$ —**
Common stock issued to founder	—	—	3,500,000	4	—	—	4
Stock-based compensation	—	—	2,500,000	2	1,759	—	1,761
Issuance of Series A redeemable convertible preferred stock, net of issuance costs	6,685,082	17,521	—	—	—	—	—
Accrued dividends on redeemable convertible preferred stock	—	643	—	—	—	(643)	(643)
Deemed dividends for accretion of redeemable convertible preferred stock issuance costs	—	840	—	—	—	(840)	(840)
Net loss	—	—	—	—	—	(7,156)	(7,156)
Balances at December 31, 2017	**6,685,082**	**$ 19,004**	**6,000,000**	**$ 6**	**$ 1,759**	**$ (8,639)**	**$ (6,874)**
Stock-based compensation	—	—	218,980	—	1,850	—	1,850
Accrued dividends on redeemable convertible preferred stock	—	1,048	—	—	—	(1,048)	(1,048)
Deemed dividends for accretion of redeemable convertible preferred stock issuance costs	—	1,694	—	—	—	(1,694)	(1,694)
Issuance of common stock in connection with initial public offering, including underwriter's over-allotment, net of offering costs and underwriter's discount	—	—	4,140,000	4	21,956	—	21,960
Conversion of redeemable convertible preferred stock (including accrued dividends) to common stock in connection with initial public offering	(6,685,082)	(21,746)	7,248,948	8	21,738	—	21,746
Reclassification of common stock warrants from liability to additional paid-in-capital	—	—	—	—	3,103	—	3,103
Beneficial conversion feature on redeemable convertible preferred stock	—	—	—	—	21,747	(21,747)	—
Net loss	—	—	—	—	—	(12,740)	(12,740)
Balances at December 31, 2018	**—**	**$ —**	**17,607,928**	**$ 18**	**$ 72,153**	**$ (45,868)**	**$ 26,303**

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

Eton Pharmaceuticals, Inc.

STATEMENTS OF CASH FLOWS
(In thousands)

	Year ended December 31, 2018	Period from April 27, 2017 (Inception) to December 31, 2017
Cash flows from operating activities		
Net loss	$ (12,740)	$ (7,156)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,850	1,761
Depreciation and amortization	63	13
Change in fair value of warrant liability	2,583	41
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(663)	(170)
Accounts payable	413	539
Accrued liabilities	349	254
Net cash used in operating activities	(8,145)	(4,718)
Cash used in investing activities		
Purchases of property and equipment	(236)	(130)
Cash flows from financing activities		
Proceeds from initial public offering, net of underwriting discounts and commissions	22,803	—
Payments of initial public offering costs	(843)	—
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	18,000
Proceeds from issuance of common stock	—	4
Net cash provided by financing activities	21,960	18,004
Change in cash and cash equivalents	13,579	13,156
Cash and cash equivalents at beginning of period	13,156	—
Cash and cash equivalents at end of period	$ 26,735	$ 13,156
Supplemental disclosures of cash flow information		
Cash paid for interest	$ —	$ —
Cash paid for income taxes	$ —	$ —
Supplemental disclosures of non-cash investing and financing activities:		
Accrued dividends on redeemable convertible preferred stock	$ 1,048	$ 643
Deemed dividends for accretion of redeemable convertible preferred stock issuance costs	$ 1,694	$ 840
Common stock warrant liability issued with redeemable convertible preferred stock financing	$ —	$ 479
Purchase of equipment included in accounts payable	$ 469	$ —
Beneficial conversion feature on redeemable convertible preferred stock	$ 21,747	$ —
Reclassification of common stock warrants from liability to additional paid-in-capital	$ 3,103	$ —

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.).

Eton raised $20,055 in start-up capital through the sale of its Series A redeemable convertible preferred stock ("Series A Preferred") in June 2017 and a separate management team was then established for Eton with its corporate offices located in Deer Park, Illinois. Eton is a specialty pharmaceutical company focused on developing and commercializing prescription drug products utilizing the U.S. Food and Drug Administration's (the "FDA") 505(b)(2) regulatory pathway. The Company's business model is to develop proprietary innovative product candidates that offer commercial and/or functional advantages to currently available alternatives.

In November 2018, the Company completed an initial public offering ("IPO"), selling 4,140,000 shares of common stock at an offering price of $6.00 per share, including the underwriter's exercise in full of its option to purchase additional shares. The Company received net proceeds of $21,960, after deducting underwriting discounts and commissions and offering-related expenses (see Note 7).

Note 2 — Liquidity Considerations

As of December 31, 2018 and 2017, the Company had an accumulated deficit of $45,868 and $8,639, respectively. In addition, for the year ended December 31, 2018 and the period from April 27, 2017 (inception) to December 31, 2017, the Company had net cash used in operating activities of $8,145 and $4,718, respectively.

To date, the Company has not generated any revenues and does not anticipate generating significant revenues unless and until it successfully completes development and obtains regulatory approval for one of its product candidates. As of December 31, 2018, the Company had an accumulated deficit of $45,868 and has incurred negative cash flow from operating activities since its inception. The Company currently believes its existing cash and cash equivalents 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 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 sale 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. Issued debt securities may contain covenants and limit the Company's ability to pay dividends or make other distributions to stockholders. If the Company is delayed in completing its product development and obtaining regulatory approval for its 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 ("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, the accrual of research and development expenses and the valuation of common stock, stock options, warrants and derivative instruments. 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. Cash equivalents consist of an interest-bearing checking account. From time to time, amounts deposited exceed federally insured limits. The Company believes the associated credit risk to be minimal.

