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, 2019

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO

Commission File Number 001-38738

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

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

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

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

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

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES [ ] NO [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 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	[X]
Non-accelerated filer	[ ]	Smaller 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 aggregate market value of all common stock (based upon the closing price on the Nasdaq Global Market) of the registrant held by non-affiliates as of June 30, 2019 was approximately $96.6 million.

As of February 28, 2020 the registrant had 17,882,486 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 2020 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, 2019, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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Note Regarding Forward-Looking Statements

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

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

- our 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 of our product candidates through the 505(b)(2) regulatory pathway for approval by the U.S. Food and Drug Administration (the "FDA");
- our ability to obtain FDA approval for 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, acquiring, and commercializing innovative pharmaceutical products that fulfill an unmet patient need. We have successfully built a diversified portfolio of high-value pharmaceutical products, primarily focused on two categories: hospital injectable products and pediatric retail prescription products.

Corporate Strategy

We plan to achieve our goal of becoming an industry leading innovative pharmaceutical company by executing on the commercialization of Biorphen® and continuing to build our product portfolio through internal product development and business development activities. Our business development activities primarily target product opportunities with the following characteristics:

Short Time to Market. We seek out innovative products that are FDA approved, under review with the FDA, or have the potential to be commercialized within 18 months.

Protection from Competition. Product protection typically takes the form of Orange Book listed patents and FDA granted exclusivities, such as orphan drug exclusivity. Protection can also include challenging to replicate formulations, complex manufacturing, or difficult to source active pharmaceutical ingredients.

Low Clinical and Regulatory Risk. We pursue product candidates where we can leverage existing safety and efficacy data to reduce the clinical burden required to receive FDA approval, providing for faster and lower cost product approvals. Typically, our products require only a single Phase 3 trial, a bioequivalence trial, or literature based clinical data for their New Drug Application ("NDA") submissions.

Low Commercial Risk. We pursue products that we believe can fulfill a proven unmet need. This may include opportunities to bring products to market to address markets that are currently relying on unapproved or compounded products.

Product Portfolio

Our currently disclosed product portfolio includes nine products: one commercial product, three products under review with the FDA, and five candidates in our late-stage pipeline.

Product (Molecule)	Dosage Form	Category	Expected Submission Timing	Reference Product Market Size
Biorphen (Phenylephrine)	Injectable	Hospital	Approved	$45 million+
EM-100 (Ketotifen)	Ophthalmic	OTC**	Submitted	$50 million +
ET-105 (Lamotrigine)	Oral Liquid	Pediatric	Submitted	$700 million +
DS-300	Injectable	Hospital	Submitted	$60 million* +
ET-104	Oral Liquid	Pediatric	2020	$65 million +
ET-103 (Levothyroxine)	Oral Liquid	Pediatric	2020	$2.5 billion +
ET-203	Injectable	Hospital	2020	$70 million +
DS-100	Injectable	Hospital	2020	$100 million* +
ET-101	Oral Liquid	Pediatric	2020	$800 million +

Note: Pipeline only includes product candidates that Eton expects to submit within twelve months.
Reference product market sizes based on IQVIA data unless noted.

*Based on management estimates

**Product will be marketed by Bausch Health

Approved Products

Biorphen (Phenylephrine Hydrochloride Injection). Biorphen is the first and only FDA-approved formulation of ready-to-use phenylephrine injection. Biorphen in indicated for the treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia. The product was approved in October 2019 and launched in December 2019.

We estimate the current market size for ready-to-use phenylephrine to be more than 20 million units of Biorphen annually. Biorphen primarily competes with FDA-approved formulations of concentrated phenylephrine injection, which must be diluted prior to administration to patients, and with unapproved formulations of ready-to-use phenylephrine sold by 503B compounding pharmacies. We acquired U.S. marketing rights to the product from Sintetica SA ("Sintetica") in February 2019.

Products Under FDA Review:

ET-105 (Lamotrigine for Oral Suspension). ET-105 is our innovative formulation of lamotrigine to be delivered to patients as an oral suspension. The NDA for ET-105 has been submitted to the FDA and is under review for the treatment of partial on-set seizures, primary generalized tonic-clonic seizures, and seizures of Lennox-Gastaut syndrome in patients two year of age and older.

ET-105 is designed to fulfill an unmet need for patients that require precision dosing or have challenges administering oral solid formulations. Due to Lamotrigine's weight-based dosing calculation and the required titration dosing upon initiation of treatment, we believe there is a significant need for ET-

105’s precision dosing. Currently the lowest strength tablet form of lamotrigine that is widely available is a 5mg tablet. ET-105 is designed to allow dosing in increments of 1.0mg.

Lamotrigine is currently only approved in oral solid formulations, for which the U.S. market is currently more than $700 million annually according to IQVIA data. We acquired U.S marketing rights to the product from Aucta Pharmaceuticals in June 2019. Aucta has been issued a patent on ET-105's innovative formula, which we expect to be listed in the FDA's Orange Book upon approval. ET-105's NDA is under review with the FDA. The application has been assigned a Prescription Drug User Fee Act (PDUFA) target action date of March 17, 2020, however, on February 19, 2020 we disclosed that we received an FDA request for changes to the Dosage and Administration section of the product's Prescribing Information to simplify the dosing information for intended users. The FDA has requested that the company conduct a human factors validation study with the revised labeling to demonstrate that the intended users can prepare and administer the oral suspension safely and effectively. The company expects the study and its final report to be completed and submitted to the FDA in 2020.

EM-100 (Ketotifen Ophthalmic Solution). EM-100 is a preservative-free formulation of ketotifen ophthalmic solution for the treatment allergic conjunctivitis. The product is expected to be the first and only preservative-free ophthalmic product approved for the treatment of allergic conjunctivitis. EM-100's preservative-free formulation is designed to deliver an improved comfort profile to patients compared to currently available ketotifen ophthalmic products that contain preservatives. EM-100 will be sold via the over-the-counter (OTC) channel. Currently the market for ketotifen ophthalmic products is estimated to be more than $75 million annually based on data from IRI and IQVIA.

We sold the EM-100 product rights to Bausch Health ("Bausch") in February 2019. Bausch Health will be responsible for commercialization of the product. We are entitled to receive a $1.5 million milestone payment upon launch of the product and will receive a double-digit percentage royalty on the product's net sales. Bausch received a Complete Response Letter on the product's application in July 2019 and responded in an amendment submitted in December 2019. The product has been assigned a target action date in August 2020.

DS-300. DS-300 is an injectable product candidate for which we have submitted an Abbreviated New Drug Application "ANDA" to the FDA. We originally submitted DS-300 as an NDA under a Rolling Review, however, due to the approval of a competitor's NDA containing the same active ingredient, the FDA requested that we resubmit the product as an ANDA. The ANDA was submitted in December 2019 and has been accepted for review by the FDA. We believe we are the first-to-file ANDA and should be entitled to 180 days of exclusivity if the patent is successfully challenged. The FDA has assigned the product's application a target action date in October 2020, however, expected Paragraph IV challenge litigation will delay final FDA approval beyond that date.

Prior to the approval of the reference product by a third party in 2019, DS-300's active ingredient was supplied in injectable form as an unapproved product. Based on the IQVIA date for the current market price and historic volumes for the unapproved product, we believe the market size is more than $65 million annually.

Late-Stage Product Candidates

ET-203. ET-203 is an innovative ready-to-use formulation of a molecule that is currently approved in a concentrated formulation 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 to patients, eliminating the need for calculations and 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, reduction of compounding errors, greater sterility assurance, and more consistent supply. ET-203's NDA was originally submitted to the FDA in July 2019 and received a refuse-to-file letter. Our development partner, Sintetica, expects to address the FDA's concerns and resubmit the NDA in 2020.

ET-104. ET-104 is 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 or manually crushing tablets to create liquid solutions. 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 are currently in discussions with the FDA regarding the application's pediatric study protocol, and we expect to submit the NDA in 2020. The current market for ET-104's active ingredient in oral solid form is more than $65 million annually according to IQVIA.

ET-103. ET-103 is a unique oral liquid formulation of levothyroxine for the treatment of hypothyroidism. Currently levothyroxine is delivered primarily in tablet and capsule form and is one of the most frequently prescribed medications in the United States with more than 5.7 billion tablets and $2.6 billion prescribed annually according to IQVIA data. We are currently in discussions with the FDA regarding the products bioequivalence data results to ensure compliance with FDA requirements prior to submission of the NDA. If we receive agreement from the FDA, we expect the product's NDA to be submitted in the first half of 2020.

DS-100. DS-100 is an injectable product candidate. DS-100's active ingredient was historically sold in injectable form as an unapproved product, but a third party recently received FDA approval. Eton is pursuing a different indication than the currently approved product. We expect an NDA for DS-100 to be submitted in 2020.

ET-101. Is an innovative oral liquid product candidate targeting a neurological condition. ET-101'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-101 is expected to address this significant unmet patient need. Based on IQVIA data, the U.S. market for ET-101's active ingredient in oral solid form is more than $800 million annually. We are currently running a bioequivalence study for the product and expect to file the NDA in 2020.

Our late-stage pipeline only includes product candidates that we believe can be submitted to the FDA within twelve-months. For competitive reasons, we typically do not disclose our additional product candidates that are more than twelve months away from NDA submission.

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.

Sales and Marketing

We currently commercialize Biorphen with the support of a co-promotion agreement with Xellia Pharmaceuticals. We intend to commercialize most of our products through our internal sales and marketing infrastructure. However, in certain scenarios we may conclude that it is financially or strategically beneficial to out-license, sell, or partner with a third party for commercialization of a product. For example, we sold our EM-100 product candidate to Bausch Health, who has an established presence in the over-the-counter ophthalmic channel, in exchange for milestone payments and future royalty payments based on Bausch's sales of the product.

Our products primarily fall into two categories for commercialization: Hospital injectables and retail prescription products.

Hospital injectables products are primarily marketed to hospitals and surgical centers and may be purchased by customers through wholesalers and/or arrangements with Group Purchasing Organizations (GPOs). Our first product launch in this category was Biorphen in December 2019, and our additional hospital injectable products include DS-300, ET-203, and DS-100.

In January 2020 we signed a co-promotion agreement with Xellia for the promotion of Biorphen. Under terms of the agreement, Xellia's US-based hospital sales force will promote Biorphen in certain customer channels in collaboration with Eton, in exchange for a commission based on net sales realized at certain customer accounts. The product will continue to be sold under Eton's brand name, and Eton has the right to continue promoting the product to all customer accounts. The agreement has a five-year term, but allows Eton to exit under various scenarios, including a change of control, and after 2021 if Biorphen net sales from Xellia designated accounts do not exceed $29.4 million in 2021, or $42.0 million in 2022 and the following years.

Our retail prescription products will be promoted to prescribing physicians, primarily neurologists and endocrinologists. We intend to distribute the products through a network of retail and specialty pharmacies. Our products in this category include ET-105, ET-104, ET-103 and ET-101.

Research and Development

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

Manufacturing and Suppliers

We rely on third party contract manufacturing organizations ("CMOs") to manufacture our products. All our manufacturing partners are based in the United States or Europe. We seek to work with CMOs that have a long history of quality and FDA compliance. All products are manufactured in compliance with current Good Manufacturing Processes ("cGMP"), and our internal quality system requires us to enter quality agreements with and audit all of our manufacturers prior to commercializing 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

Certain products in our portfolio were acquired externally through the licensing or acquisition of existing development products including:

Biorphen. We acquired the exclusive license to market Biorphen in the United States 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 $2 million upon execution of the agreement and paid an additional $750,000 upon commercial launch of the product. Sintetica supplies product to us at its direct costs. We retain 5% of net sales as a marketing fee. Sintetica receives the first $500,000 of product profits, and 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-105. On June 12, 2019, we entered into an Exclusive Licensing and Supply Agreement (the "ET-105 License Agreement") with Aucta Pharmaceuticals, Inc. ("Aucta") for marketing rights in the United States to ET-105. Pursuant to the terms of the ET-105 License Agreement, we will be responsible for marketing activities and Aucta will be responsible for development, manufacturing, and regulatory activities related to obtaining regulatory approval. We paid Aucta a licensing payment of $2,000,000 in August 2019 upon receiving an acceptance for review letter from the FDA and will pay $2,000,000 upon FDA approval and the commencement of commercial sales of the product and another $1,000,000 upon issuance of an Orange-book listed patent. Aucta will receive a low double-digit royalty on net sales and will be entitled to receive additional milestone payments of up to $18,000,000 in total based on commercial success of the product, including: $1,000,000 when net sales exceed $10 million in a calendar year; $2,000,000 when net sales exceed $20 million in a calendar year; $5,000,000 when net sales exceed $50 million in a calendar year; and $10,000,000 when net sales exceed $100 million in a calendar year.

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 a milestone payment of $1,500,000 upon the first sale of the product. 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 pharmaceutical ingredient ("API") 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.

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. 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. In February 2020, we executed an amendment to the Sales and Marketing Agreement. Under the revised terms, Eton will be responsible for Paragraph IV related litigation and will be entitled to 62.5% of product profit, generally defined as gross profit less certain fees and costs incurred by us.

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-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. In January of 2020, we amended the agreement as a result of the product's initial new drug application receiving a refuse to file letter from the FDA, Eton was returned the initial $1 million licensing payment that we paid to Sintetica upon execution of the original agreement. If Sintetica resubmits the product NDA and the FDA accepts it for review, Eton will repay the $1 million licensing fee.

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.

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.

Our development partner for ET-105 was granted a patent by the United States Patent and Trademark Office for the product's unique formulation. We expect the patent to be Orange Book listed after product approval.

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

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

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

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

After the FDA evaluates the NDA and inspects manufacturing facilities where the drug product and/or its API will be produced, it will either approve commercial marketing of the drug product with prescribing information for specific indications or issue a 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 ("REMS") plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing. Such post-marketing testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and efficacy after approval.

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

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

Section 505(b)(2) New Drug Applications

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

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

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

Section 505(j) Abbreviated New Drug Applications

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

Other U.S. Healthcare Laws and Compliance Requirements

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

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

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

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

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

- The Physician Payments Sunshine Act which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services ("CMS") information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

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

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

Reimbursement

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

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

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

Healthcare Reform.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval pharmaceutical products, restrict or regulate post-approval activities and affect our ability to profitably sell our product candidates. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, (collectively, the "Health Care Reform Law") was enacted, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Health Care Reform Law, among other things, imposed reporting requirements on manufacturers related to drug samples and financial relationships with physicians and teaching hospitals, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees on manufacturers of certain branded prescription drugs, and established a Medicare Part D coverage gap discount program.

Some of the provisions of the Health Care Reform Law have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the Health Care Reform Law, 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 Health and Human Services ("HHS") Office of Inspector General proposed modifications to the U.S. Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While some of these and other proposed measures may require additional authorization to become effective, Congress and 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 17 full-time employees, ten of whom are engaged in research and development activities and seven of whom are engaged in general corporate and strategy roles. We periodically utilize outside consultants on an as-needed basis, including medical consultants.

Corporate and Other Information

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

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

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

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

To date, we are not profitable and have incurred losses since our inception in April 2017. For the years ended December 31, 2019 and 2018, we incurred a net loss of $18.3 million and $12.7 million, respectively, and our operations used $18.0 million and $8.1 million of cash and cash equivalents, respectively. We have realized limited revenues from two products and expect to incur significant development expenses for our product candidates in the United States and elsewhere. We may never be able to obtain regulatory approval for the marketing of our additional product candidates for any indication in the United States or internationally and 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, 2019, we had total assets of $17.1 million and working capital of $13.0 million. We received $22.0 million in net proceeds from our initial public offering ("IPO") in November 2018. In November 2019, we entered into a $10.0 million debt facility with SWK Holdings Corporation, and we received $5.0 million at closing with the option to drawdown additional capital if certain product candidates are approved. We 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 additional 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 commercialization of our Biorphen product and clinical testing of our product candidates and will face an even greater risk if we commercialize our current product candidates or any other future product. For example, we may be sued if Biorphen or any product we develop, including any of our product candidates, or any materials that we use in our products allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. In the United States, claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for Biorphen or any of our product candidates or any future products that we may develop;
- injury to our reputation;

- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- the inability to commercialize some or all of our product candidates; and
- a decline in the value of our stock.