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 software and hardware 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.

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 periods ended December 31, 2018 and 2017.

Classification and Accretion of Redeemable Convertible Preferred Stock

Prior to the Company's IPO in November 2018, the Company had classified the Series A Preferred outside of stockholders' equity (deficit) because the shares contained certain redemption features that were not solely within the control of the Company. The carrying value of the Series A Preferred was accreted to its redemption value from the date of issuance through November 15, 2018, the date of the Company's IPO. In conjunction with the IPO, the Series A Preferred, including accrued and unpaid dividends, automatically converted to shares of the Company's common stock (see Note 6).

Beneficial Conversion Feature

Prior to the IPO in November 2018, the Company classified its Series A Preferred as temporary equity due to a possible cash redemption feature in the event that an IPO or alternate financing was not completed by December 31, 2018. At the IPO date, the Series A Preferred, and related accrued and unpaid dividends, automatically converted into shares of the Company's common stock. The conversion share calculation was based on the $3.00 initial issuance price for the Series A Preferred plus any accrued but unpaid dividends and converted to common stock using a stated divisor conversion price equal to 50% of the IPO price to the public, which was $6.00 per share. In accordance with relevant accounting literature, since the stated terms of the conversion option did not permit the Company to compute the additional number of shares that it would need to issue upon conversion of the Series A Preferred when the contingent event occurred, the Company recorded the beneficial conversion amount of $21,747 as a deemed dividend at the date of the IPO in November 2018.

Leases

Leases are categorized as either operating or capital leases at inception. Operating lease costs are recognized on a straight-line basis over the term of the lease. An asset and a corresponding liability for the capital lease obligation are established for the cost of capital leases. The capital lease obligation is amortized over the life of the lease. The Company does not have any capital leases as of December 31, 2018 and 2017.

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 recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Significant Suppliers

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

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 2018 or 2017 as the Company reported a net loss for the periods ended December 31, 2018 and 2017 and including the effects of common stock equivalents in the diluted earnings per share calculation would have been antidilutive (See Note 10).

Warrant Liability

The Company estimated the fair value of certain warrants at each reporting period using Level 3 inputs. The estimates in valuation models were based, in part, on subjective assumptions, including but not limited to stock price volatility, the expected life of the warrants, the risk-free interest rate and the exercise price of the warrants, and could differ materially in the future. Changes in the fair value of the warrant liability during the period were recorded as a component of other income (expense) at the end of each reporting period for changes in fair value until the Company's IPO in November 2018, which established a fixed number of shares for these warrants. At the date of the IPO, the warrant liability amount was reclassified as a component of additional paid-in-capital.

Stock-Based Compensation

The Company accounts for stock-based compensation under the provisions of the Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("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 for employees and directors and record expense over the related service periods, which are generally the vesting period of the equity awards. Awards for consultants are accounted for under ASC 505-50 — Equity Based Payments to Non-Employees. Compensation expense is recognized over the period during which services are rendered by such 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 the Company's common stock and updated assumption inputs in the Black-Scholes-Merton option-pricing model ("BSM").

The Company estimates the fair value of stock-based option awards to its employees and directors 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, 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.

Prior to the IPO, the fair value of the shares of the Company's common stock underlying its stock-based awards was determined by its board of directors, with input from management. Because there had been no public market for the Company's common stock prior to the IPO, the 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 its common stock performed by an unrelated third-party specialist, valuations of comparable companies, sales of its convertible preferred stock to unrelated third parties, operating and financial performance, the lack of liquidity of the capital stock, and general and industry-specific economic outlook. Following the IPO in November 2018, the Company uses the closing stock price on the date of grant for the fair value of the common stock.

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 statement of operations. As of December 31, 2018 and 2017, the Company has established a 100% valuation reserve against its deferred tax assets.

The Company accounts for income taxes under the provisions of FASB ASC 740 - Income Taxes. As of December 31, 2018 and 2017, there was no unrecognized tax benefits included in the balance sheet 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 sheet at December 31, 2018 or 2017, and has not recognized interest and penalties in the statements of operations for the periods ended December 31, 2018 and 2017. As of December 31, 2018, the Company is subject to taxation in the United States and Illinois. The Company's tax loss from 2018 and 2017 is subject to examination by the federal and state tax authorities due to the carryforward of unutilized net operating losses ("NOLs").

The Tax Cuts and Jobs Act of 2017 (the "Tax Act") significantly revised U.S. corporate income tax law by, among other things, reducing the corporate income tax rate to 21% and implementing a modified territorial tax system. In response to the Tax Act, the SEC issued Staff Accounting Bulletin ("SAB") 118 which allows issuers to recognize provisional estimates of the impact of the Tax Act in their financial statements and adjust in the period in which the estimate becomes finalized, or in circumstances where estimates cannot be made, to disclose and recognize within a one-year measurement period.

Implementation of the Tax Act resulted in a $733 charge for the revaluation of the Company's net deferred tax assets offset by a corresponding $733 reduction in the valuation reserve for income taxes during the period ended December 31, 2017.

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, 2018 or 2017.

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 carrying amounts of cash and cash equivalents, accounts payable and accrued liabilities approximate their fair values due to the short-term maturities of these instruments.