We carry product liability insurance we consider adequate for our current level of expected Biorphen sales, clinical testing and product development. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of Biorphen or additional 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.

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

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our product development and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. Cybersecurity attacks in particular are evolving and include, but are not limited to, malicious software, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in systems, misappropriation of our confidential or otherwise protected information and corruption of data. The loss, theft or sabotage of product development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs and the development of our product candidates could be delayed.

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

Our Biorphen product on 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 Biorphen product on 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 Biorphen and our product candidates. If we are unable to generate revenues from our product candidates, our ability to create stockholder value will be limited.

We have various product candidates are in the early stages of clinical development, and we do not generate revenues from any FDA approved drug products other than Biorphen. An abbreviated new drug application (“ANDA”) was submitted for our EM-100 product candidate and our DS-300 product. In addition, an NDA was submitted for ET-105 in May 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 additional product approvals from the FDA or comparable foreign regulatory authorities for any indication. We note that most product candidates never reach the clinical development stage and even those that do commence clinical development have only a small chance of successfully completing clinical development and gaining regulatory approval. Therefore, our business substantially depends entirely on the successful development, regulatory approval and commercialization of our product candidates, which may never occur.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid or unenforceable, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. Under the Hatch-Waxman Act, the holder of patents that the 505 (b)(2) application references may file a patent infringement lawsuit after receiving notice of the Paragraph IV certification. Filing of a patent infringement lawsuit against the filer of the 505(b)(2) applicant within 45 days of the patent owner's receipt of notice triggers a one-time, automatic, 30-month stay of the FDA's ability to approve the 505(b)(2) NDA, unless patent litigation is resolved in favor of the Paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all.

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

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

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

We are subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates could be subject to labeling and other restrictions and withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates.

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

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

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

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

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

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- issuance of warning letters or untitled letters;
- clinical holds;
- injunctions or the imposition of civil or criminal penalties or monetary fines;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- suspension or imposition of restrictions on operations, including costly new manufacturing requirements; or
- product seizure or detention or refusal to permit the import or export of product.

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

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

We currently have a limited sales and marketing organization and one partner for co-promotion of our Biorphen product. If we are unable to secure a sales and marketing partner for potential future products or establish satisfactory sales and marketing capabilities, we may not successfully commercialize 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 additional 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% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". On December 14, 2018, a Texas U.S. District Court Judge ruled that the Health Care Reform is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Health Care Reform will impact the ACA and our business. We cannot predict the impact on our business of changes to current laws and regulations. However, any changes that lower reimbursements for products for which we may obtain regulatory approval, or that impose administrative and financial burdens on us, could adversely affect our business.

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

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. On January 31, 2019, the U.S. Department of Health and Human Services, Office of Inspector General, proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While some of these and other proposed measures may require additional authorization to become effective, Congress and 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 Biorphen or 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 contract manufacturer caused by problems at suppliers could delay shipment of Biorphen or any of our product candidates, increase our cost of goods sold and result in lost sales.

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

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

We face significant competition in seeking appropriate third parties. 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 sufficient product revenues will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to generate sufficient revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical studies may also ultimately lead to the denial of regulatory approval of our product candidates. In addition, if one or more clinical studies are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of any of our product candidates could be significantly reduced.

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

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

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

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

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

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

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

We are subject to laws and regulations governing data privacy and the protection of personal information. These laws and regulations govern our processing of personal data, including the collection, access, use, analysis, modification, storage, transfer, security breach notification, destruction and disposal of personal data. There are foreign and state law versions of these laws and regulations to which we are currently and/or may in the future, be subject. For example, the collection and use of personal health data in the European Union is governed by the GDPR. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States, provides an enforcement authority and imposes large monetary penalties for noncompliance. The GDPR requirements apply not only to third-party transactions, but also to transfers of information within our company, including employee information. In addition, in 2018 California adopted a new privacy law that became effective on January 1, 2020, which borrows heavily from the GDPR. The GDPR and similar data privacy laws of other jurisdictions place significant responsibilities on us and create potential liability in relation to personal data that we or our third-party service providers process, including in clinical trials conducted in the United States and the European Union. In addition, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the European Union and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

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. Our development partner has filed a patent application for ET-104. In addition, our development partner for ET-105 was granted a patent by the United States Patent and Trademark office. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowable or enforceable in our patents. Patent and patent applications relating to our product candidates and related technologies may be challenged, invalidated or circumvented by third parties and might not protect us against competitors with similar products or technologies.

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

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

In the future, we may rely on know-how and trade secrets to protect technology, especially in cases when we believe patent protection is not appropriate or obtainable. However, know-how and trade secrets are difficult to protect. While we intend to require employees, academic collaborators, consultants and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary or licensed information. Typically, research collaborators and scientific advisors have rights to publish data and information in which we may have rights. If we cannot maintain the confidentiality of our proprietary technology and other confidential information, our ability to receive patent protection and our ability to protect valuable information owned by us may be imperiled. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts are sometimes less willing to protect trade secrets than patents. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Owning Our Common Stock

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

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

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

We filed a Form S-3 registration statement ("Shelf Registration") with the SEC that became effective in December 2019 which will allow us to sell any combination of common stock, preferred stock, debt securities, warrants to purchase any of these securities, subscription rights to purchase any of these securities, and/or units consisting of one or more of the foregoing in one or more offerings up to a total dollar amount of $100 million. The issuance of additional shares of our common stock pursuant to the Shelf Registration, or issuances of securities convertible into or exercisable for our common stock or other equity-linked securities, including preferred stock, warrants, debt securities or units, would dilute the ownership interest of our common shareholders and could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities. If we raise additional funds by issuing debt securities, these debt securities would have rights senior to those of our common stock and the terms of the debt securities issued could impose significant restrictions on our operations, including liens on our assets. If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our technologies or candidate products, or to grant licenses on terms that are not favorable to us.

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

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

- actual or anticipated variations in our and our competitors' results of operations and financial condition;
- market acceptance of our products;
- the mix of products that we sell and related services that we provide;
- changes in earnings estimates or recommendations by securities analysts, if our shares are covered by analysts;

- development of technological innovations or new competitive products by others;
- announcements of technological innovations or new products by us;
- publication of the results of preclinical or clinical trials for our other product candidates;
- failure by us to achieve a publicly announced milestone;
- delays between our expenditures to develop and market new or enhanced products and the generation of sales from those products;
- developments concerning intellectual property rights, including our involvement in litigation brought by or against us;
- regulatory developments and the decisions of regulatory authorities as to the approval or rejection of new or modified products;
- changes in the structure of healthcare payment systems;
- changes in the amounts that we spend to develop, acquire or license new products, technologies or businesses;
- changes in our expenditures to promote our products;
- our sale or proposed sale, or the sale by our significant stockholders, of our shares or other securities in the future;
- changes in key personnel;
- success or failure of our research and development projects or those of our competitors;
- the trading volume of our shares; and
- general economic and market conditions and other factors, including factors unrelated to our operating performance.

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

We are an "emerging growth company" under the JOBS Act of 2012 and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

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

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

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

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

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

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

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

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

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

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

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

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

We will continue to incur significant 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 incur significant legal, accounting and other expenses that we did not incur as a private company. We are 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 before December 31, 2017, is limited. It is uncertain if and to what extent various states will conform to the Tax Act. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. We are currently performing a study to determine if we have triggered any "ownership change" limitations. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership some of which may be outside of our control. As a result, if we earn net taxable income, our ability to use our pre-ownership change NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

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

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

As of February 28, 2020, we had 17,882,486 shares of common stock outstanding, all of which, other than shares held by our directors and certain officers, are eligible for sale in the public market, subject in some cases to compliance with the requirements of Rule 144, including volume limitations and manner of sale requirements.

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

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

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

We have broad discretion over the use of proceeds from our IPO, a recent debt financing and potential future securities offerings.

Our management has considerable discretion in the application of the net proceeds from our IPO and debt financing in November 2019. We expect to use the proceeds from our IPO and the debt financing 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 and the debt financing 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 and debt financing 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.

In addition, our management will have broad discretion to use the net proceeds from any offerings under the Shelf Registration, and you will be relying on the judgment of our management regarding the application of these proceeds. Except as described in any future prospectus supplement, the net proceeds received by us from our sale of these securities will be added to our general funds and will be used for our general corporate purposes. Our management might not apply the net proceeds from the offering of our securities in ways that increase the value of your investment and might not be able to yield a significant return, if any, on any investment of such net proceeds. You may not have the opportunity to influence our decisions on how to use such proceeds.

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 11.4% of our common stock. Additionally, Harrow Health, Inc. ("Harrow"), our former parent company, holds approximately 19.6% 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.

We may be constrained by our obligations under our Credit Agreement to operate our business to its full potential.

On November 13, 2019, we entered into a $10 million credit facility with SWK Holdings Corporation (the "Credit Agreement"). The Credit Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness and dividends and other distributions. Under the terms of the Credit Agreement, we are required to comply with (a) a maximum senior secured net leverage ratio, (b) a maximum total net leverage ratio and a minimum fixed charge coverage ratio. These terms may restrict our ability to operate our business in the manner we deem most effective or desirable, and may restrict our ability to fund our operations through new public offerings of our common stock or strengthen our candidate development pipeline through acquisitions or licenses which cause us to exceed our maximum senior secured net leverage ratio.

Failure to comply with the representations and warranties or affirmative and negative covenants could constitute an event of default which, if continued beyond the cure period, would allow the Agent (as defined in the Credit Agreement), at the request of or with the consent of the lenders holding a majority of the loans and commitments under the facility, to terminate the commitments of the lenders to make further loans and declare all the obligations of the loan parties under the Credit Agreement to be immediately due and payable, either of which could harm our business.

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 is listed on the Nasdaq Global Market under the symbol "ETON." The closing price of our common stock on the Nasdaq Global Market on December 31, 2019, the last trading date in 2019, was $7.20 per share.

Record Holders

As of February 28, 2020, we had 16 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, 2020 was $5.40

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.

In November 2019, in connection with the Credit Agreement, we issued a warrant exercisable for shares of common stock equal to six percent (6%) of the principal amount of draws upon exercise of each tranche under the Credit Agreement divided by the average trading price of common stock for the ten trading days immediately preceding such exercise.

The issuance of this warrant was made in reliance on the exemption from registration contained in Section 4(a)(2) of the Securities Act and/or Regulation as private transactions not involving a public offering of securities.

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.

In December 2019 we launched our Biorphen product and we have established a diversified pipeline of other 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 bioequivalence 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

To date we have realized only limited revenues from a licensing arrangement on our EM-100 product and the launch of our Biorphen product. We anticipate successfully completing development of additional product candidates in 2020 and beyond and growing our business.

Year Ended December 31, 2019 Compared to Year Ended December 31, 2018

For the years ended December 31, 2019 and 2018, we generated $1.0 and $0 in revenue, respectively. The revenue realized in 2019 was from a licensing arrangement for our EM-100 product which is pending additional FDA review and the launch of our Biorphen product in December 2019. For the years 2019 and 2018, we incurred $11.6 million and $5.6 million of research and development ("R&D") expenses, respectively, and $7.6 million and $4.7 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 $2.9 million increase in G&A expenses was primarily due to additional expenses related to becoming a public company, sales and marketing for the launch of our Biorphen product, and the impact of personnel additions in the second half of 2018 and first half of 2019. This was partially offset by lower stock-based consulting expenses. In addition, the change in the fair value of our warrant liability reflected in other expense decreased by $2.6 million as this mark–to–market accounting treatment was terminated in conjunction with our November 2018 IPO. We incurred a net loss of $18.3 million and $12.7 million for the years ended December 31, 2019 and 2018, respectively.

General and Administrative Expenses

G&A expenses consist primarily of employee compensation expenses, stock-based consulting service fees, sales and marketing expenses, business insurance, legal and professional fees and travel expenses.

Research and Development Expenses

Set forth below is our R&D spending for our current product candidates. We currently have ten employees that support our overall product development and we also have facility and operating costs for a laboratory that supports our product development. The laboratory personnel and related capital equipment additions were added in late 2018. 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, 2019	Year ended December 31, 2018
DS-200	$ 1,901	$ 910
DS-300	1,237	1,251
EM-100	150	1,265
ET-105	2,127	—
ET-202	2,000	—
Other products	1,374	1,026
Indirect expenses	2,766	1,175
Total	**$ 11,555**	**$ 5,627**

Year Ended December 31, 2018 Compared to Period Ended December 31, 2017

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
DS-200	$ 910	$ 1,686
DS-300	1,251	402
EM-100	1,265	470
Other products	1,026	975
Indirect expenses	1,175	397
Total	**$ 5,627**	**$ 3,930**

Liquidity and Capital Resources

As of December 31, 2019, we had total assets of $17.1 million and working capital of $13.0 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 and we also entered into a Credit Agreement with SWK Holdings in November 2019 which provides for up to $10 million in additional borrowing, $5.0 million of which was received at closing. We believe that our existing funding and the revenue from our Biorphen product and potential milestones and royalty payments from EM-100 will be sufficient for at least the next twelve months of our operations. However, our projected estimates for our product development spending, administrative expenses and our working capital requirements could be inaccurate, or we may experience growth more quickly or on a larger scale than we expect, any of which could result in the depletion of capital resources more rapidly than anticipated and could require us to seek additional financing earlier than we expect to support our operations.

Cash Flows

The following table sets forth a summary of our cash flows for the periods ended December 31, 2019, 2018 and 2017 (amounts are in thousands):

	Year ended December 31, 2019	Year ended December 31, 2018	Period from April 27, 2017 (Inception) to December 31, 2017
Net cash used in operating activities	$ (18,026)	$ (8,145)	$ (4,718)
Cash used in investing activities	(1,846)	(236)	(130)
Cash flows provided by financing activities	5,203	21,960	18,004
Net increase in cash and cash equivalents	$ (14,669)	$ 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 licensing fees for Biorphen and capital expenditures for setting up our laboratory facility and our headquarters office. The financing activity primarily consists of the Series A Preferred private placement funding in June 2017, the November 2018 IPO and the November 2019 Credit Agreement with SWK Holdings.

Critical Accounting Policies

Our financial statements are prepared in accordance with GAAP. The preparation of our financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses in our 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.

Revenue

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

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

We recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied at a point in time or over time, and if over time this is based on the use of an output or input method. Any amounts received prior to revenue recognition will be recorded as deferred revenue. Amounts expected to be recognized as revenue within the twelve months following the balance sheet date will be classified as current portion of deferred revenue in our balance sheets. Amounts not expected to be recognized as revenue within the twelve months following the balance sheet date are classified as long-term deferred revenue, net of current portion.

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

Royalties – For arrangements that include sales-based royalties, including milestone payments based on a level of sales, which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, we will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, we have not recognized any royalty revenue resulting from any of our licensing arrangements.

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

We sell Biorphen in the U.S. to wholesale pharmaceutical distributors, who then sell the product to hospitals and other end-user customers. Sales to wholesalers are made pursuant to purchase orders subject to the terms of a master agreement, and delivery of individual shipments of Biorphen represent performance obligations under each purchase order. We use a third-party logistics ("3PL") vendor to process and fulfill orders and have concluded it is the principal in the sales to wholesalers because it controls access to the 3PL vendor services rendered and directs the 3PL vendor activities. We have no significant obligations to wholesalers to generate pull-through sales.

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

We estimate the transaction price when we receive each purchase order, taking into account the expected reductions of the selling price initially billed to the wholesaler arising from all of the above factors. We have developed estimates for future returns and chargebacks of Biorphen and the impact of the other discounts and fees we pay. When estimating these adjustments to the transaction price, we reduce it sufficiently to be able to assert that it is probable that there will be no significant reversal of revenue when the ultimate adjustment amounts are known.

We recognize revenue from Biorphen product sales and related cost of sales upon product delivery to the wholesaler location. At that time, the wholesalers take control of the product as they take title, bear the risk of loss of ownership, and have an enforceable obligation to pay us. They also have the ability to direct sales of product to their customers on terms and at prices they negotiate. Although wholesalers have product return rights, we do not believe they have a significant incentive to return the product to us.

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

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

Stock-Based Compensation

We account for stock-based compensation under the provisions of 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 our initial public offering in November 2018 (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, we use the closing stock price on the date of grant for the fair value of the common stock.

Research and Development Expenses

R&D expenses include both internal R&D activities and external contracted services. Internal R&D activity expenses include salaries, benefits and stock-based compensation and other costs to support our R&D operations. External contracted services include product development efforts including certain product licensor milestone payments, clinical trial activities, manufacturing and control-related activities and regulatory costs. R&D expenses are charged to operations as incurred. We review and accrue R&D expenses based on services performed and rely upon estimates of those costs applicable to the stage of completion of each project. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from our estimates.

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

Off Balance Sheet Transactions

We do not have any off-balance sheet transactions.

JOBS Act Transition Period

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

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, 2019, 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, 2019 and 2018, the related statements of operations, redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows for the years ended December 31, 2019 and 2018, and the period from April 27, 2017 (inception) to December 31, 2017 and the related notes and the financial statement schedule listed in the index at Item 15 (2) (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, 2019 and 2018, and the results of its operations and its cash flows for each of the years ended December 31, 2019 and 2018 and the period from April 27, 2017 (inception) to 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 5, 2020

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

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 12,066	$ 26,735
Accounts receivable, net	473	—
Inventory	380	—
Prepaid expenses and other current assets	2,090	767
Total current assets	**15,009**	**27,502**
Property and equipment, net	1,117	773
Intangible assets, net	725	—
Operating lease right-of-use assets, net	160	—
Other long-term assets, net	61	52
Total assets	**$ 17,072**	**$ 28,327**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 575	$ 1,421
Accrued liabilities	1,388	603
Total current liabilities	**1,963**	**2,024**
Long-term debt, net of discount and including accrued fees	4,540	—
Operating lease liabilities, net of current portion	19	—
Total liabilities	**6,522**	**2,024**
Commitments and contingencies (Note 16)		
Stockholders' equity		
Common stock, $0.001 par value; 50,000,000 shares authorized as of December 31, 2019 and 2018; 17,877,486 and 17,607,928 shares issued and outstanding at December 31, 2019 and 2018, respectively	18	18
Additional paid-in capital	74,720	72,153
Accumulated deficit	(64,188)	(45,868)
Total stockholders' equity	**10,550**	**26,303**
Total liabilities and stockholders' equity	**$ 17,072**	**$ 28,327**

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

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

	For the years ended		Period from April 27, 2017 (Inception) to
	December 31, 2019	December 31, 2018	December 31, 2017
Revenues:			
Product sales	$ 459	$ —	$ —
Licensing revenue	500	—	—
Total revenues	**959**	**$ —**	**—**
Cost of product sales	453	—	—
Gross profit	**506**	**—**	**—**
Operating expenses:			
Research and development	11,555	5,627	3,930
General and administrative	7,552	4,694	3,220
Total operating expenses	**19,107**	**10,321**	**7,150**
Loss from operations	**(18,601)**	**(10,321)**	**(7,150)**
Other income (expense):			
Interest and other income, net	281	164	35
Change in fair value of warrant liability	—	(2,583)	(41)
Loss before income tax expense	**(18,320)**	**(12,740)**	**(7,156)**
Income tax expense	—	—	—
Net loss	**(18,320)**	**(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	**$ (18,320)**	**$ (37,229)**	**$ (8,639)**
Net loss per share attributable to common stockholders, basic and diluted	**$ (1.03)**	**$ (5.80)**	**$ (2.50)**
Weighted average number of common shares outstanding, basic and diluted	17,761	6,418	3,453

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

Eton Pharmaceuticals, Inc.
STATEMENTS OF REEDEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share amounts)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	(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**
Stock-based compensation	—	—	—	—	1,888	—	1,888
Stock option exercises	—	—	167,622	—	214	—	214
Common stock issued under employee stock purchase plan	—	—	44,885	—	239	—	239
Stock warrant exercises	—	—	57,051	—	—	—	—
Relative fair value of warrants to purchase common stock issued in connection with debt	—	—	—	—	226	—	226
Net loss	—	—	—	—	—	(18,320)	(18,320)
Balances at December 31, 2019	**—**	**$ —**	**17,877,486**	**$ 18**	**$ 74,720**	**$ (64,188)**	**$ 10,550**

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

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

	For the years ended		Period from April 27, 2017 (Inception) to
	December 31, 2019	December 31, 2018	December 31, 2017
Cash flows from operating activities			
Net loss	$ (18,320)	$ (12,740)	$ (7,156)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	1,888	1,850	1,761
Depreciation and amortization	447	63	13
Debt discount amortization	16	—	—
Change in fair value of warrant liability	—	2,583	41
Changes in operating assets and liabilities:			
Accounts receivable	(473)	—	—
Inventory	(380)	—	—
Prepaid expenses and other assets	(1,361)	(663)	(170)
Accounts payable	(377)	413	539
Accrued liabilities	534	349	254
Net cash used in operating activities	**(18,026)**	**(8,145)**	**(4,718)**
Cash used in investing activities			
Purchases of property and equipment	(1,096)	(236)	(130)
Purchase of product licensing rights	(750)	—	—
Net cash used in investing activities	**(1,846)**	**(236)**	**(130)**
Cash flows from financing activities			
Proceeds from issuance of long-term debt, net of issuance costs	4,750	—	—
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
Proceeds from employee stock purchase plan and stock option exercises	453	—	—
Net Cash provided by financing activities	**5,203**	**21,960**	**18,004**
Change in cash and cash equivalents	**(14,669)**	**13,579**	**13,156**
Cash and cash equivalents at beginning of period	26,735	13,156	—
Cash and cash equivalents at end of period	$ 12,066	$ 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
Relative fair value of common stock warrants issued in connection with debt	$ 226	$ —	$ —
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 8).

The Company's Biorphen® product was approved by the FDA in October 2019 and sales commenced for this product at the end of 2019.

Note 2 — Liquidity Considerations

As of December 31, 2019, the Company had an accumulated deficit of $64,188 and for the year ended December 31, 2019 the Company used net cash in operating activities of $18,026.

To date, the Company has realized limited revenues from two products, but expects further growth in 2020 and beyond and 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 estimated sales and its ability to manage its spending. The Company could use its available capital resources sooner than currently expected. Accordingly, the Company could seek to obtain additional capital through equity financings, the issuance of debt or other arrangements. However, there can be no assurance that the Company will be able to raise additional capital if needed or under acceptable terms, if at all. The sale of additional equity may dilute existing stockholders and newly issued shares may contain senior rights and preferences compared to currently outstanding common shares. The Company's existing long-term debt obligation contains covenants and limits the Company's ability to pay dividends or make other distributions to stockholders. If the Company experiences delays in product sales growth and completing its product development and obtaining regulatory approval for its other product candidates and is unable to obtain such additional financing, operations would need to be scaled back or discontinued.

Note 3 — Summary of Significant Accounting Policies

Basis of Presentation

The Company has prepared the accompanying financial statements in accordance with accounting principles generally accepted in the United States of America ("GAAP").

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, the useful lives of long-lived assets, 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.

Note 3 — Summary of Significant Accounting Policies (continued)

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.

Accounts Receivable

Accounts receivable is recorded at the invoiced amount and is non-interest bearing. Accounts receivable is recorded net of allowances for doubtful accounts, cash discounts for prompt payment, distribution fees, chargebacks and returns and allowances.

Inventory

The Company values its inventory at the lower of cost or net realizable value using the first-in, first-out method of valuation. The Company reviews its inventory for potential excess or obsolete issues and will record a write-down if an impairment is identified. Inventory at December 31, 2019 consists solely of purchased finished goods.

Property and Equipment

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

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

Intangible Assets

The Company capitalizes payments it makes for licensed products when the payment is based on FDA approval for the product and the cost is recoverable based on expected future cash flows from the product. The cost is amortized on a straight-line basis over the estimated useful life of the product commencing on the approval date in accordance with ASC 350-30. To date, a $750 payment related to the approval of its Biorphen product has been capitalized and that cost is being amortized over five years.

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, 2019, 2018 and 2017.

Note 3 — Summary of Significant Accounting Policies (continued)

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

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

Classification and Accretion of Redeemable Convertible Preferred Stock

Prior to the Company's IPO in November 2018, the Company 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 7).

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

The Company adopted ASC Topic 842- "Leases", effective January 1, 2019, using the modified retrospective method. The reported results for fiscal year 2019 reflect the application of ASC Topic 842, while the reported results for prior fiscal years are not adjusted and continue to be reported under the prior ASC Topic 840 guidance for leases. Refer to *Impact of New Accounting Pronouncements* regarding the adoption impact of ASC Topic 842 in the year ended December 31, 2019.

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

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

Operating leases are reflected on the balance sheets as operating lease right-of-use assets, current accrued liabilities and long-term operating lease liabilities. The Company does not have any finance leases as of December 31, 2019 and 2018.

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

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

Note 3 — Summary of Significant Accounting Policies (continued)

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.

Concentrations of Credit Risk, Sources of Supply and Significant Customers

The Company is subject to credit risk for its cash and cash equivalents invested in money market funds. The Company maintains its cash and cash equivalent balances with one major commercial bank and the deposits held with the financial institution exceed the amount of insurance provided on such deposits and is exposed to credit risk in the event of a default by the financial institutions holding its cash and cash equivalents to the extent recorded on the balance sheets.

The Company is dependent on third-party 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.

The Company is also subject to credit risk from its accounts receivable related to product sales as it extends credit based on an evaluation of the customer's financial condition, and collateral is not required. Management monitors its exposure to accounts receivable by periodically evaluating the collectability of the account receivable based on a variety of factors including the length of time the receivables are past due, the financial health of the customer and historical experience. Based upon the review of these factors, the Company recorded no allowance for doubtful accounts at December 31, 2019. The accounts receivable balance at December 31, 2019 and product sales revenue recognized during the year ended December 31, 2019 consist of sales to and amounts due from AmerisourceBergen Corporation, Cardinal Health Services and McKesson Corporation for sales of its Biorphen product.

Revenue Recognition for Contracts with Customers

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

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

The Company recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied at a point in time or over time, and if over time this is based on the use of an output or input method. Any amounts received prior to revenue recognition will be recorded as deferred revenue. Amounts expected to be recognized as revenue within the twelve months following the balance sheet date will be classified as current portion of deferred revenue in the Company's balance sheets. Amounts not expected to be recognized as revenue within the twelve months following the balance sheet date are classified as long-term deferred revenue, net of current portion.

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

Note 3 — Summary of Significant Accounting Policies (continued)

Royalties – For arrangements that include sales-based royalties, including milestone payments based on a level of sales, which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, the Company will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

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

The Company sells Biorphen in the U.S. to wholesale pharmaceutical distributors, who then sell the product to hospitals and other end-user customers. Sales to wholesalers are made pursuant to purchase orders subject to the terms of a master agreement, and delivery of individual shipments of Biorphen represent performance obligations under each purchase order. The Company uses a third-party logistics ("3PL") vendor to process and fulfill orders and has concluded it is the principal in the sales to wholesalers because it controls access to the 3PL vendor services rendered and directs the 3PL vendor activities. The Company has no significant obligations to wholesalers to generate pull-through sales.

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

The Company estimates the transaction price when it receives each purchase order taking into account the expected reductions of the selling price initially billed to the wholesaler arising from all of the above factors. The Company has developed estimates for future returns and chargebacks of Biorphen and the impact of the other discounts and fees it pays. When estimating these adjustments to the transaction price, the Company reduces it sufficiently to be able to assert that it is probable that there will be no significant reversal of revenue when the ultimate adjustment amounts are known.

The Company recognizes revenue from Biorphen product sales and related cost of sales upon product delivery to the wholesaler location. At that time, the wholesalers take control of the product as they take title, bear the risk of loss of ownership, and have an enforceable obligation to pay the Company. They also have the ability to direct sales of product to their customers on terms and at prices they negotiate. Although wholesalers have product return rights, the Company does not believe they have a significant incentive to return the product.

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

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

Cost of Product Sales

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

Note 3 — Summary of Significant Accounting Policies (continued)

Research and Development Expenses

Research and development ("R&D") expenses include both internal R&D activities and external contracted services. Internal R&D activity expenses include salaries, benefits and stock-based compensation and other costs to support the Company's R&D operations. External contracted services include product development efforts such as certain product licensor milestone payments, clinical trial activities, manufacturing and control-related activities and regulatory costs. R&D expenses are charged to operations as incurred. The Company reviews and accrues R&D expenses based on services performed and 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 2019, 2018 or 2017 as the Company reported a net loss for the periods ended December 31, 2019, 2018 and 2017 and including the effects of common stock equivalents in the diluted earnings per share calculation would have been antidilutive (See Note 11).

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 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.

Note 3 — Summary of Significant Accounting Policies (continued)

Prior to the Company's 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 statements of operations. As of December 31, 2019 and 2018, 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, 2019 and 2018, there were no unrecognized tax benefits included in the balance sheets that would, if recognized, affect the effective tax rate. The Company's practice is to recognize interest and penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties in its balance sheets at December 31, 2019 or 2018, and has not recognized interest and penalties in the statements of operations for the periods ended December 31, 2019, 2018 and 2017. As of December 31, 2019, the Company is subject to taxation in the United States and Illinois. The Company's tax losses from 2019, 2018 and 2017 are 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 estimates become 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, 2019 or 2018.

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.

Note 3 — Summary of Significant Accounting Policies (continued)

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

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

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

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 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 Notes 4 and 9).

Impact of New Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02 (Topic 842) – Leases ("ASC 842"), which requires the lease rights and obligations arising from lease contracts, including existing and new arrangements for substantially all leases with terms more than twelve months to be recognized as assets and liabilities on the balance sheet. Recognition, measurement and presentation of expenses depends upon classification as a finance or operating lease. The Company adopted ASC 842 effective January 1, 2019 utilizing the modified retrospective approach such that prior year financial statements were not recast under the new standard. The adoption of ASU 2016-02 did not have a material effect on the Company's financial condition from the recognition of the lease rights and obligations as assets and liabilities or its results of operations and cash flows. See Note 13 for additional information regarding the new standard and its impact on the Company's financial statements.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments. The standard amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses for most financial assets and certain other instruments that aren't measured at fair value through net income. For available-for-sale debt securities, entities will be required to recognize an allowance for credit losses rather than a reduction in carrying value of the asset. Entities will no longer be permitted to consider the length of time that fair value has been less than amortized cost when evaluating when credit losses should be recognized. The Company plans to adopt the new guidance on January 1, 2020 and does not anticipate the adoption will have a material impact on its financial position or results of operations.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820). The new guidance removes, modifies and adds to certain disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement. The Company plans to adopt the new guidance on January 1, 2020 and does not anticipate the adoption will have a material impact on its financial position or results of operations.

In December 2019, the FASB issued ASU 2019-12, Simplifying the Accounting for Income Taxes. The new guidance removes certain exceptions to the general principles of ASC 740 in order to simplify the complexities of its application. These changes include eliminations to the exceptions for intraperiod tax allocation, recognizing deferred tax liabilities related to outside basis differences, and year-to-date losses in interim periods among others. The Company will adopt ASU 2019-12 in January 2020 and does not anticipate it will have a material impact on its financial position or results of operations.

(in thousands, except share and per share amounts)

Note 4 — Fair Value of Financial Assets and Liabilities

Valuation of Warrant Liability

The Company previously accounted for a warrant to purchase shares of its common stock that was issued to the Company's placement agent in connection with the Series A Preferred offering (see Note 9) as a liability. 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 had never paid or declared dividends and did 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 9). The Company remeasured the estimated fair value on the date of the IPO and reclassified this amount to additional paid-in-capital.

The following table provides a roll forward of the aggregate fair values of the Company's warrant liability, for which fair value was 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, 2019	December 31, 2018
Computer hardware and software	$ 174	$ 93
Furniture and fixtures	133	98
Equipment	994	99
Leasehold improvements	152	53
Construction in progress	9	492
	1,462	835
Less: accumulated depreciation and amortization	(345)	(62)
Property and equipment, net	$ 1,117	$ 773

Depreciation and amortization expense for the periods ended December 31, 2019, 2018 and 2017 was $283, $51 and $11, respectively.