The fair values of the Company's warrant liability at inception and for subsequent mark-to-market fair value measurements were based on management's valuation model and expectations with respect to the method and timing of settlement. The Company had determined that the warrant liability fair values were classified as Level 3 measurements within the fair value hierarchy. At the date of the Company's IPO in November 2018, the fair value was reclassified to additional paid-in-capital as the final number of shares for the warrants previously reflected as a liability became fixed (see Note 4).

Impact of New Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02 (Topic 842) – Leases, which requires the lease rights and obligations arising from lease contracts, including existing and new arrangements, with terms more than 12 months to be recognized as assets and liabilities on the balance sheet. Recognition, measurement and presentation of expenses will depend on classification as a finance or operating lease. The amendments also require certain quantitative and qualitative disclosures about leasing arrangements. ASU 2016-02 is effective for reporting periods beginning after December 15, 2018 with early adoption permitted. While the Company is still evaluating ASU 2016-02, the Company expects the adoption of ASU 2016-02 will not have a material effect on the Company's financial condition from the recognition of the lease rights and obligations as assets and liabilities. The Company is currently evaluating ASU 2016-02 to determine the effect on the Company's results of operations and cash flows.

In June 2018, the FASB issued ASU 2018-07, Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, which simplifies the accounting for nonemployee share-based payment transactions. The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. ASU 2018-07 will be effective for financial statements issued for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years with early adoption permitted (but no sooner than the adoption of Topic 606). The Company is currently evaluating ASU 2018-07 to determine the effect on the Company's financial statements.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of operations is required to be filed. This final rule became effective on November 5, 2018. On September 25, 2018, the SEC released guidance advising that it will not object to a registrant adopting the requirement to include changes in stockholders' equity in the Form 10-Q for the first quarter beginning after the effective date of the rule. The Company does not expect the adoption of SEC Release No. 33-10532 to have a material impact on its financial position, results of operations and related disclosures. The Company anticipates adopting SEC Release No. 33-10532 in its Form 10-Q filing for the quarter ending March 31, 2019.

Note 4 — Fair Value of Financial Assets and Liabilities

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	Fair Value Measurements as of December 31, 2018 Using:			
	Level 1	**Level 2**	**Level 3**	**Total**
Liabilities:				
Warrant liability	$ —	$ —	$ —	$ —

	Fair Value Measurements as of December 31, 2017 Using:			
	Level 1	**Level 2**	**Level 3**	**Total**
Liabilities:				
Warrant liability	$ —	$ —	$ 520	$ 520

During the periods ended December 31, 2018 and December 31, 2017, there were no transfers between Level 1, Level 2 and Level 3.

Valuation of Warrant Liability

The warrant liability in the table above was composed of the fair value of a warrant to purchase shares of common stock that were issued to the Company's placement agent in connection with the Series A Preferred offering (see Note 6). The fair value of the warrant liability was determined based on significant inputs not observable in the market, which represented a Level 3 measurement within the fair value hierarchy. The Company used the BSM, which incorporates assumptions and estimates, to value the warrant. Estimates and assumptions impacting the fair value measurement included the fair value per share of the underlying shares of common stock, the remaining contractual term of the warrant, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying common stock. The Company determined the fair value per share of the underlying common stock by taking into consideration the most recent sales of its preferred stock, results obtained from third-party valuations and additional factors that were deemed relevant. The Company historically had been a private company and lacked company-specific historical and implied volatility information of its common stock. Therefore, the Company estimated its expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrant. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrant. The Company estimated a 0% expected dividend yield based on the fact that the Company has never paid or declared dividends and does not intend to do so in the foreseeable future.

In November 2018, in connection with the Company's IPO, the number of shares issuable upon the exercise of the warrant became fixed (see Note 8). The Company remeasured the estimated fair value on the date of the IPO and reclassified this amount to additional paid-in-capital.

(in thousands, except share and per share amounts)

The following table provides a roll forward of the aggregate fair values of the Company's warrant liability, for which fair value is determined using Level 3 inputs:

	Year ended December 31, 2018	Period from April 27, 2017 (inception) to December 31, 2017
Balance as of the beginning of the period	$ 520	—
Initial fair value of warrant liability	—	479
Change in fair value	2,583	41
Warrant liability reclassified to additional paid-in-capital	(3,103)	—
Balance as of the end of the period	$ —	520

Note 5 – Property and Equipment

Property and equipment consist of the following:

	December 31, 2018	December 31, 2017
Computer hardware and software	$ 93	$ 46
Furniture and fixtures	98	42
Equipment	99	—
Leasehold improvements	53	42
Construction in progress	492	—
	835	130
Less: accumulated depreciation	(62)	(11)
Property and equipment, net	$ 773	$ 119

Depreciation expense for the periods ended December 31, 2018 and 2017 was $51 and $11, respectively.

Note 6 — Redeemable Convertible Preferred Stock — Series A

The Company has 10,000,000 authorized shares of $0.001 par value preferred stock as per its Amended and Restated Certificate of Incorporation. In June 2017, the Company issued 6,685,082 Series A Preferred at a price of $3.00 per share and all shares remained outstanding until the Company's IPO in November 2018. The gross proceeds were $20,055 from the Series A Preferred stock offering. The Series A Preferred shares, including accrued and unpaid dividends, automatically converted to the Company's common shares at the date of the IPO (See Note 7).

As of December 31, 2017, the liquidation value of the mezzanine Series A Preferred was $20,698, which consisted of the issuance amount of $20,055 plus accrued dividends of $643. As of the date of the IPO on November 15, 2018, the liquidation value of the mezzanine Series A Preferred was $21,746, which consisted of the issuance amount of $20,055 plus accrued dividends of $1,691.