(in thousands, except share and per share amounts)

Note 6 – Long-term Debt

On November 13, 2019, the Company entered into a credit agreement (the "SWK Credit Agreement") with SWK Holdings Corporation ("SWK") which provides for up to $10,000 in financing. The Company received proceeds of $5,000 at closing and may borrow an additional $5,000 upon the FDA approval of a second product developed by the Company, excluding EM-100. Alternatively, the Company can borrow $2,000 upon FDA approval of the EM-100 product candidate and then an additional $3,000 upon FDA approval of another one of its product candidates. The term of the SWK Credit Agreement is five years and borrowings bear interest at a rate of LIBOR 3-month plus 10.0%, subject to a stated LIBOR floor rate of 2.0%. In connection with the SWK Credit Agreement, the Company paid $250 in cash for issuance costs and issued warrants to SWK to purchase common stock of the Company in an amount equal to 6.0% of the principal amounts drawn under the SWK Credit Agreement, utilizing the prior ten-day average closing price of the Company's common stock as a divisor to calculate the number shares issuable under the warrant. A 2.0% unused credit limit fee is assessed during the first twelve months after the date of the SWK Credit Agreement and loan fees include a 5.0% exit fee based on the principal amounts drawn which is payable at the end of the term of the SWK Credit Agreement. The Company is required to maintain a minimum cash balance of $3,000, will only pay interest on the debt until May 2021 and then will pay 4.0% of the loan principal balance commencing on May 15, 2021 and then every three months thereafter until November 13, 2024 at which time the remaining principal balance is due. Borrowings under the SWK Credit Agreement are secured by the Company's assets. The SWK Credit Agreement contains customary default provisions and covenants which include limits on additional indebtedness. SWK and the Company will negotiate covenant targets for EBITDA and revenue within 180 days of the date of the SWK Credit Agreement.

In connection with the SWK Credit Agreement, the Company issued warrants to SWK to purchase 51,239 shares of the Company's common stock (the "SWK Warrants") with an exercise price of $5.86 per share. The SWK Warrants are exercisable immediately and have a term of seven years. The SWK Warrants are subject to a cashless exercise feature, with the exercise price and number of shares issuable upon exercise subject to change in connection with stock splits, dividends, reclassifications and other conditions. The relative fair value of the SWK Warrants was $226 and was estimated using the Black-Scholes-Merton option pricing model with the following assumptions: fair value of the Company's common stock at issuance of $5.75 per share; seven-year contractual term; 95% volatility; 0% dividend rate; and a risk-free interest rate of 1.8%.

The debt discount amortization recorded in 2019 was $16 and $82 was recorded for accrued interest and included in accrued liabilities.

The table below reflects the future payments for the SWK loan principal and interest as of December 31, 2019.

	Amount
2020	$ 717
2021	1,165
2022	1,173
2023	996
2024	3,805
Total payments	7,856
Less: amount representing interest	(2,856)
Loan payable, gross	5,000
Less: unamortized discount	(460)
Long-term debt, net of unamortized discount	$ 4,540

Note 7 — 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 8).

As of the date of the IPO on November 15, 2018, the liquidation value of the 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.

Note 8 — 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, 2019, 2018 and 2017, the Company recorded $59, $1,388 and $1,403, respectively, in stock-based compensation expense for these RSAs (see Note 10).

In conjunction with the Company's IPO in November 2018, 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 7).

During 2019, there were 97,088 warrant shares exercised (all on a cashless basis) resulting in 57,051 shares of common stock being issued by the Company. In addition, 167,622 stock option shares were exercised and issued under the Company's 2018 Equity Incentive Plan and 44,885 shares were issued under the Company's Employee Stock Purchase Program.

Note 9 — 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 7), 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. 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 connection with the SWK Credit Agreement, the Company issued warrants to SWK to purchase 51,239 shares of the Company's common stock (the "SWK Warrants") with an exercise price of $5.86 per share. The SWK Warrants are exercisable immediately and have a term of seven years ending November 13, 2026. The SWK Warrants are subject to a cashless exercise feature, with the exercise price and number of shares issuable upon exercise subject to change in connection with stock splits, dividends, reclassifications and other conditions. The relative fair value of the SWK Warrants was $226 and was estimated using the Black-Scholes-Merton option pricing model with the following assumptions: fair value of the Company's common stock at issuance of $5.75 per share; seven-year contractual term; 95% volatility; 0% dividend rate; and a risk-free interest rate of 1.8%. The $226 relative fair value for these warrants was reflected as a component of paid-in-capital in the Company's balance sheet.

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, placement agent and debt holder as of December 31, 2019 and 2018 was $3.13 and $3.04 per share, respectively.

(in thousands, except share and per share amounts)

Note 9 — Common Stock Warrants (continued)

Listed below is a summary of warrants outstanding as of December 31, 2019:

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
SWK Warrants - Debt	51,239	$	5.86
Total	**1,672,335**	**$**	**3.13 (Avg)**

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

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

	No. of Shares
Balance as of the beginning of the year	1,718,184
Issuance of SWK Warrants with long-term debt	51,239
Placement Agent Warrants exercised – Series A Preferred	(97,088)
Balance as of the end of the year	**1,672,335**

During 2019, 97,088 warrants were exercised (all on a cashless basis) resulting in 57,051 shares of common stock being issued by the Company. The intrinsic value of the warrants exercised was $401.

Note 10 — Share-Based Payment Awards

The Company's board of directors and stockholders approved the Eton Pharmaceuticals, Inc. 2017 Equity Incentive Plan in May 2017 (the "2017 Plan"), which authorized the issuance of up to 5,000,000 shares of the Company's common stock. In conjunction with the Company's IPO in November 2018, the Company's stockholders and board of directors approved the 2018 Equity Incentive Plan (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 887,837 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. On January 1, 2019, the share reserve was increased by 704,317 shares based on the 17,607,928 shares of common stock outstanding at December 31, 2018. The exercise price for stock options granted is not less than the fair value of common stock as determined by the board of directors as of the date of grant. 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 has used the closing stock price on the date of grant as the exercise price.

(in thousands, except share and per share amounts)

Note 10 — Share-Based Payment Awards (continued)

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, 2019, 2018 and 2017, the Company's total stock-based compensation expense was $1,888, $1,850 and $1,761, respectively. Of these amounts, $1,574, $1,770 and $1,735 was recorded in general and administrative expenses, respectively, and $314, $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 January 1, 2019	1,295,000	$ 1.78	8.3	$ 5,627
Issued	717,500	7.44		
Exercised	(167,622)	1.28		
Forfeited/Cancelled	(15,000)	6.20		
Options outstanding as of December 31, 2019	1,829,878	$ 4.01	8.1	$ 6,014
Options exercisable at December 31, 2019	730,193	$ 3.09	7.5	$ 3,038
Options vested and expected to vest at December 31, 2019	1,779,878	$ 4.08	8.1	$ 5,723

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had strike prices lower than the fair value of the Company's common stock at December 31. The intrinsic value of the options exercised was $932.

There were 167,622 shares issued for exercises of stock options during the year ended December 31, 2019 for proceeds of $214.

The assumptions used to calculate the fair value of options granted during the periods ended December 31, 2019, 2018 and 2017 under the BSM were as follows:

	December 31, 2019	December 31, 2018	December 31, 2017
Expected dividends	—%	—%	—%
Expected volatility	90%	85%	85%
Risk-free interest rate	1.9-2.5%	2.8-2.9%	1.7-2.3%
Expected term	5.9 years	6.3 years	5.8-10 years
Weighted average fair value	$ 5.54	$ 3.39	$ 0.91

(in thousands, except share and per share amounts)

Note 10 — Share-Based Payment Awards (continued)

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

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

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 January 1, 2019	312,500
Issued	—
Vested	(312,500)
Forfeited/Cancelled	—
Unvested as of December 31, 2019	—

No RSA's were issued in 2019 and the weighted average grant date fair value of the RSAs issued during the year ended December 31, 2018 was $1.37. The fair value of the RSAs vested during the periods ended December 31, 2019, 2018 and 2017 was $66, $2,784 and $0, respectively.

Restricted Stock Units

No RSUs were issued in 2019 or 2018 and no RSU's were unvested at December 31, 2019 or 2018. The fair value of the RSUs vesting during the periods ended December 31, 2019, 2018 and 2017 was $0, $69 and $69, respectively.

As of December 31, 2019, there was a total of $3,463, $0 and $0 of unrecognized compensation costs related to non-vested stock option awards, RSAs and RSUs, respectively.

(in thousands, except share and per share amounts)

Note 10 — Share-Based Payment Awards (continued)

In December 2018, the Company's board of directors adopted an initial offering of the Company's common stock under the Company's 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 ended on December 10, 2019. The initial offering consisted 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 period, subsequent twelve-month offering periods automatically commence over the term of the ESPP on the day that immediately follows the conclusion of the preceding offering, each consisting of two purchase periods approximately six months in duration ending on or around June 10 and December 10 each year.

The Company recorded an expense of $112 and $5 in 2019 and 2018, respectively, related to the ESPP. The weighted average grant date fair value of share awards in 2019 and 2018 was $2.56 and $2.59 per share, respectively. Employees contributed $247 and $8 to the ESPP during 2019 and 2018, respectively. Of these amounts, $16 and $8 at December 31, 2019 and 2018, respectively, is included in accrued liabilities in the accompanying balance sheets.

Note 11 — Basic and Diluted Net Loss per Common Share

Basic and diluted net loss per share is computed using the weighted average number of shares of common stock outstanding during the period. Common stock equivalents (using the treasury stock and "if converted" method) from stock options, unvested RSAs and RSUs, warrants and convertible preferred stock at December 31, 2019, 2018 and 2017 were 3,590,465, 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, 2019	Year ended December 31, 2018	Period from April 27, 2017 (inception) through December 31, 2017
Net loss	$ (18,320)	$ (12,740)	$ (7,156)
Series A Preferred – dividends (accrued and deemed)	—	(24,489)	(1,483)
Net loss attributable to common stockholders	(18,320)	(37,229)	$ (8,639)
Weighted average common shares outstanding (basic and diluted)	17,760,761	6,417,840	3,453,213
Net loss per common share (basic and diluted)	$ (1.03)	$ (5.80)	$ (2.50)

Note 12 — 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.

On May 6, 2019, the Company entered into an Asset Purchase Agreement (the "CT-100 Asset Purchase Agreement") with Harrow. Pursuant to the CT-100 Asset Purchase Agreement, the Company sold all of its right, title and interest in CT-100 to Harrow, including any such product that incorporates or utilizes its intellectual property rights (a "Product" or, collectively, "Products"). Pursuant to the CT-100 Asset Purchase Agreement, Harrow will make certain payments to the Company upon the achievement of certain development and commercial milestones. In addition, Harrow is required to pay the Company a royalty in the low-single digit percentage range worldwide on a country-by-country basis on net sales for a period of the longer of 15 years from the date of the first commercial sale of a product in a particular country or the time that a valid intellectual property claim on such Product remains in force in the applicable country. The CT-100 Asset Purchase Agreement also contains customary representations, warranties, covenants and indemnities by the parties.

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 $0, $970 and $1,370 for the Harrow restricted common stock and $0, $51 and $112 for Harrow stock options, respectively, for the periods ended December 31, 2019, 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 ("Eyemax"), an entity affiliated with the Company's CEO. The Company also held a right of first refusal to obtain the exclusive license rights for geographic areas outside of the United States. Pursuant to the Eyemax Agreement, the Company 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, 2019 or 2018.

Note 12 — Related Party Transactions (continued)

On February 18, 2019, The Company entered into an Amended and Restated Agreement with Eyemax amending the Sales Agreement (the "Amended Agreement"). Pursuant to the Amended Agreement, Eyemax sold the Company all of its right, title and interest in EM-100, including any such product that incorporates or utilizes Eyemax's intellectual property rights. Under the Amended Agreement, the Company assumed certain liabilities of Eyemax under its Exclusive Development & Supply Agreement with Excelvision SAS dated as of July 11, 2013, as amended (the "Excelvision Agreement"), with respect to certain territories and arising during certain time periods. Pursuant to the Amended Agreement, the Company remains obligated to pay Eyemax two milestones payments: (i) one milestone payment for $250 upon regulatory approval in the territory by the FDA of the first single agent product and (ii) one milestone payment for $500 following the first commercial sale of the first single agent product in the territory. Following payment of the milestones, the Company is entitled to retain all of the non-royalty transaction revenues and royalties up to $2,000 (the "Recovery Amount"). After the Company has retained the full Recovery Amount, it is entitled to retain half of all royalty and non-royalty transaction revenue. The Amended Agreement also contains customary representations, warranties, covenants and indemnities by the parties. The EM-100 asset and its associated product rights were sold to Bausch on February 18, 2019 and future potential royalties on Bausch sales of EM-100, pending an FDA approval for EM-100, will be split between Eyemax and the Company. There were no amounts due under the terms of the Amended Agreement as of December 31, 2019 or 2018.

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, 2019 or 2018. 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.

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 ("Selenix"), an entity affiliated with the Company's CEO. Pursuant to the Selenix Agreement, the Company paid Selenix $1,500 at signing, which was recorded as a component of R&D expense and paid $1,500 in April 2019 upon submission of an NDA on March 13, 2019 which was reflected as a component of R&D expense for the nine-month period ended September 30, 2019. The Company will pay $1,000 upon FDA approval of the DS-200 product. 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, 2019 or 2018.

Note 13 — Leases

Effective January 1, 2019, the Company adopted ASC 842, which requires an entity to recognize a right-of-use ("ROU") asset and a lease liability on the balance sheet for substantially all leases, including operating leases, using the modified retrospective approach. The Company elected to use the package of practicable expedients which allows companies to not reassess the following: (1) the lease classification for any expired or existing leases, (2) the treatment of initial direct costs as they related to existing leases, and (3) whether expired or existing contracts are or contain leases. The Company did not elect the use of the hindsight practical expedient, but did elect to separate lease components from non-lease components related to its office space lease.

Upon adoption of ASC 842, the Company had non-cancellable operating leases for its office and laboratory space subject to recognition as ROU assets. Accordingly, on January 1, 2019 the Company recorded $281 in ROU assets and $272 in operating lease liabilities (the difference of $9 related to existing prepaid rent as of December 31, 2018). The Company has not entered into any other lease arrangements through December 31, 2019.

(in thousands, except share and per share amounts)

Note 13 — Leases (continued)

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.

The Company does not have any lease contracts that contain: (1) an option to extend that the Company is reasonably certain to exercise, (2) an option to terminate that the Company is reasonably certain not to exercise, or (3) an option to extend (or not to terminate) in which exercise of the option is controlled by the lessor. Additionally, the Company does not have any leases with residual value guarantees or material restrictive covenants. For leases already commenced, the lease term was determined to be the remaining months in the lease term as of January 1, 2019, the date of adoption. Lease liabilities and their corresponding right-of-use assets have been recorded based on the present value of the future lease payments over the expected lease term. One of the Company's lease agreements contains provisions for escalating rent payments over the term of the lease.

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

For the periods ended December 31, 2019, 2018 and 2017, the Company recorded $140, $115 and $14, respectively, in rent expense

The Company's operating lease cost as presented in the "Research and Development" and "General and Administrative" captions in the statements of operations was $55 and $85 for the year ended December 31, 2019. Cash paid for amounts included in the measurement of operating lease liabilities was $120 for year ended December 31, 2019. The ROU asset amortization for year ended December 31, 2019 was $121 and is reflected in depreciation and amortization in the Company's statements of cash flows. As of December 31, 2019, the weighted-average remaining lease term was 1.2 years, and the weighted-average incremental borrowing rate was 7.8%.

The table below presents the lease-related assets and liabilities recorded on the balance sheet as of December 31, 2019:

Assets	**Classification**	
Operating lease right-of-use assets	Operating lease right-of-use assets, net	$ 160
Total leased assets		$ 160
Liabilities		
Operating lease liabilities, current	Accrued liabilities	$ 133
Operating lease liabilities, noncurrent	Operating lease liabilities, net of current portion	19
Total operating lease liabilities		$ 152

The Company's future lease commitments as of December 31, 2019 are as indicated below:

	Total	**2020**	**2021**
Undiscounted lease payments	**$ 159**	**$ 140**	**$ 19**
Less: Imputed interest	**(7)**		
Total lease liabilities	**$ 152**		

The Company's future operating lease payments as of December 31, 2018 were as follows:

Total	**2019**	**2020**	**2021**
$ 308	$ 137	$ 140	$ 31

(in thousands, except share and per share amounts)

Note 14 – Income Taxes

The provision for income taxes for the Company consists of the following for the periods ended December 31, 2019, 2018 and 2017:

	Year ended December 31, 2019	Year ended December 31, 2018	Year ended December 31, 2017
Current:			
Federal	$ —	$ —	$ —
State	—	—	—
Total current expense	—	—	—
Deferred:			
Federal	3,961	1,900	1,308
State	1,415	679	468
Change in valuation allowance	(5,376)	(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, 2019 and 2018 are as follows:

	December 31, 2019	December 31, 2018
Net operating losses	$ 8,879	$ 3,968
Stock-based expenses	662	233
Accruals and other	190	154
Total deferred tax assets	9,731	4,355
Valuation allowance	(9,731)	(4,355)
Net deferred tax assets	$ —	$ —

Based on the uncertainty of future taxable income at this time management believes a 100% valuation reserve for the $9,731 and $4,355 deferred tax asset at December 31, 2019 and 2018, respectively, is appropriate.

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

	Year ended December 31 2019	Year ended December 31, 2018	Period from April 27, 2017 (inception) through December 31, 2017
Benefit at statutory rate	(21.0)%	(21.0)%	(34.0)%
Permanent items (primarily warrants and stock compensation)	(0.6)	6.0	4.4
State tax benefit	(7.7)	(5.3)	(5.5)
Federal rate change	—	—	10.2
Other items	—	—	—
Establishment of valuation allowance	29.3	20.3	24.9
Income tax expense	—%	—%	—%

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 $31,151 as of December 31, 2019, of which $5,652 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 before December 31, 2017, is limited. It is uncertain if and to what extent various states will conform to the Tax Act.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards 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 and tax attributions will be adjusted when the study is complete, if required.

Note 15 - Employee Savings Plan

The Company established an employee savings plan pursuant to Section 401(k) of the Internal Revenue Code, effective January 1, 2018. The plan allows participating employees to deposit into tax deferred investment accounts up to 100% of their salary, subject to annual limits. The Company makes certain matching contributions to the plan in amounts up to 4% of the participants' annual cash compensation, subject to annual limits. For the periods ended December 31, 2019, 2018 and 2017, the Company made $113, $62 and $0 in matching contributions, respectively.

Note 16 — Commitments and Contingencies

Legal

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

License and Product Development Agreements

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

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 was to pay the third party 50% of the net profit from the sale of the product, however, in February 2020, it executed an amendment to the Sales and Marketing Agreement. Under the revised terms, the Company will be responsible for paragraph IV related litigation and will be entitled to 62.5% of product profit. The initial term is for the first 10 years following the first commercial sale of the product.

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 ("LMW"), an unaffiliated entity. Pursuant to the agreement, the Company will be responsible for, and will 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.

Note 16 — Commitments and Contingencies (continued)

On January 23, 2019 the Company entered into a Licensing and Supply Agreement (the "Agreement") with LMW for ET-104 oral liquid, a development stage product candidate ("ET-104"). Pursuant to the terms of the Agreement, the Company will be responsible for regulatory and marketing activities. LMW will be responsible for development and manufacturing of ET-104. The Company paid the licensor $350 upon execution of the Agreement and an additional $350 after receiving successful bioequivalence study results, and will pay $325 upon the FDA's acceptance of an NDA for review, $325 upon FDA approval of the NDA, $650 upon issuance of patent covering ET-104 listed in the FDA's Orange Book and $500 in the event that product sales in excess of $10,000 are achieved within a calendar year. In addition, the Company is 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. The Company 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 Biorphen® which is used for the treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia. The product was submitted to the FDA for review and subsequently received FDA approval on October 21, 2019. Pursuant to the terms of the ET-202 License Agreement, the Company will be responsible for marketing activities and Sintetica is responsible for development, manufacturing, and regulatory activities related to obtaining regulatory approval. The Company paid Sintetica a licensing payment of $2,000 upon execution of the ET-202 License Agreement and $750 upon the commencement of commercial product shipments. Sintetica will supply Biorphen to the Company at its direct costs and the Company will retain 5% of net sales as a marketing fee. Sintetica is entitled to receive the first $500 of product profits. All additional profit will be split 50% to the Company and 50% to Sintetica. The ET-202 License Agreement has a ten-year term from the first commercial sale of Biorphen which occurred in November 2019.

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 ET-203 License Agreement, the Company will be responsible for marketing activities and Sintetica will be responsible for development, manufacturing, and regulatory activities related to obtaining regulatory approval. The Company paid Sintetica a licensing payment of $1,000 upon execution of the ET-203 License Agreement which was refunded to Eton in early 2020 due to the FDA not accepting the ET-203 file submission by Sintetica. The refund was reflected as a component of prepaid and other current assets on the Company's balance sheet at December 31, 2019. The Company expects the submission will be successfully resubmitted in the near future and will pay the $1,000 milestone at that time. The Company will pay $750 upon FDA approval and the commercial sale of the product candidate. Upon approval, Sintetica will supply ET-203 to the Company at its direct costs. The Company will retain 5% of net sales as a marketing fee. Sintetica will be entitled to receive the first $500 of product profits. All additional profit will be split 50% to the Company and 50% to Sintetica. The ET-203 License Agreement has a ten-year term from first commercial sale of product.

On June 12, 2019, the Company entered into an Exclusive Licensing and Supply Agreement (the "ET-105 License Agreement") with Aucta Pharmaceuticals, Inc. ("Aucta") for marketing rights in the United States to ET-105, a product candidate for use as an adjunct therapy for partial seizures, primary generalized tonic-clonic seizures, and generalized seizures of Lennox-Gastaut syndrome in patients two years of age and older. Pursuant to the terms of the ET-105 License Agreement, the Company will be responsible for marketing activities and Aucta will be responsible for development, manufacturing, and regulatory activities related to obtaining regulatory approval. The Company paid Aucta a licensing payment of $2,000 in August 2019 upon receiving an acceptance for review letter from the FDA and will pay $2,000 upon FDA approval and commercial sales of the product candidate and another $1,000 upon issuance of an Orange-book listed patent. Aucta will receive a low double-digit royalty on net sales and will be entitled to receive milestone payments of up to $18,000 based on commercial success of the product, including:

- $1,000 when net sales exceed $10 million in a calendar year
- $2,000 when net sales exceed $20 million in a calendar year
- $5,000 when net sales exceed $50 million in a calendar year
- $10,000 when net sales exceed $100 million in a calendar year

Note 16 — Commitments and Contingencies (continued)

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, 2019 or 2018.

Note 17 — Summary of Unaudited Quarterly Financial Information

The following is a summary of our unaudited quarterly results for the years ended December 31, 2019 and 2018 (in thousands):

	For the Quarter Ended				
	March 31, 2019	**June 30, 2019**	**September 30, 2019**	**December 31, 2019**	**Total Year 2019**
	(in thousands except per share amounts)				
Revenues	$ 500	$ —	$ —	$ 459	$ 959
Operating expenses	$ 8,054	$ 3,349	$ 5,042	$ 2,662	$ 19,107
Net loss	$ (7,410)	$ (3,249)	$ (4,965)	$ (2,696)	$ (18,320)
Net loss attributable to common stockholders	$ (7,410)	$ (3,249)	$ (4,965)	$ (2,696)	$ (18,320)
Net loss per share attributable to common stockholders- basic and diluted	$ (0.42)	$ (0.18)	$ (0.28)	$ (0.15)	$ (1.03)
Weighted average shares outstanding, basic and diluted	17,502	17,733	17,878	17,924	17,761

	For the Quarter Ended				
	March 31, 2018	**June 30, 2018**	**September 30, 2018**	**December 31, 2018**	**Total Year 2018**
	(in thousands except per share amounts)				
Revenues	$ —	$ —	$ —	$ —	$ —
Operating expenses	$ 2,964	$ 2,697	$ 2,374	$ 2,286	$ 10,321
Net loss	$ (3,018)	$ (3,082)	$ (2,910)	$ (3,730)	$ (12,740)
Net loss attributable to common stockholders **(1)**	$ (3,724)	$ (3,804)	$ (3,639)	$ (26,062)	$ (37,229)
Net loss per share attributable to common stockholders- basic and diluted	$ (1.05)	$ (0.79)	$ (0.65)	$ (2.24)	$ (5.80)
Weighted average shares outstanding, basic and diluted	3,551	4,786	5,615	11,640	6,418

(1) Net loss attributable to common stockholders for the quarter ended December 31, 2018 included $21,747 related to deemed dividends for the beneficial conversion feature of the Company's redeemable convertible preferred stock.

Note 18 — Subsequent Events

The Company has performed an evaluation of events occurring subsequent to December 31, 2019 through the filing date of this Annual Report and determined that no subsequent events have occurred that would require recognition in the financial statements or disclosures in the notes thereto.

Eton Pharmaceuticals, Inc.

Schedule II

Valuation and Qualifying Accounts
(in thousands)

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
For the year ended December 31, 2019				
Accounts receivable allowances (1)	$ —	$ 116	$ —	$ 116
For the year ended December 31, 2018				
Accounts receivable allowances (1)	$ —	$ —	$ —	$ —
For the period ended December 31, 2017				
Accounts receivable allowances (1)	$ —	$ —	$ —	$ —

(1) Allowances are for chargebacks, prompt payment discounts, distribution fees, and returns & allowances related to Biorphen product sales.

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

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, to allow timely decisions regarding required disclosure.

The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

With respect to the year ended December 31, 2019, 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 principal executive officer and principal financial officer have concluded that the Company's disclosure controls and procedures are effective.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for our Company, as such term is defined in Rule 13a-15(f) under the Exchange Act. Our management conducted an evaluation, with the participation of our principal executive officer and principal financial officer, of the effectiveness of our internal control over financial reporting as of December 31, 2019, based on the criteria set forth in the 2013 Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2019.

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

Changes in Internal Control over Financial Reporting

There has not been any change in our internal control over financial reporting (as defined in Rules 13a-15(f) under the Exchange Act) that occurred during the quarter ended December 31, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

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

Item 9B. Other Information

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item and not set forth below will be set forth in the section headed " *Election of Directors* " and " *Executive Officers* " in our Proxy Statement for our 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*

The following financial statement schedule of Eton Pharmaceuticals, Inc. is filed as part of this Annual Report on Form 10-K and should be read in conjunction with the financial statements of Eton Pharmaceuticals, Inc.

All other schedules are omitted because they are not applicable, or the required information is shown in the 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).
4.5	Warrant dated November 13, 2019 issued to SWK Holdings LLC.
10.1	Registration Rights Agreement dated June 19, 2017 by and among the Registrant and certain of its stockholders (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).

Exhibit No.	Description
10.2†	Asset Purchase Agreement (DS-200) dated June 23, 2017 between Selenix, LLC and the Registrant (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.3†	Exclusive Development and Supply Agreement (DS-100) dated July 9, 2017 between Andersen Pharma, LLC and the Registrant (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.4	Amended and Restated Agreement relating to sales and marketing dated February 18, 2019 between the Registrant and Eyemax, LLC (incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019)
10.5†	Sales/Marketing Agreement (DS-300) dated November 17, 2017 by and among AL Pharma, Inc., SCS National, LLC, Dry Creek Project, LLC and the Registrant (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.6+	Eton Pharmaceuticals, Inc. 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.7+	Offer Letter Agreement by and between the Registrant and Sean E. Brynjelsen, dated as of May 17, 2017 (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.8+	Offer Letter Agreement by and between the Registrant and W. Wilson Troutman, dated as of June 27, 2017 (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.9	Exclusive License and Supply Agreement (ET-103) dated August 3, 2018 between the Registrant, Liqmeds Worldwide Limited and LM Manufacturing, Ltd. (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.10+	Eton Pharmaceuticals, Inc. 2018 Stock Incentive Plan (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.11+	2018 Equity Incentive Plan (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
10.12+	2018 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.13	Amendment No. 1 dated August 29, 2018 to Sales/Marketing Agreement (DS-300) dated November 17, 2017 between AL Pharma, Inc. and the Registrant (incorporated by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-226774), originally filed August 10, 2018).
10.14.	Credit Agreement dated as of November 13, 2019, by and among the Company and SWK Funding LLC
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, 2019, 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 5, 2020

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 5, 2020
/s/ W. Wilson Troutman W. Wilson Troutman	Chief Financial Officer, Treasurer and Secretary *(Principal Financial and Accounting Officer)*	March 5, 2020
/s/ Mark L. Baum Mark L. Baum	Director	March 5, 2020
/s/ Charles J. Casamento Charles J. Casamento	Director	March 5, 2020
/s/ Paul V. Maier Paul V. Maier	Director	March 5, 2020
/s/ Norbert G. Riedel, Ph.D. Norbert G. Riedel, Ph.D.	Director	March 5, 2020

Execution Version

THIS WARRANT AND THE SECURITIES ISSUED HEREUNDER HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR ANY OTHER SECURITIES LAWS AND MAY NOT BE OFFERED FOR SALE, SOLD, TRANSFERRED, PLEDGED OR HYPOTHECATED IN THE ABSENCE OF (1) AN EFFECTIVE REGISTRATION STATEMENT COVERING SUCH SECURITIES UNDER THE SECURITIES ACT AND ANY OTHER APPLICABLE SECURITIES LAWS, OR (2) AN EXEMPTION FROM REGISTRATION UNDER SUCH SECURITIES LAWS.

ETON PHARMACEUTICALS, INC. WARRANT for shares of Common Stock
November 13, 2019
(Corrected January 24, 2020)

This **WARRANT** (this "**Warrant**") of Eton Pharmaceuticals, Inc., a corporation, duly organized and validly existing under the laws of the State of Delaware (the "**Company**"), is being issued pursuant to that certain Credit Agreement, dated November 13, 2019 (the "**Credit Agreement**"), between the Company and SWK Funding LLC (the "**Agent**") granting Agent the right to purchase shares of common stock, $0.001 par value, of the Company (the "**Common Stock**") as set forth herein. Defined terms used herein and not otherwise defined shall have the meaning given them in the Credit Agreement.

FOR VALUE RECEIVED, the Company hereby grants to Agent and its permitted successors and assigns (collectively, the "**Holder**") the right to purchase from the Company shares of Common Stock (such shares underlying this Warrant, the "**Warrant Shares**"), at a per share purchase price as calculated (the "**Exercise Price**"), subject to the terms, conditions and adjustments set forth below in this Warrant.

1. Exercise of Warrant. This Warrant shall be exercisable pursuant to the terms of this Section 1.

1.1 Manner of Exercise.

(a) This Warrant shall be exercisable as follows (each, a "**Warrant Tranche**"):

(i) within 7 years of funding of the initial funding of the Term Loan on or about the Closing Date, into a number of shares of Common Stock equal to six percent (6%) of the principal amount of the Initial Advance divided the applicable Exercise Price (as defined below);

(ii) within 7 years of funding of the EM-100 Term Loan, into a number of shares of Common Stock equal to six percent (6%) of the principal amount of the EM-100 Term Loan divided by the applicable Exercise Price; and

(iii) within 7 years of funding of the Subsequent Term Loan, into a number of shares of Common Stock equal to six percent (6%) of the principal amount of the Subsequent Term Loan divided by the applicable Exercise Price.

The number of shares of Common Stock into which this Warrant is exercisable are sometimes hereinafter referred to as "**Warrant Shares**." For purposes of this Section 1.1, the applicable "**Exercise Price**" for each Warrant Tranche shall equal the average trading price of the Common Stock as officially reported by the principal securities exchange on which the Common Stock is then listed or admitted to trading, or,

if the Common Stock is not listed or admitted to trading on any securities exchange as determined in good faith by resolution of the Board of Directors of the Company, based on the best information available to it, for the ten (10) trading days immediately preceding the applicable Issuance Date for such Warrant Tranche. The date of each applicable funding date shall be the "**Issuance Date**" of such Warrant Tranche and the 7 year period following such Issuance Date shall be the "**Exercise Period**" with respect to such Warrant Tranche. The last day of each applicable Exercise Period shall be the "**Expiration Date**" of such Warrant Tranche. Except as set forth in Section 1.4, any portion of any Warrant Tranche not exercised within the applicable Exercise Period and before the close of business on the Expiration Date shall be cancelled and not exercisable thereafter.