The Series A Preferred automatically converted to common shares upon completion of the IPO in November 2018. The conversion share calculation was based on the $3.00 initial issue price for the Series A Preferred plus accrued and unpaid dividends, and automatically converted into shares of the Company's common stock using a stated divisor conversion price equal to 50% of the IPO price to the public which was $6.00 per share. In accordance with relevant accounting literature, since the terms of the conversion option did not permit the Company to compute the additional number of shares that it would need to issue upon conversion of the Series A Preferred when the contingent event occurred, the Company recorded the beneficial conversion amount of $21,747 as a deemed dividend at the date of the IPO in November 2018.

As a result of the Series A Preferred having a possible cash redemption feature in the event that an IPO or alternate financing was not completed by December 31, 2018, the Series A Preferred was classified as temporary equity and not included as part of Company's stockholders' equity (deficit) prior to the November 2018 IPO. In accordance with that classification, the $2,534 of issuance costs associated with the Series A Preferred offering were being ratably accreted as a deemed dividend using the effective interest method through the expected redemption date.

The following is a reconciliation of the carrying value of the Series A Preferred (in thousands):

	December 31, 2018	December 31, 2017
Gross proceeds from Series A Preferred offering	$ 20,055	$ 20,055
Issuance costs – cash	(2,055)	(2,055)
Issuance costs – common stock warrants	(479)	(479)
Accrued dividends on Series A Preferred	1,691	643
Deemed dividends for accretion of Series A Preferred issuance costs	2,534	840
Automatic conversion to common shares at the IPO date	(21,746)	—
Balance as of the end of the period	**$ —**	$ 19,004

Note 7 — 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 May 2017, the Company issued 3,500,000 shares of its common stock to Harrow, 1,500,000 shares of restricted stock to certain executives and staff of Harrow and 1,000,000 shares of restricted stock to the CEO of the Company. On January 1, 2018, the Company issued 54,745 restricted shares of its common stock to each of its four outside directors (218,980 total shares) as part of their compensation for board service to the Company in 2018. The restricted shares issued to the Harrow executives and staff vested over a 12-month period, the restricted shares issued to the CEO vest over a 24-month period and the restricted shares issued to the outside directors vested 25% at each quarter-end in 2018 and were fully vested as of December 31, 2018. The Company accounted for the restricted stock awards ("RSAs") in accordance with ASC 718 or ASC 505-50. For the periods ended December 31, 2018 and 2017, the Company recorded $1,388 and $1,403 respectively, in stock-based compensation expense for these RSAs (see Note 9).

In conjunction with the Company's November 2018 IPO, the Series A Preferred shares, including accrued dividends, converted into 7,248,948 shares of the Company's common stock, and the Company issued 4,140,000 additional shares of its common stock to investors in its IPO (See Notes 1 and 6).

Note 8 — Common Stock Warrants

In May 2017, the Company issued a warrant to purchase 600,000 shares of its common stock to consultants for business strategy and intellectual property advisory services. The warrant vested at issuance in May 2017 and has a $0.01 exercise price per warrant share and expires five years from the date of issuance. The Company used the BSM to value the warrant and the fair value at the date of issuance was $121 based on an expected term of five years, volatility of 85%, a risk-free interest rate of 1.8% and a 0% rate on expected dividends. The $121 amount for the consulting warrants was expensed as a component of the Company's general and administrative expenses in May 2017.

In conjunction with the closing of the Series A Preferred offering in June 2017 (see Note 6), the Company issued a warrant to purchase 649,409 shares of its common stock to the placement agent at an exercise price of $3.00 per share, provided, however, upon the conversion of the Series A Preferred, the warrant adjusted to entitle the holder to purchase shares of common stock equal to 10.0% of the shares of common stock issuable upon conversion of the Series A Preferred (excluding 191,000 shares of Series A Preferred that were purchased by insiders) and the exercise price would adjust to the conversion price of the Series A Preferred. This warrant vested at issuance in June 2017. The Company used the BSM to value the warrant and the fair value at the date of issuance was $479. Prior to the Company's IPO in November 2018, the number of common shares issuable upon the exercise of this warrant was not fixed as it could vary by a factor of 1.000 to 1.333 common shares per warrant share in accordance with the IPO price, and the Company considered the warrant to be a derivative instrument (see Note 4). The $479 amount was recorded as a component of the issuance costs for the Series A Preferred in June 2017. As of December 31, 2017, the fair value of the warrant was $520 and the $41 increase in fair value during 2017 was recorded as a component of other income and expense.

(in thousands, except share and per share amounts)

As of November 15, 2018, the fair value of the warrants was $3,103 and the $2,583 increase in fair value during 2018 was recorded as a component of other income and expense. The fair value assumptions included an expected term of five years, expected volatility of 85%, a risk-free interest rate of 2.9% and estimate of the conversion rate. These warrants were classified as warrant liability on the Company's balance sheets prior to the IPO in November 2018. In connection with the Company's IPO, the number of shares issuable upon the exercise of these warrants became fixed at 704,184 shares which eliminated the fair value adjustment after that date. At the IPO date, the warrant liability was reclassified to additional paid-in-capital.

During November 2018, in connection with the IPO, the Company issued warrants for 414,000 shares of its common stock to the placement agent at an exercise price of $7.50 per share.

The weighted average exercise price of the outstanding warrants for the consultant and placement agent as of December 31, 2018 and 2017 was $3.04 and $1.56 per share, respectively.

Listed below is a summary of warrants outstanding as of December 31, 2018:

Description of Warrants	No. of Shares	Exercise Price
Business Advisory Warrants	600,000	$ 0.01
Placement Agent Warrants - Series A Preferred	704,184	$ 3.00
Placement Agent Warrants - IPO	414,000	$ 7.50
Total	**1,718,184**	**$ 3.04 (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.

Note 9 — Share-Based Payment Awards

The Company's board of directors and stockholders approved the Eton Pharmaceuticals, Inc. 2017 Equity Incentive Plan in May 2017 (the "2017 Plan"), which authorized the issuance of up to 5,000,000 shares of the Company's common stock. In conjunction with the Company's IPO in November 2018, the Company's stockholders and board of directors approved the 2018 Equity Incentive Plan (the "2018 Plan") which succeeded the 2017 Plan. The Company has granted RSAs, stock options and restricted stock units ("RSUs") for its common stock under the 2017 Plan and 2018 Plan as detailed in the tables below. There were 886,020 shares available for future issuance under the 2018 Plan as of December 31, 2018.

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. The exercise price for stock options granted is not less than the fair value of common shares as determined by the board of directors as of the date of grant. Prior to the IPO, the Company's board of directors valued the Company's common stock, taking into consideration its most recently available valuation of common stock performed by third parties as well as additional factors which might have changed since the date of the most recent contemporaneous valuation through the date of grant. Following the IPO, the Company uses the closing stock price on the date of grant as the exercise price.

(in thousands, except share and per share amounts)

On January 1, 2018, the Company issued 54,745 restricted shares of its common stock to each of its four outside directors (218,980 total shares). The restricted shares issued to the outside directors vested 25% at each quarter-end in 2018 and became fully vested at December 31, 2018.

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 periods ended December 31, 2018 and 2017, the Company's total stock-based compensation expense was $1,850 and $1,761, respectively. Of these amounts, $1,770 and $1,735 was recorded in general and administrative expenses, respectively, and $80 and $26 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 December 31, 2017	1,090,000	$ 1.24	9.7	$ 151
Issued	225,000	4.26		
Exercised	—	—		
Forfeited/Cancelled	(20,000)	0.21		
Options outstanding as of December 31, 2018	1,295,000	$ 1.78	8.3	$ 5,627
Options exercisable at December 31, 2018	404,167	$ 1.06	6.9	$ 2,046
Options vested and expected to vest at December 31, 2018	1,245,000	$ 1.79	8.3	$ 5,390

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 assumptions used to calculate the fair value of options granted during the periods ended December 31, 2018 and 2017 under the BSM were as follows:

	December 31, 2018	December 31, 2017
Expected dividends	—%	—%
Expected volatility	85%	85%
Risk-free interest rate	2.8-2.9%	1.7-2.3%
Expected term	6.3 years	5.8-10 years
Weighted average fair value	$ 3.39	$ 0.91

(in thousands, except share and per share amounts)

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.

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 — Prior to the Company's IPO in November 2018, the fair value of the shares of common stock underlying the stock-based awards was determined by the board of directors, with input from management. Because there was no public market for the Company's common stock, the board of directors 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 the Company's common stock performed by an unrelated third-party specialist, valuations of comparable companies, sales of the Company's convertible preferred stock to unrelated third parties, operating and financial performance, the lack of liquidity of the Company's capital stock, and general and industry-specific economic outlook. The board of directors intended all options granted to be exercisable at a price per share not less than the estimated per share fair value of common stock underlying those options on the date of grant. Following the IPO, 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 and RSUs is as follows:

Restricted Stock Awards	**Number of shares**
Unvested as of December 31, 2017	2,500,000
Issued	218,980
Vested	(2,406,480)
Forfeited/Cancelled	—
Unvested as of December 31, 2018	312,500

The weighted average grant date fair value of the RSAs issued was $1.37 and $0.21 during the periods ended December 31, 2018 and 2017, respectively. The fair value of the RSAs vested during the periods ended December 31, 2018 and 2017 was $2,784 and $0, respectively.

Restricted Stock Units	**Number of shares**
Unvested as of December 31, 2017	50,000
Issued	—
Vested	(50,000)
Forfeited/Cancelled	—
Unvested as of December 31, 2018	—

The grant date fair value of the RSUs issued in 2017 was $1.38 and no RSUs were issued in 2018. The fair value of the RSUs vesting during the periods ended December 31, 2018 and 2017 was $69 and $69, respectively.

(in thousands, except share and per share amounts)

As of December 31, 2018, there was a total of $1,277, $59 and $0 of unrecognized compensation costs related to non-vested stock option awards, RSAs and RSUs, respectively. There were no exercises of stock options during the year ended December 31, 2018.

In December 2018, the Company's board of directors adopted an initial offering of the Company's common stock under the Company's 2018 Employee Stock Purchase Plan (the "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 will end on December 10, 2019, unless terminated earlier pursuant to the ESPP. The initial offering will consist of two purchase periods, with the first purchase period ending on June 10, 2019 and the second purchase period ending 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 ends, subsequent twelve-month offering periods will 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.

The weighted average grant date fair value of share awards in 2018 was $2.59 per share. Employees contributed $8 during 2018, which is included in accrued liabilities in the accompanying balance sheet, and the Company recorded an expense of $5 in 2018 related to the ESPP offering period that commenced on December 17, 2018.