(b) Each Warrant Tranche may only be exercised by the Holder hereof during the applicable Exercise Period, in accordance with the terms and conditions hereof, in whole or in part (but not as to fractional shares) with respect to any portion of any Warrant Tranche, during the Company's normal business hours on any day other than a Saturday or a Sunday or a day on which commercial banking institutions in New York, New York are authorized by law to be closed (a "**Business Day**"), by surrender of this Warrant to the Company at its office maintained pursuant to Section 7.2(a) hereof, accompanied by a written exercise notice in the form attached as Exhibit A to this Warrant (or a reasonable facsimile thereof) duly executed by the Holder, together with the payment of the aggregate Exercise Price for the number of Warrant Shares purchased upon exercise of this Warrant. Upon surrender of this Warrant, the Company shall cancel this Warrant document and shall, in the event of partial exercise or any exercise prior to the funding event relating to the issuance of any of the Warrant Tranches, replace it with a new Warrant document in accordance with Section 1.3.

(c) Except as provided for in Section 1.1(d) below, each exercise of this Warrant must be accompanied by payment in full of the aggregate Exercise Price in cash by check or wire transfer in immediately available funds for the number of Warrant Shares being purchased by the Holder upon such exercise.

(d) The aggregate Exercise Price for the number of Warrant Shares being purchased may also, in the sole discretion of the Holder, be paid in full or in part on a "cashless basis" at the election of the Holder:

(i) In the form of Common Stock owned by the Holder (based on the Fair Market Value (as defined below) of such Common Stock on the date of exercise);

(ii) In the form of Warrant Shares withheld by the Company from the Warrant Shares otherwise to be received upon exercise of this Warrant having an aggregate Fair Market Value on the date of the exercise equal to the aggregate applicable Exercise Price of the Warrant Shares being purchased by the Holder; or

(iii) By a combination of the foregoing, provided that the combined value of all cash and the Fair Market Value of any shares surrendered to the Company is at least equal to the aggregate applicable Exercise Price for the number of Warrant Shares being purchased by the Holder.

For purposes of this Warrant, the term "**Fair Market Value**" means with respect to a particular date, the average closing price of the Common Stock for the ten (10) trading days immediately preceding the applicable exercise herein as officially reported by the principal securities exchange on which the Common Stock is then listed or admitted to trading, or, if the Common Stock is not listed or admitted to

trading on any securities exchange as determined in good faith by resolution of the Board of Directors of the Company, based on the best information available to it.

To illustrate a cashless exercise of this Warrant under Section 1.1(d)(ii) (or for a portion thereof for which cashless exercise treatment is requested as contemplated by Section 1.1(d)(iii) hereof), the calculation of such exercise shall be as follows:

$$X = Y (A-B)/A$$

where:

X = the number of Warrant Shares to be issued to the Holder (rounded to the nearest whole share).

Y = the number of Warrant Shares with respect to which this Warrant is being exercised.

A = the Fair Market Value of the Common Stock.

B = the applicable Exercise Price.

(e) For purposes of Rule 144 and sub-Section 1.1(d)(ii) thereof, it is intended, understood, and acknowledged that the Common Stock issuable upon exercise of this Warrant in a cashless exercise transaction as described in Section 1.1(d) above shall be deemed to have been acquired at the time this Warrant was issued. Moreover, it is intended, understood, and acknowledged that the holding period for the Common Stock issuable upon exercise of this Warrant in a cashless exercise transaction as described in Section 1.1(d) above shall be deemed to have commenced on the date this Warrant was issued.

1.2 When Exercise Effective. Each exercise of this Warrant shall be deemed to have been effected immediately prior to the close of business on the Business Day on which this Warrant shall have been duly surrendered to the Company as provided in Sections 1.1 and 7 hereof, and, at such time, the Holder in whose name any certificate or certificates for Warrant Shares shall be issuable upon exercise as provided in Section 1.3 hereof shall be deemed to have become the holder or holders of record thereof of the number of Warrant Shares purchased upon exercise of this Warrant.

1.3 Delivery of Common Stock Certificates and New Warrant. As soon as reasonably practicable after each exercise of this Warrant, in whole or in part, and in any event within three (3) Business Days thereafter, the Company, at its expense (including the payment by it of any applicable issue taxes), will cause to be issued in the name of and delivered to the Holder hereof or, subject to Sections 6 and 7 hereof, as the Holder (upon payment by the Holder of any applicable transfer taxes) may direct:

(a) a certificate or certificates (with appropriate restrictive legends, as applicable) for the number of duly authorized, validly issued, fully paid and non-assessable Warrant Shares to which the Holder shall be entitled upon exercise; and

(b) in case exercise is in part only, a new Warrant document of like tenor, dated the date hereof, for the remaining number of Warrant Shares issuable upon exercise of this Warrant after

giving effect to the partial exercise of this Warrant (including the delivery of any Warrant Shares as payment of the Exercise Price for such partial exercise of this Warrant).

1.4 Automatic Exercise. In the event that, upon any applicable Expiration Date or other termination of this Warrant, the Fair Market Value of one Warrant Share (or other security issuable upon the exercise hereof) as determined in accordance with Section 1.3 hereof is greater than the applicable Exercise Price in effect on such date for each applicable Warrant Tranche, then this Warrant shall automatically be deemed on and as of such date to be exercised pursuant to this Section 1.4 as to all Warrant Shares (or such other securities) for which it shall not previously have been exercised and which are then expiring, and the Company shall promptly deliver a certificate representing the Warrant Shares (or such other securities) issued upon such exercise to Holder.

2. Certain Adjustments. For so long as this Warrant is outstanding:

2.1 Mergers or Consolidations. If at any time after the date hereof there shall be a capital reorganization (other than a combination or subdivision of Common Stock otherwise provided for herein) resulting in a reclassification to or change in the terms of securities issuable upon exercise of this Warrant (a "**Reorganization**"), or a merger or consolidation of the Company with another corporation, association, partnership, organization, business, individual, government or political subdivision thereof or a governmental agency (a "**Person**" or the "**Persons**") (other than a merger with another Person in which the Company is a continuing corporation and which does not result in any reclassification or change in the terms of securities issuable upon exercise of this Warrant or a merger effected exclusively for the purpose of changing the domicile of the Company) (a "**Merger**"), then, as a part of such Reorganization or Merger, lawful provision and adjustment shall be made so that the Holder shall thereafter be entitled to receive, upon exercise of this Warrant, the number of shares of stock or any other equity or debt securities or property receivable upon such Reorganization or Merger by a holder of the number of shares of Common Stock which might have been purchased upon exercise of this Warrant immediately prior to such Reorganization or Merger. In any such case, appropriate adjustment shall be made in the application of the provisions of this Warrant with respect to the rights and interests of the Holder after the Reorganization or Merger to the end that the provisions of this Warrant (including adjustment of the Exercise Price then in effect and the number of Warrant Shares) shall be applicable after that event, as near as reasonably may be, in relation to any shares of stock, securities, property or other assets thereafter deliverable upon exercise of this Warrant. The provisions of this Section 2.1 shall similarly apply to successive Reorganizations and/or Mergers.

2.2 Splits and Subdivisions; Dividends. In the event the Company should at any time or from time to time effectuate a split or subdivision of the outstanding shares of Common Stock or pay a dividend in or make a distribution payable in additional shares of Common Stock or other securities, or rights convertible into, or entitling the holder thereof to receive, directly or indirectly, additional shares of Common Stock (hereinafter referred to as "**Common Stock Equivalents**") without payment of any consideration by such holder for the additional shares of Common Stock or Common Stock Equivalents (including the additional shares of Common Stock issuable upon conversion or exercise thereof), then, as of the applicable record date (or the date of such distribution, split or subdivision if no record date is fixed), the per share Exercise Price shall be appropriately decreased and the number of Warrant Shares shall be appropriately increased in proportion to such increase (or potential increase) of outstanding shares; provided, however, that no adjustment shall be made in the event the split, subdivision, dividend or distribution is not effectuated.

2.3 Combination of Shares. If the number of shares of Common Stock outstanding at any time after the date hereof is decreased by a combination of the outstanding shares of Common Stock, the per share Exercise Price shall be appropriately increased and the number of shares of Warrant Shares shall be appropriately decreased in proportion to such decrease in outstanding shares.

2.4 Adjustments for Other Distributions. In the event the Company shall declare a distribution payable in securities of other Persons, evidences of indebtedness issued by the Company or other Persons, assets (excluding cash dividends or distributions to the holders of Common Stock paid out of current or retained earnings and declared by the Company's Board of Directors) or options or rights not referred to in Sections 2.2 or 2.3 then, in each such case for the purpose of this Section 2.4, upon exercise of this Warrant, the Holder shall be entitled to a proportionate share of any such distribution as though the Holder was the actual record holder of the number of Warrant Shares as of the record date fixed for the determination of the holders of Common Stock of the Company entitled to receive such distribution.

3. No Impairment. The Company will not, by amendment of its certificate of incorporation or by-laws or through any consolidation, merger, reorganization, transfer of assets, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all of the terms and in the taking of all actions necessary or appropriate in order to protect the rights of the Holder against impairment.

4. Notice as to Adjustments. With respect to each adjustment pursuant to Section 2 of this Warrant, the Company, at its expense, will promptly compute the adjustment or re-adjustment in accordance with the terms of this Warrant and furnish the Holder with a certificate certified and confirmed by the Secretary or Chief Financial Officer of the Company setting forth, in reasonable detail, the event requiring the adjustment or re-adjustment and the amount of such adjustment or re-adjustment, the method of calculation thereof and the facts upon which the adjustment or re-adjustment is based, and the Exercise Price and the number of Warrant Shares or other securities purchasable hereunder with respect to each Warrant Tranche after giving effect to such adjustment or re-adjustment, which report shall be mailed by first class mail, postage prepaid to the Holder.

5. Reservation of Shares. The Company shall, solely for the purpose of effecting the exercise of this Warrant, at all times during the term of this Warrant, reserve and keep available out of its authorized shares of Common Stock, free from all taxes, liens and charges with respect to the issue thereof and not subject to preemptive rights of shareholders of the Company, such number of its shares of Common Stock as shall from time to time be sufficient to effect in full the exercise of this Warrant. If at any time the number of authorized but unissued shares of Common Stock shall not be sufficient to effect in full the exercise of this Warrant, in addition to such other remedies as shall be available to Holder, the Company will promptly take such corporate action as may, in the opinion of its counsel, be necessary to increase the number of authorized but unissued shares of Common Stock to such number of shares as shall be sufficient for such purposes, including without limitation, using its Reasonable Commercial Efforts (as defined in Section 17 hereof) to obtain the requisite shareholder approval necessary to increase the number of authorized shares of Common Stock. The Company hereby represents and warrants that all shares of Common Stock issuable upon proper exercise of this Warrant shall be duly authorized and, when issued and paid for upon proper exercise, shall be validly issued, fully paid and nonassessable.

6. Restrictions on Transfer.

6.1 Restrictive Legends. This Warrant and each Warrant issued upon transfer or in substitution for this Warrant pursuant to Section 7 hereof, each certificate for Common Stock issued upon the exercise of the Warrant and each certificate issued upon the transfer of any such Common Stock shall be transferable only upon satisfaction of the conditions specified in this Section 6. Each of the foregoing securities shall be stamped or otherwise imprinted with a legend reflecting the restrictions on transfer set forth herein and any restrictions required under the Securities Act or other applicable securities laws.

6.2 Notice of Proposed Transfer. Prior to any transfer of any securities which are not registered under an effective registration statement under the Securities Act **("Restricted Securities"),** which transfer may only occur if there is an exemption from the registration provisions of the Securities Act and all other applicable securities laws, the Holder will give written notice to the Company of the Holder's intention to effect a transfer (and shall describe the manner and circumstances of the proposed transfer). The following provisions shall apply to any proposed transfer of Restricted Securities:

(i) If, in the opinion of counsel for the Holder reasonably satisfactory to the Company, the proposed transfer may be effected without registration of the Restricted Securities under the Securities Act (which opinion shall state in detail the basis of the legal conclusions reached therein), the Holder shall thereupon be entitled to transfer the Restricted Securities in accordance with the terms of the notice delivered by the Holder to the Company. Each certificate representing the Restricted Securities issued upon or in connection with any transfer shall bear the restrictive legends required by Section 6.1 hereof.

(ii) If the opinion called for in (i) above is not delivered, the Holder shall not be entitled to transfer the Restricted Securities until either: (x) receipt by the Company of a further notice from such Holder pursuant to the foregoing provisions of this Section 6.2 and fulfillment of the provisions of clause (i) above, or (y) such Restricted Securities have been effectively registered under the Securities Act; *provided, however*, that no opinion shall be required in the event that the Holder transfers the Warrant (or any portion thereof) to (A) any Person not involving a change in beneficial ownership, (B) any parent, subsidiary or other Affiliate, (C) any Lender under the Credit Agreement, or (D) any Person acquiring all or any substantial portion of Holder's assets; *provided, further*, that any such transferee(s) in clauses (A) through (D) is an "accredited investor" as defined in Rule 501 of Regulation D as promulgated under the Securities Act.

7. Ownership, Transfer, Sale, and Substitution of Warrant.

7.1 Ownership of Warrant. The Company may treat any Person in whose name this Warrant is registered in the Warrant Register maintained pursuant to Section 7.2(b) hereof as the owner and holder thereof for all purposes, notwithstanding any notice to the contrary, except that, if and when any Warrant is properly assigned in blank, the Company may (but shall not be obligated to) treat the bearer thereof as the owner of such Warrant for all purposes, notwithstanding any notice to the contrary. Subject to Sections 6 and 7 hereof, this Warrant, if properly assigned, may be exercised by a new holder without a new Warrant first having been issued.

7.2 Office; Exchange of Warrant.

(a) The Company will maintain its principal office at the location identified in the Company's most current filing (as of the date notice is to be given) under the Securities Exchange Act of 1934, as amended, or as the Company otherwise notifies the Holder.

(b) The Company shall cause to be kept at its office maintained pursuant to Section 7.2(a) hereof a Warrant Register for the registration and transfer of the Warrant. The name and address of the holder of the Warrant, the transfers thereof and the name and address of the transferee of the Warrant shall be registered in such Warrant Register. The Person in whose name the Warrant shall be so registered shall be deemed and treated as the owner and holder thereof for all purposes of this Warrant, and the Company shall not be affected by any notice or knowledge to the contrary.

(c) Upon the surrender of this Warrant, properly endorsed, for registration of transfer or for exchange at the office of the Company maintained pursuant to Section 7.2(a) hereof, the Company at its expense will (subject to compliance with Section 6 hereof, if applicable) execute and deliver to or upon the order of the Holder thereof a new Warrant of like tenor, in the name of such holder or as such holder (upon payment by such holder of any applicable transfer taxes) may direct, calling in the aggregate on the face thereof for the number of shares of Common Stock called for on the face of the Warrant so surrendered (after giving effect to any previous adjustment(s) to the number of Warrant Shares).

7.3 Replacement of Warrant. Upon receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and, in the case of any such loss, theft or destruction of this Warrant, upon delivery of indemnity reasonably satisfactory to the Company in form and amount or, in the case of any mutilation, upon surrender of this Warrant for cancellation at the office of the Company maintained pursuant to Section 7.2(a) hereof, the Company will execute and deliver, in lieu thereof, a new Warrant of like tenor and dated the date hereof.

7.4 Opinions. In connection with the sale of the Warrant Shares by Holder, the Company agrees to cooperate with the Holder, and at the Company's expense, to have its counsel provide any legal opinions required to remove the restrictive legends from the Warrant Shares in connection with a sale, transfer or legend removal request of Holder.

8. Registration and Listing.

8.1 Definition of Registrable Securities. As used herein, the term "**Registrable Securities**" means any shares of Common Stock issuable upon the exercise of this Warrant until the date (if any) on which such shares shall have been transferred or exchanged and new certificates for them not bearing a legend restricting further transfer shall have been delivered by the Company and subsequent disposition of the shares shall not require registration or qualification under the Securities Act or any similar state law then in force.