Note 10 — Basic and Diluted Net Loss per Common Share

Basic and diluted net loss per share is computed using the weighted average number of shares of common stock outstanding during the period. Common stock equivalents (using the treasury stock and "if converted" method) from stock options, unvested RSAs and RSUs, warrants and convertible preferred stock at December 31, 2018 and 2017 were 8,262,381 and 6,977,547, 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, 2018	Period from April 27, 2017 (inception) through December 31, 2017
Net loss	$ (12,740)	$ (7,156)
Series A Preferred – dividends (accrued and deemed)	(24,489)	(1,483)
Net loss attributable to common stockholders	(37,229)	$ (8,639)
Weighted average common shares outstanding (basic and diluted)	6,417,840	3,453,213
Net loss per common share (basic and diluted)	$ (5.80)	$ (2.50)

Note 11 — 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. The Company and Harrow signed licensing agreements for two products developed by Harrow whereby Harrow assigned the product rights to the Company. The Company will pay Harrow a $50 milestone payment upon patent approval for each product and a royalty fee at a rate of six percent on the net sales of those two products. On December 26, 2017, one of the products had its patent approved and a $50 milestone fee was recognized as R&D expense by the Company in 2017 and paid to Harrow in January 2018. In July 2018, the Company determined the patent-approved product was not viable for its portfolio of product opportunities and Harrow paid the Company $50 to cancel the licensing agreement for the one product and retain the product rights at Harrow.

As part of the early start-up for the Company's pharmaceutical business, key executives at Harrow received 1,500,000 shares of restricted common stock in the Company for consulting services and certain Harrow managers also received options to purchase 130,000 shares of common stock from the Company (20,000 of these options were forfeited in 2018). The restricted stock and stock options vested 100% after one year on April 30, 2018. The Company recorded stock-based compensation expense of $970 and $1,370 for the Harrow restricted common stock and $51 and $112 for Harrow stock options, respectively, for the periods ended December 31, 2018 and 2017 as a component of its general and administrative expenses.

Additionally, the Chief Executive Officer of Harrow is a member of the Company's board of directors.

Chief Executive Officer

The CEO has a partial interest in several companies that the Company is working with for product development and potential marketing if the products are approved by the FDA as detailed 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, an entity affiliated with the CEO ("Eyemax"). 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 is responsible for all costs of testing and FDA approval of the product, other than the FDA filing fee which will be paid by Eyemax. The Company was also 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, 2018 and 2017. On February 18, 2019 the Company entered into an Amended and Restated Agreement with Eyemax amending the terms of the prior Eyemax Agreement. See Note 15 "Subsequent Events" for more information on the Amended and Restated Agreement.

The Company acquired the exclusive rights to sell the DS-100 product in the United States pursuant to an exclusive development and supply agreement (the "Andersen Agreement") dated July 9, 2017 between the Company and Andersen Pharma, LLC, an entity affiliated with the CEO ("Andersen"). The Company also holds an option to purchase the DS-100 product and all related intellectual property and government approvals at a price of one dollar. Pursuant to the Andersen Agreement, Andersen is responsible for obtaining FDA approval at its expense and manufacturing the product for sale to the Company at its cost. The Company is responsible for commercializing the product in the United States at its expense. The Company paid Andersen $750 upon execution of the Andersen Agreement, which was recorded as a component of R&D expense and will pay Andersen $750 upon successful completion of three registration batches of product, $750 upon submission of a New Drug Application ("NDA") and $750 upon FDA approval. The Company will also pay Andersen 50% of the net profit from the sale of the product. The Andersen Agreement is for an initial term of five years from the first commercial sale of the product, subject to successive two-year renewals unless either party elects to terminate the Andersen Agreement. There were no amounts due under the terms of the Andersen Agreement as of December 31, 2018 or 2017. The aforementioned option to purchase the product and all related intellectual property and government approvals was considered to represent variable interest in the affiliated entity. The affiliated entity was not considered to be a variable interest entity.

(in thousands, except share and per share amounts)

The Company acquired the DS-200 product and all related intellectual property and government approvals pursuant to an asset purchase agreement (the "Selenix Agreement") dated June 23, 2017 between the Company and Selenix LLC, an entity affiliated with the CEO ("Selenix"). Pursuant to the Selenix Agreement, the Company paid Selenix $1,500, which was recorded as a component of R&D expense and has agreed to pay $1,500 upon submission of an NDA and $1,000 upon FDA approval. The Company has also agreed to pay Selenix 50% of the net profit from the sale of the product for the first 10 years following the date of the Selenix Agreement. There were no amounts due under the terms of the Selenix Agreement as of December 31, 2018 or 2017.

Note 12 – Income Taxes

The provision for income taxes for the Company consists of the following for the periods ended December 31, 2018 and 2017:

	December 31, 2018	December 31, 2017
Current:		
Federal	$ —	$ —
State	—	—
Total current expense	—	—
Deferred:		
Federal	1,900	1,308
State	679	468
Change in valuation allowance	(2,579)	(1,776)
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, 2018 and 2017 are as follows:

	December 31, 2018	December 31, 2017
Net operating losses	$ 3,968	$ 1,610
Stock-based expenses	233	102
Accruals and other	154	64
Total deferred tax assets	4,355	1,776
Valuation allowance	(4,355)	(1,776)
Net deferred tax assets	$ —	$ —

Based on the uncertainty of future taxable income at this time management believes a 100% valuation reserve for the $4,355 deferred tax asset is appropriate.

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

	Year ended December 31, 2018	Period from April 27, 2017 (inception) through December 31, 2017
Benefit at statutory rate	(21.0)%	(34.0)%
Permanent items (primarily warrants and stock compensation)	6.0	4.4
State tax benefit	(5.3)	(5.5)
Federal rate change	—	10.2
Other items	—	—
Establishment of valuation allowance	20.3	24.9
Income tax expense	—%	—%

(in thousands, except share and per share amounts)

The Tax Act significantly revised U.S. corporate income tax law by, among other things, reducing the corporate income tax rate from 34% to 21% and implementing a modified territorial tax system. Implementation of the Tax Act resulted in a $733 charge for the revaluation of the Company's net deferred tax assets offset by a corresponding $733 reduction in the valuation reserve for income taxes during the period ended December 31, 2017.

The Company has a federal and state NOL carryforward of $13,921 as of December 31, 2018, of which $5,648 will begin to expire in 2037 and 2039, respectively. 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 after 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 and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. The Company is currently performing a study to determine if it has triggered an "ownership change" limitation at the completion of its IPO in November 2018.

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 periods ended December 31, 2018 and 2017, the Company made $62 and $0 in matching contributions, respectively.

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.

Leases

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 runs through the end of March 2021.

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 runs through the end of February 2021.

For the periods ended December 31, 2018 and 2017, the Company recorded $115 and $14, respectively, in rent expense.

The Company's lease commitments for its administrative offices in Deer Park, Illinois and its laboratory facility in Lake Zurich, Illinois for 2019 and beyond are as indicated below:

Total	2019	2020	2021	Thereafter
$ 308	$ 137	$ 140	$ 31	$ —

License and Product Development Agreements

The Company has entered into various agreements in addition to those discussed above which are described below.

The Company entered into a contract for development and production of its CT-100 product with an unaffiliated third party on November 7, 2017. Pursuant to the agreement, the third party is responsible for development and production of the product and for obtaining FDA approval and the Company is responsible for commercializing the product in the United States. The Company will pay the third party 30% of the net profits from the sale of the product. The initial term is for the first 10 years following the first commercial sale of the product.

The Company acquired the exclusive rights to sell the DS-300 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 will pay the third party 50% of the net profit from the sale of the product. The initial term is for the first 10 years following the first commercial sale of the product.

The Company entered into a contract with a clinical research organization ("CRO") for clinical studies on its EM-100 product candidate and those studies were completed in 2018. The Company paid milestones at each phase of completion of the clinical study. Total milestone payments under the contract were $1,104 and the study was completed in August 2018.

The Company acquired the exclusive license to develop, manufacture and sell ET-103 in the United States pursuant to an Exclusive License and Supply Agreement dated August 3, 2018 between the Company and Liqmeds Worldwide Limited, an unaffiliated entity. Pursuant to the agreement, the Company will be responsible for, and shall own, all regulatory filings and approvals at its expense, provided that it shall have the right to recoup 35% of any regulatory filing fees from the initial profits from the sale of ET-103 and, provided further, the licensor shall be responsible for any bioequivalence study and shall be responsible for 60% of the costs of such study. An affiliate of the licensor shall manufacture the ET-103 and sell it to the Company at its cost. The Company paid the licensor $350 upon execution of the agreement and will pay the licensor $1,500 upon the FDA's acceptance of an NDA for review, $1,000 upon FDA approval, $1,500 upon issuance of patent covering ET-103 listed in the FDA's Orange Book and $500 in the event of product sales in excess of $10,000 in any calendar year. In addition, the Company is required to pay the licensor 35% of the net profit from product sales. The license agreement is for an initial term of 10 years from the date of the first commercial sale of the product, subject to two-year renewals unless either party elects to terminate no less than 12 months prior to the then current term. The agreement also contains customary representations, warranties, covenants and indemnities by the parties.

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, 2018 or 2017.

Note 15 — Subsequent Events

The Company has performed an evaluation of events occurring subsequent to December 31, 2018 through the filing date of this Annual Report. Based on its evaluation, nothing other than the events described below need to be disclosed.

On January 23, 2019, the Company entered into a Licensing and Supply Agreement (the "Agreement") with Liqmeds Worldwide Limited ("LMW") for ET-104 oral liquid, a development stage product candidate ("ET-104"). Pursuant to the terms of the Agreement, Eton will be responsible for regulatory and marketing activities. LMW will be responsible for development and manufacturing of ET-104. Eton is obligated to pay to LMW licensing payments of up to $2.5 million based on achievement of the following milestones:

- $350,000 upon execution of the Agreement;
- $350,000 upon successful bioequivalence study results;
- $325,000 upon NDA acceptance for review by the FDA;
- $325,000 upon NDA approval;
- $650,000 upon issuance of patent listed in the FDA's Orange Book; and
- $500,000 when product sales first exceed $10 million in a calendar year.

Eton will also pay to LMW 35% of product profit from commercial sales. The Agreement has a ten-year term, and Eton will retain sole ownership of the NDA after expiration of the Agreement.

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 ET-202, an injectable product candidate for use in the hospital setting that has been submitted to the FDA for review. Pursuant to the terms of the Agreement, Eton will be responsible for marketing activities and Sintetica will be responsible for development, manufacturing, and regulatory activities related to obtaining regulatory approval. Eton will pay to Sintetica a licensing payment of $2,000,000 upon execution of the agreement and $750,000 upon FDA approval of the product candidate. Upon approval, Sintetica will supply ET-202 to Eton at its direct costs. Eton will retain 5% of net sales as a marketing fee. Sintetica will be entitled to receive the first $500,000 of product profits. All additional profit will be split 50% to Eton and 50% to Sintetica. The agreement has a ten-year term from first commercial sale of product.