8.2 Incidental Registration Rights.

(a) If the Company, at any time during the Exercise Period, proposes to register any of its securities under the Securities Act (other than in connection with a transaction contemplated by Rule 145(a) promulgated under the Securities Act or pursuant to registration on Form S-4 or S-8 or any successor forms) whether for its own account or for the account of any holder or holders of its shares other

than Registrable Securities (any shares of such holder or holders (but not those of the Company and not Registrable Securities) with respect to any registration are referred to herein as, "**Other Shares**"), the Company shall at each such time give prompt (but not less than thirty (30) days prior to the anticipated effectiveness thereof) written notice to the holders of Registrable Securities of its intention to do so. The holders of Registrable Securities shall exercise the "piggy-back" rights provided herein by giving written notice within fifteen (15) days after the receipt of any such notice (which request shall specify the Registrable Securities intended to be disposed of by such holder). Except as set forth in Section 8.2(b), the Company will use its Reasonable Commercial Efforts to effect the registration under the Securities Act of all of the Registrable Securities which the Company has been so requested to register by such holder, to the extent required to permit the disposition of the Registrable Securities so to be registered, by inclusion of such Registrable Securities in the registration statement which covers the securities which the Company proposes to register. The Company will pay all Registration Expenses, as defined in Section 8.5 herein, in connection with each registration of Registrable Securities pursuant to this Section 8.2.

(b) In the event the Company at any time proposes to register any of its securities under the Securities Act as contemplated by this Section 8.2 and such securities are to be distributed by or through one or more underwriters, the Company will, if requested by a holder of Registrable Securities, use its Reasonable Commercial Efforts to arrange for such underwriters to include all the Registrable Securities to be offered and sold by such holder among the securities to be distributed by such underwriters. If the managing underwriter, in good faith, advises the Company and the holders of Registrable Securities in writing that the dollar amount or number of shares the Common Stock that the Company desires to sell, taken together with (i) the Other Shares, if any, as to which Registration has been requested, and (ii) the Registrable Securities as to which registration has been requested pursuant to Section 8 hereof, exceeds the maximum number of shares of Common Stock that can be sold without adversely affecting the proposed offering price, the timing, the distribution method or the probability of success of such offering (the "Maximum Number of Shares"), then the Company shall include in any such Registration (A) first, the Common Stock that the Company desires to sell, which can be sold without exceeding the Maximum Number of Shares; (B) second, to the extent that the Maximum Number of Shares has not been reached under the foregoing clause (A), the Registrable Securities, which can be sold without exceeding the Maximum Number of Shares; and (C) third, to the extent that the Maximum Number of Shares has not been reached under the foregoing clauses (A) and (B), the Other Shares which can be sold without exceeding the Maximum Number of Shares.

8.3 Registration Procedures. Whenever the holders of Registrable Securities have properly requested that any Registrable Securities be registered pursuant to the terms of this Warrant, the Company shall use its Reasonable Commercial Efforts to effect the registration for the sale of such Registrable Securities in accordance with the intended method of disposition thereof, and pursuant thereto the Company shall as expeditiously as possible:

(a) prepare and file with the SEC a registration statement with respect to such Registrable Securities and use its Reasonable Commercial Efforts to cause such registration statement to become effective;

(b) notify such holders of the effectiveness of each registration statement filed hereunder and prepare and file with the SEC such amendments and supplements to such registration statement and the prospectus used in connection therewith as may be necessary to (i) keep such registration statement effective and the prospectus included therein usable for a period commencing on the date that such registration statement is initially declared effective by the SEC and ending on the earlier of (A) the

date when all Registrable Securities covered by such registration statement have been sold pursuant to the registration statement or cease to be Registrable Securities, or (B) nine months from the effective date of the registration statement; and (ii) comply with the provisions of the Securities Act with respect to the disposition of all securities covered by such registration statement during such period in accordance with the intended methods of disposition by the sellers thereof set forth in such registration statement;

(c) furnish to such holders such number of copies of such registration statement, each amendment and supplement thereto, the prospectus included in such registration statement (including each preliminary prospectus) and such other documents as such seller may reasonably request in order to facilitate the disposition of the Registrable Securities owned by such holders;

(d) use its Reasonable Commercial Efforts to register or qualify such Registrable Securities under such other securities or blue sky laws of such jurisdictions as such holders reasonably request and do any and all other acts and things which may be reasonably necessary or advisable to enable such holders to consummate the disposition in such jurisdictions of the Registrable Securities owned by such holders; provided, however, that the Company shall not be required to: (i) qualify generally to do business in any jurisdiction where it would not otherwise be required to qualify but for this subparagraph; (ii) subject itself to taxation in any such jurisdiction; or (iii) consent to general service of process in any such jurisdiction;

(e) notify such holders, at any time when a prospectus relating thereto is required to be delivered under the Securities Act, of the happening of any event as a result of which the prospectus included in such registration statement contains an untrue statement of a material fact or omits any material fact necessary to make the statements therein, in light of the circumstances in which they are made, not materially misleading, and, at the reasonable request of such holders, the Company shall prepare a supplement or amendment to such prospectus so that, as thereafter delivered to the purchasers of such Registrable Securities, such prospectus shall not contain an untrue statement of a material fact or omit to state any material fact necessary to make the statements therein, in light of the circumstances in which they are made, not materially misleading;

(f) provide a transfer agent and registrar for all such Registrable Securities not later than the effective date of such registration statement;

(g) make available for inspection by any underwriter participating in any disposition pursuant to such registration statement, and any attorney, accountant or other agent retained by any such underwriter, all financial and other records, pertinent corporate documents and properties of the Company, and cause the Company's officers, directors, managers, employees and independent accountants to supply all information reasonably requested by any such underwriter, attorney, accountant or agent in connection with such registration statement;

(h) otherwise use its Reasonable Commercial Efforts to comply with all applicable rules and regulations of the SEC, and make available to its security holders, as soon as reasonably practicable, an earnings statement of the Company, which earnings statement shall satisfy the provisions of Section 11(a) of the Securities Act and, at the option of the Company, Rule 158 thereunder;

(i) in the event of the issuance of any stop order suspending the effectiveness of a registration statement, or of any order suspending or preventing the use of any related prospectus or suspending the qualification of any Registrable Securities included in such registration statement for sale

in any jurisdiction, the Company shall use its Reasonable Commercial Efforts promptly to obtain the withdrawal of such order; and

(j) if the offering is underwritten, use its Reasonable Commercial Efforts to furnish on the date that Registrable Securities are delivered to the underwriters for sale pursuant to such registration, an opinion dated such date of counsel representing the Company for the purposes of such registration, addressed to the underwriters covering such issues as are reasonably required by such underwriters.

8.4 Listing. The Company shall secure the listing of the Common Stock underlying this Warrant upon each national securities exchange or automated quotation system upon which shares of Common Stock are then listed or quoted (subject to official notice of issuance) and shall maintain such listing of shares of Common Stock. The Company shall at all times comply in all material respects with the Company's reporting, filing and other obligations under the by-laws or rules of the Nasdaq Capital Market (or such other national securities exchange or market on which the Common Stock may then be listed, as applicable).

8.5 Expenses. The Company shall pay all Registration Expenses relating to the registration and listing obligations set forth in this Section 8. For purposes of this Warrant, the term "**Registration Expenses**" means: (a) all registration, filing and FINRA fees, (b) all reasonable fees and expenses of complying with securities or blue sky laws, (c) all word processing, duplicating and printing expenses, (d) the fees and disbursements of counsel for the Company and of its independent public accountants, including the expenses of any special audits or "cold comfort" letters required by or incident to such performance and compliance, (e) premiums and other costs of policies of insurance (if any) against liabilities arising out of the public offering of the Registrable Securities being registered if the Company desires such insurance, if any, and (f) fees and disbursements of one counsel for the selling holders of Registrable Securities; provided however, that, in any case where Registration Expenses are not to be borne by the Company, such expenses shall not include (and such expenses shall be borne by the Company): (i) salaries of Company personnel or general overhead expenses of the Company, (ii) auditing fees, or (iii) other expenses for the preparation of financial statements or other data, to the extent that any of the foregoing either is normally prepared by the Company in the ordinary course of its business or would have been incurred by the Company had no public offering taken place. Registration Expenses shall not include any underwriting discounts and commissions which may be incurred in the sale of any Registrable Securities and transfer taxes of the selling holders of Registrable Securities.

8.6 Information Provided by Holders. Any holder of Registrable Securities included in any registration shall furnish to the Company such information as the Company may reasonably request in writing, including, but not limited to, a completed and executed questionnaire requesting information customarily sought of selling security holders, to enable the Company to comply with the provisions hereof in connection with any registration referred to in this Warrant. The Holder agrees to suspend all sales of Registrable Securities pursuant to a registration statement filed under Section 8.2 in the event the Company notifies Holder pursuant to Section 8.3(e) that the prospectus relating thereto is no longer current and will not resume sales under such registration statement until advised by the Company that the prospectus has been appropriately supplemented or amended.

8.7 Effectiveness Period. The Company shall use its Reasonable Commercial Efforts to keep each registration statement contemplated hereunder continuously effective under the Securities Act until the date which is the earlier date of when (i) all Registrable Securities covered by such

registration statement have been sold, (ii) all Registrable Securities covered by such registration statement may be sold immediately without registration under the Securities Act and without volume restrictions pursuant to Rule 144 under the Securities Act, as determined by the counsel to the Company pursuant to a written opinion letter to such effect, addressed and reasonably acceptable to the Company's transfer agent and the affected holders of Registrable Securities, or (iii) nine months from the effective date of such registration statement.

9. Indemnification. In the event of any piggyback registration of any Warrant Shares under the Securities Act, and in connection with any registration statement or any other disclosure document pursuant to which securities of the Company are sold, the Company will, and hereby does, jointly and severally, indemnify and hold harmless the Holder, its directors, officers, fiduciaries, and agents (each, a "**Covered Person**") against any losses, claims, damages or liabilities, joint or several, to which such Covered Person may be or become subject under the Securities Act, any other securities or other laws of any jurisdiction, common law or otherwise, insofar as such losses, claims, damages or liabilities (or actions or proceedings in respect thereof) arise out of or are based upon (1) any untrue statement or alleged untrue statement of any material fact contained or incorporated by reference in any registration statement under the Securities Act, any preliminary prospectus or final prospectus included therein, or any amendment or supplement thereto, or any document incorporated by reference therein, or any other such disclosure document, or (2) any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statement therein not misleading, and will reimburse such Covered Person for any legal or any other expenses incurred in connection with investigating or defending any such loss, claim, damage, liability, action or proceeding, provided, however, the Company shall not be liable to any Covered Person in any such case to the extent that any such loss, claim, damage, liability, action or proceeding is determined, by a final, non-appealable judgment by a court or arbitral tribunal of competent jurisdiction, to have arisen out of or is based upon an untrue statement or alleged untrue statement or omission or alleged omission made in such registration statement, any such preliminary prospectus, final prospectus, amendment or supplement, any document incorporated by reference or other such disclosure document in reliance upon and in conformity with written information furnished to the Company through an instrument duly executed by such Covered Person specifically stating that it is for use in the preparation thereof.

10. Rights or Liabilities as Stockholder. No Holder shall be entitled to vote or be deemed the holder of any equity securities which may at any time be issuable on the exercise hereof, nor shall anything contained herein be construed to confer upon the Holder, as such, any of the rights of a stockholder of the Company or any right to vote for the election of directors or upon any matter submitted to stockholders at any meeting thereof, or to give or withhold consent to any corporate action (whether upon any recapitalization, issuance of stock, reclassification of stock, change of par value, consolidation, merger, conveyance, or otherwise). Notwithstanding the above, so long as Holder holds this Warrant and/or any of the Warrant Shares, the Company shall deliver to Holder (i) promptly, copies of all notices or other written communications to which Holder would be entitled if it held Shares as to which this Warrant was then exercisable, and (ii) within 45 days after the end of each of the first three quarters of each fiscal year, the Company's quarterly, unaudited financial statements and within 90 days after the end of each fiscal year, the Company's annual, audited financial statements; provided, however, that with regard to annual meeting proxy statements and clause (ii) of this Section 10, it is understood and agreed that there shall be no such delivery requirement with respect to any such proxy statements or financial statements if such documents are available on EDGAR.

11. Notices. Any notice or other communication in connection with this Warrant shall be given in writing and directed to the parties hereto as follows: (a) if to the Holder, at the address of the holder in the Warrant Register maintained pursuant to Section 7 hereof, or (b) if to the Company, to the attention of its Chief Executive Officer at its office maintained pursuant to Section 7.2(a) hereof; provided, that the exercise of the Warrant shall also be effected in the manner provided in Section 1 hereof. Notices shall be deemed properly delivered and received when delivered to the notice party (i) if personally delivered, upon receipt or refusal to accept delivery, (ii) if sent via facsimile, upon mechanical confirmation of successful transmission thereof generated by the sending telecopy machine, (iii) if sent by a commercial overnight courier for delivery on the next Business Day, on the first Business Day after deposit with such courier service, (iv) if sent by registered or certified mail, five (5) Business Days after deposit thereof in the U.S. mail, or (v) if sent by email, the date of transmission if such notice or communication is delivered via email at the email address specified in the Credit Agreement prior to 5:00 p.m. (prevailing Pacific time) on a Business Day, or the next Business Day after the date of transmission if such notice or communication is delivered via email at the email address specified in the Credit Agreement on a day that is not a Business Day or later than 5:00 p.m. (prevailing Pacific time) on a Business Day.

12. Payment of Taxes. The Company will pay all documentary stamp taxes attributable to the issuance of shares of Common Stock underlying this Warrant upon exercise of this Warrant; provided, however, that the Company shall not be required to pay any tax which may be payable in respect of any transfer involved in the transfer or registration of this Warrant or any certificate for shares of Common Stock underlying this Warrant in a name other than that of the Holder. The Holder is responsible for all other tax liability that may arise as a result of holding or transferring this Warrant or receiving shares of Common Stock underlying this Warrant upon exercise hereof.

13. Amendments. This Warrant and any term hereof may be changed, waived, discharged or terminated only by an instrument in writing signed by the party against which enforcement of the change, waiver, discharge or termination is sought.

14. Governing Law. This Warrant shall be construed and enforced in accordance with and governed by the laws of the state of New York. Each of the parties consents to the exclusive jurisdiction of the courts of the state of New York and of the United States District Court for the state of New York in connection with any dispute arising under this Agreement and hereby waives, to the maximum extent permitted by law, any objection, including any objection based on *forum non conveniens,* to the bringing of any such proceeding in such jurisdictions. Each party to this Agreement irrevocably consents to the service of process in any such proceeding by any manner permitted by law.

15. Section Headings. The section headings in this Warrant are for purposes of convenience only and shall not constitute a part hereof.

16. Severability. In case any one or more of the provisions of this Warrant shall be invalid or unenforceable in any respect, the validity and enforceability of the remaining terms and provisions of this Warrant shall not in any way be affected or impaired thereby, and the parties will attempt in good faith to agree upon a valid and enforceable provision which shall be a commercially reasonable substitute therefor, and upon so agreeing, shall incorporate such substitute provision in this Warrant.

17. Reasonable Commercial Efforts. When used herein, the term "**Reasonable Commercial Efforts**" means, with respect to the applicable obligation of the Company, reasonable commercial efforts for similarly situated, publicly traded companies.

18. Provisions for the Benefit of the Lenders. Notwithstanding anything herein to the contrary, nothing contained in this Warrant shall affect, limit or impair the rights and remedies of Holder (or its Affiliates) in its capacity as a lender to the Company or any of the Company's subsidiaries pursuant to the Credit Agreement, or any other agreements or instruments entered into in connection therewith. Without limiting the generality of the foregoing, SWK in exercising its rights as Agent or lender will not have any duty to consider (a) its status as a direct or indirect stockholder of the Company and the Company's subsidiaries, (b) the direct or indirect ownership of the Shares, or (c) any duty it may have to any other direct or indirect stockholder of the Company and the Company's subsidiaries, except as may be required under the applicable loan documents.

19. Correction. This Warrant corrects, restates and supersedes in all respects that certain Warrant issued to SWK Funding LLC and dated November 13, 2019 (the "**Original Warrant**"). The Original Warrant is hereby replaced by this Warrant and the Original Warrant is henceforth void and shall be of no further force or effect.

(*Signature on Following Page*)

IN WITNESS WHEREOF, the Company has caused this Warrant to be duly executed as of the date first above written.

ETON PHARMACEUTICALS, INC.