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 ET-203, an injectable product candidate for use in the hospital setting. Pursuant to the terms of the Agreement, Eton will be responsible for marketing activities and Sintetica will be responsible for development, manufacturing, and regulatory activities related to obtaining regulatory approval. Eton will pay to Sintetica a licensing payment of $1,000,000 upon execution of the agreement and $750,000 upon FDA approval of the product candidate. Upon approval, Sintetica will supply ET-202 to Eton at its direct costs. Eton will retain 5% of net sales as a marketing fee. Sintetica will be entitled to receive the first $500,000 of product profits. All additional profit will be split 50% to Eton and 50% to Sintetica. The agreement has a ten-year term from first commercial sale of product.

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 Eton 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, Eton 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 remain obligated to pay Eyemax two milestones: (i) one milestone payment for $250,000 upon regulatory approval in the territory by the FDA of the first single agent product and (ii) one milestone payment for $500,000 following the first commercial sale of the first single agent product in the territory. Following payment of the milestones, Eton is entitled to retain all of the non-royalty transaction revenues and royalties up to $2,000,000 (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 Amended Agreement also contains customary representations, warranties, covenants and indemnities by the parties. The Company's CEO, Sean Brynjelsen, has a 33% ownership interest in Eyemax.

In conjunction with the Amended Agreement with Eyemax, on February 18, 2019, the Company entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") with Bausch Health Ireland Limited ("Bausch"). Pursuant to the Asset Purchase Agreement, Eton sold all of its right, title and interest in EM-100 in the United States, including any such product that incorporates or utilizes its intellectual property rights with respect to EM-100. Under the Asset Purchase Agreement, Bausch assumed all of Eton's liabilities under the Excelvision Agreement, related to the United States and arising during certain time periods. Pursuant to the Asset Purchase Agreement, Bausch paid Eton an upfront payment of $500,000 and Bausch is required to pay the Company commercial milestone payments of up to $2,500,000. Additionally, Bausch is required to pay Eton a royalty in the low-double digit percentage range on net sales for a period of 10 years from the date of the first commercial sale of the first single agent EM-100 product in the United States. In the event that any product with the same sole active ingredient as EM-100 is launched in the United States by any person other than Bausch (or its affiliates) during the term of Bausch's royalty commitment, then the royalty rate will be reduced to a lower specified percentage. In the event that EM-100's market share in the territory falls below a certain percentage of the target market during the term of Bausch's royalty commitment, then the royalty rate will be further reduced to a lower specified percentage. The Asset Purchase Agreement also contains customary representations, warranties, covenants and indemnities by the parties.

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 Chief Executive Officer and our Chief 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.

With respect to the year ended December 31, 2018, under the supervision and with the participation of our management, we conducted an evaluation of the effectiveness of the design and operations of our disclosure controls and procedures. Based upon this evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures are effective.

Management's Report on Internal Control over Financial Reporting

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

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) and 15d-15(f) under the Exchange Act) that occurred during the year ended December 31, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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 2019 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, 2018, 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:

(2) *Financial Statement Schedules*

All required information has been included in the consolidated financial statements or notes thereto.

(3) *Exhibits*

The following exhibits have been 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).
10.1	Securities Purchase Agreement dated June 19, 2017 by and among the Registrant and the Buyers named therein (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.2	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
10.3	Asset Purchase and License Agreement (CT-100) dated May 9, 2017 between Imprimis Pharmaceuticals, Inc. and the Registrant (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.4	Asset Purchase and License Agreement (CT-200) dated May 9, 2017 between Imprimis Pharmaceuticals, Inc. and the Registrant (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.5†	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).
10.6†	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).
10.7	Exclusive Sales and Marketing Agreement (EM-100) dated August 11, 2017 between Eyemax, LLC and the Registrant (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.8†	Development, Supply and Commercialization Agreement (CT-100) dated November 7, 2017 (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.9†	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).
10.10+	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).
10.11+	Consulting Agreement by and between the Registrant and Mark L. Baum, dated as of May 1, 2017 (incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.12+	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).
10.13+	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).
10.14	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).
10.15+	Eton Pharmaceuticals, Inc. 2017 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).
10.16+	2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).

Exhibit No.	Description
10.17+	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).
10.18	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).
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 period ended December 31, 2018, 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 25, 2019

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 25, 2019
/s/ W. Wilson Troutman W. Wilson Troutman	Chief Financial Officer, Treasurer and Secretary *(Principal Financial and Accounting Officer)*	March 25, 2019
/s/ Mark L. Baum Mark L. Baum	Director	March 25, 2019
/s/ Charles J. Casamento Charles J. Casamento	Director	March 25, 2019
/s/ Paul V. Maier Paul V. Maier	Director	March 25, 2019
/s/ Norbert G. Riedel, Ph.D. Norbert G. Riedel, Ph.D.	Director	March 25, 2019

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-228493 on Form S-8 of our report dated March 25, 2019, 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, 2018.

/s/ KMJ Corbin & Company LLP

Costa Mesa, California
March 25, 2019

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)) 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) 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

(c) 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 25, 2019

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)) 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) 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

(c) 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 25, 2019

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, 2018, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic 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 25th day of March, 2019.

/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.