By: W. Wilson Troutman
Name: W. Wilson Troutman
Title: CFO, Corporate Secretary

EXHIBIT A FORM OF EXERCISE NOTICE

[To be executed only upon exercise of Warrant]

To ETON PHARMACEUTICALS, INC.:

The undersigned registered holder of the within Warrant hereby irrevocably exercises the Warrant pursuant to Section 1.1 of the Warrant with respect to [_____] Warrant Shares, at an exercise price of $_____ per share, and requests that the certificates for such Warrant Shares be issued, subject to Sections 11 and 12, in the name of and delivered to:

The undersigned is hereby making payment for the Warrant Shares in the following manner:
[check one]

- ♦ by cash in accordance with Section 1.1(c)of the Warrant
- ♦ via cashless exercise in accordance with Section 1.1(d)of the Warrant in the following manner:

The undersigned hereby represents and warrants that it is, and has been since its acquisition of the Warrant, the record and beneficial owner of the Warrant.

Dated:			
Print or Type Name			
(Signature must conform in all respects to name of holder as specified on the face of Warrant)			
(Street Address)			
(City)	(State)	(Zip Code)	

EXHIBIT B FORM OF ASSIGNMENT

[To be executed only upon transfer of Warrant]

For value received, the undersigned registered holder of the within Warrant hereby sells, assigns and transfers unto_____ [include name and addresses] the rights represented by the Warrant to purchase_____ shares of Common Stock of ETON PHARMACEUTICALS, INC. to which the Warrant relates, and appoints_____ Attorney to make such transfer on the books of ETON PHARMACEUTICALS maintained for the purpose, with full power of substitution in the premises.

Dated:					
	(Signature must conform in all respects to name of holder as specified on the face of Warrant)				
	(Street Address)				
	(City)	(State)	(Zip Code)		
Signed in the presence of:					
	(Signature of Transferee)				
	(Street Address)				
	(City)	(State)	(Zip Code)		
Signed in the presence of:					

EXECUTION VERSION

CREDIT AGREEMENT

among

ETON PHARMACEUTICALS, INC.,
as Borrower,

SWK FUNDING LLC,
as Agent, Sole Lead Arranger and Sole Bookrunner,

and

the financial institutions party hereto from time to time as Lenders

Dated as of November 13, 2019

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CREDIT AGREEMENT

This CREDIT AGREEMENT (as may be amended, restated, supplemented, or otherwise modified from time to time, this "Agreement") dated as of November 13, 2019 (the "Closing Date"), among ETON PHARMACEUTICALS, INC., a Delaware corporation ("Borrower"), the financial institutions party hereto from time to time as lenders (each a "Lender" and collectively, the "Lenders") and SWK FUNDING LLC, a Delaware limited liability company (in its individual capacity, "SWK"), as Agent for all Lenders.

In consideration of the mutual agreements herein contained, the parties hereto agree as follows:

Section 1 Definitions; Interpretation.

1.1 Definitions.

When used herein the following terms shall have the following meanings:

Account Control Agreement means, individually and collectively, any account control or similar agreement(s) entered into from time to time at Agent's request, among a Loan Party, Agent and any third party bank or financial institution at which such Loan Party maintains a Deposit Account.

Acquisition means any transaction or series of related transactions for the purpose of or resulting, directly or indirectly, in (a) the acquisition of all or substantially all of the assets of a Person, or of all or substantially all of any business or division of a Person, (b) the acquisition of in excess of fifty percent (50%) of the capital stock, partnership interests, membership interests or equity of any Person, or otherwise causing any Person to become a Subsidiary, (c) the acquisition of a product license or a product line (excluding, for purposes of Section 7.10 hereof, any pending Acquisitions as of the Closing Date as set forth on Schedule 1.1 hereto), or (d) a merger or consolidation or any other combination (other than a merger, consolidation or combination that effects a Disposition) with another Person (other than a Person that is already a Subsidiary).

Affiliate of any Person means (a) any other Person which, directly or indirectly, controls or is controlled by or is under common control with such Person, (b) any employee, manager, officer or director of such Person and (c) with respect to any Lender, any entity administered or managed by such Lender or an Affiliate or investment advisor thereof which is engaged in making, purchasing, holding or otherwise investing in commercial loans. For purposes of the definition of the term "Affiliate," a Person shall be deemed to be "controlled by" any other Person if such Person possesses, directly or indirectly, power to vote ten percent (10%) or more of the securities (on a fully diluted basis) having ordinary voting power for the election of directors or managers or power to direct or cause the direction of the management and policies of such Person whether by contract or otherwise. Unless expressly stated otherwise herein, neither Agent nor any Lender shall be deemed an Affiliate of Borrower or of any Subsidiary.

Agent means SWK in its capacity as administrative and collateral agent for all Lenders hereunder and any successor thereto in such capacity.

Aggregate Revenue shall have the meaning set forth in Section 2.9.1(a).

Agreement shall have the meaning set forth in the Preamble.

Approved Fund means (a) any fund, trust or similar entity that invests in commercial loans in the ordinary course of business and is advised or managed by (i) a Lender, (ii) an Affiliate of a Lender, (iii) the same investment advisor that manages a Lender or (iv) an Affiliate of an investment advisor that manages

a Lender or (b) any finance company, insurance company or other financial institution which temporarily warehouses loans for any Lender or any Person described in clause (a) above.

Assignment Agreement means an agreement substantially in the form of Exhibit A.

Authorization shall have the meaning set forth in Section 5.22(b).

Borrower shall have the meaning set forth in the Preamble.

Business Day means any day on which commercial banks are open for commercial banking business in Dallas, Texas, and, in the case of a Business Day which relates to the calculation of LIBOR, on which dealings are carried on in the London interbank Eurodollar market.

Capital Lease means, with respect to any Person, any lease of (or other agreement conveying the right to use) any real or personal property by such Person that, in conformity with GAAP, is accounted for as a capital lease and as a liability on the balance sheet of such Person.

Cash Equivalent Investment means, at any time, (a) any evidence of Debt, maturing not more than one year after such time, issued or guaranteed by the United States Government or any agency thereof, (b) commercial paper, or corporate demand notes, in each case (unless issued by a Lender or its holding company) rated at least "A-1" by Standard & Poor's Ratings Group or "P-1" by Moody's Investors Service, Inc., (c) any certificate of deposit (or time deposit represented by a certificate of deposit) or banker's acceptance maturing not more than one year after such time, or any overnight Federal Funds transaction that is issued or sold by any Lender (or by a commercial banking institution that is a member of the Federal Reserve System or is a U.S. branch of a foreign banking institution and has a combined capital and surplus and undivided profits of not less than $500,000,000), (d) any repurchase agreement entered into with any Lender (or commercial banking institution of the nature referred to in clause (c) above) which (i) is secured by a fully perfected security interest in any obligation of the type described in any of clauses (a) through (c) above and (ii) has a market value at the time such repurchase agreement is entered into of not less than one-hundred percent (100%) of the repurchase obligation of such Lender (or other commercial banking institution) thereunder, (e) money market accounts or mutual funds which invest exclusively or substantially in assets satisfying the foregoing requirements, (f) cash, and (g) other short term liquid investments approved in writing by Agent.

Change of Control means the occurrence of any of the following, unless such action has been consented to in advance in writing by Agent in its sole discretion:

(i) any Person acquires the direct or indirect ownership of more than fifty-one percent (51%) of the issued and outstanding voting Equity Interests of Borrower;

(ii) Borrower shall at any time fail to own, directly or indirectly, one hundred percent (100%) of the Equity Interests of each of its Subsidiaries;

(iii) a Key Person Event; or

(iv) any "change in/of control" or "sale" or "disposition" or "merger" or similar event as defined in any certificate of incorporation or formation or statement of designations or bylaws or operating agreement, as applicable, of Borrower or in any document governing indebtedness of any Loan Party (other than any Loan Documents) in excess of $250,000, individually or in the aggregate which gives the holder of such indebtedness the right to accelerate or otherwise require payment of such indebtedness prior to the maturity date thereof; or

(v) the sale of all or substantially all of the assets of Borrower or any of its Subsidiaries, the sale of any material portion of the assets relating to the Product, or any merger, consolidation or acquisition by Borrower or any of its Subsidiaries which does not result in such Person being the sole surviving entity.

CLIA means (a) the Clinical Laboratory Improvement Act of 1967, as the same may be amended, modified or supplemented from time to time, including without limitation the Clinical Laboratory Improvement Amendments, 42 U.S.C. § 263a et seq. ("CLIA 88"), and any successor statute thereto, and any and all rules or regulations promulgated from time to time thereunder, or (b) any equivalent state statute (and any and all rules or regulations promulgated from time to time thereunder) recognized by the relevant Governmental Authority as (*x*) having an "Equivalency" (as defined by CLIA) to CLIA, and (*y*) offering a compliance and regulatory framework that is applicable to a Person in such state in lieu of CLIA.

Closing Date shall have the meaning set forth in the Preamble.

Closing Date Warrant means that certain warrant issued to SWK Funding LLC by Borrower on the Closing Date.

CMS means the Centers for Medicare and Medicaid Services of the United States of America.

Collateral has the meaning set forth in the Guarantee and Collateral Agreement.

Collateral Access Agreement means an agreement in form and substance reasonably satisfactory to Agent pursuant to which a mortgagee or lessor of real property on which Collateral (or any books and records) is stored or otherwise located, or a warehouseman, processor or other bailee of Inventory or other property owned by any Loan Party, acknowledges the Liens of Agent and waives (or, if approved by Agent, subordinates) any Liens held by such Person on such property, and, in the case of any such agreement with a mortgagee or lessor, permits Agent reasonable access to any Collateral stored or otherwise located thereon.

Collateral Documents means, collectively, the Guarantee and Collateral Agreement, the IP Security Agreement, each Collateral Access Agreement, any mortgage delivered in connection with the Loan from time to time, each Account Control Agreement and each other agreement or instrument pursuant to or in connection with which any Loan Party or any other Person grants a Lien in any Collateral to Agent for the benefit of Agent and Lenders, each as amended, restated or otherwise modified from time to time.

Commitment means, as to any Lender, such Lender's Pro Rata Term Loan Share.

Commitment Fee shall have the meaning set forth in Section 2.7(b).

Compliance Certificate means a certificate substantially in the form of Exhibit B.

Consolidated Net Income means, with respect to any Person and its Subsidiaries, for any period, the consolidated net income (or loss) of such Person and its respective Subsidiaries for such period, as determined under GAAP.

Consolidated Unencumbered Liquid Assets means as of any date of determination (i) any Cash Equivalent Investment owned by Borrower and its Subsidiaries on a consolidated basis which are not the subject of any Lien or other arrangement with any creditor to have its claim satisfied out of the asset (or proceeds thereof) prior to the general creditors of Borrower and such Subsidiaries other than the Lien for the benefit of Agent and Lenders, minus (ii) the aggregate amount of Borrower's accounts payable under

GAAP that are ninety (90) days or more past due unless the charges for such account payable are being actively disputed by the applicable Loan Party.

Contingent Obligation means any agreement, undertaking or arrangement by which any Person guarantees, endorses or otherwise becomes or is contingently liable upon (by direct or indirect agreement, contingent or otherwise, to provide funds for payment, to supply funds to or otherwise to invest in a debtor, or otherwise to assure a creditor against loss) any indebtedness, obligation or other liability of any other Person (other than by endorsements of instruments in the course of collection), or guarantees the payment of dividends or other distributions upon the shares of any other Person. The amount of any Person's obligation in respect of any Contingent Obligation shall be deemed to be the amount for which the Person obligated thereon is reasonably expected to be liable or responsible.

Contract Rate means a rate per annum equal to (*x*) the LIBOR Rate, plus (*y*) ten percent (10%).

Controlled Group means all members of a controlled group of corporations and all members of a controlled group of trades or businesses (whether or not incorporated) under common control which, together with a Loan Party, are treated as a single employer under Section 414 of the IRC or Section 4001 of ERISA.

Controlled Substances Act means the Drug Abuse Prevention and Control Act; Title 21 of the United States Code, 13 U.S.C., as amended from time to time.

Copyrights shall mean all of each Loan Party's (or if referring to another Person, such other Person's) now existing or hereafter acquired right, title, and interest in and to: (i) copyrights, rights and interests in copyrights, works protectable by copyright, all applications, registrations and recordings relating to the foregoing as may at any time be filed in the United States Copyright Office or in any similar office or agency of the United States, any state thereof or any political subdivision thereof, or in any other country, and all research and development relating to the foregoing; and (ii) all renewals of any of the foregoing.

DEA means the Federal Drug Enforcement Administration of the United States of America.

Debt of any Person means, without duplication, (a) all indebtedness of such Person for borrowed money, (b) all indebtedness evidenced by bonds, debentures, notes or similar instruments, (c) all obligations of such Person as lessee under Capital Leases which have been or should be recorded as liabilities on a balance sheet of such Person in accordance with GAAP, (d) all obligations of such Person to pay the deferred purchase price of property or services (excluding trade accounts payable in the ordinary course of business), other than royalty payments or milestone payments made or to be made by such Person from time to time in connection with an Acquisition, (e) all indebtedness secured by a Lien on the property of such Person, whether or not such indebtedness shall have been assumed by such Person (with the amount thereof being measured as the lesser of (*x*) the aggregate unpaid amount of such indebtedness and (*y*) the fair market value of such property), (f) all reimbursement obligations, contingent or otherwise, with respect to letters of credit (whether or not drawn), banker's acceptances and surety bonds issued for the account of such Person, other than obligations that relate to trade accounts payable in the ordinary course of business, (g) all Hedging Obligations of such Person, (h) all Contingent Obligations of such Person in respect of Debt of others, (i) all indebtedness of any partnership of which such Person is a general partner except to the extent such Person is not liable for such Debt, and (j) all obligations of such Person under any synthetic lease transaction, where such obligations are considered borrowed money indebtedness for tax purposes but the transaction is classified as an operating lease in accordance with GAAP.

Debtor Relief Law means, collectively: (a) Title 11 of the United States Code, 11 U.S.C. § 101 et. seq., as amended from time to time, and (b) all other United States or foreign applicable liquidation,

conservatorship, bankruptcy, moratorium, rearrangement, receivership, insolvency, reorganization or similar debtor relief laws from time to time in effect affecting the rights of creditors generally, in each case as amended from time to time.

Default means any event that, if it continues uncured, will, with the lapse of time or the giving of notice or both, constitute an Event of Default.

Default Rate means a rate per annum equal to the lesser of (i) three percent (3%) over the Contract Rate, or (ii) the maximum rate of interest permitted to be charged by applicable laws or regulation governing this Agreement until paid.

Deposit Account means, individually and collectively, any bank or other depository accounts of a Loan Party.

Disposition means, as to any asset or right of any Loan Party, (a) any sale, lease, assignment or other transfer (other than to any other Loan Party), but specifically excluding any license or sublicense, (b) any loss, destruction or damage thereof or (c) any condemnation, expropriation, confiscation, requisition, seizure or taking thereof, in each case excluding (i) the sale of inventory or Product in the ordinary course of business, (ii) any issuance of Equity Interests by Borrower and (iii) any other Disposition where the Net Cash Proceeds or any sale, lease, assignment, transfer, condemnation, expropriation, confiscation, requisition, loss, destruction, damage, seizure or taking do not in the aggregate exceed $250,000 in any Fiscal Year.

Division means, with respect to any Person which is an entity, the division of such Person into two (2) or more separate such Persons, with the dividing Person either continuing or terminating its existence as part of such division, including as contemplated under Section 18-217 of the Delaware Limited Liability Act for limited liability companies formed under Delaware law, or any analogous action taken pursuant to any other applicable law with respect to any corporation, limited liability company, partnership or other entity. The word "Divide," when capitalized, shall have a correlative meaning.

Dollar and $ mean lawful money of the United States of America.

Drug Application means a new drug application, an abbreviated drug application, or a product license application for any Product, as appropriate, as those terms are defined in the FDA Law and Regulation.

EBITDA means, for any Person and its Subsidiaries for any period, Consolidated Net Income for such period plus, to the extent deducted in determining such Consolidated Net Income for such period (and without duplication), (i) Interest Expense, (ii) income tax expense (including tax accruals), (iii) depreciation and amortization, (iv) nonrecurring cash fees, costs and expenses incurred in connection with the Acquisitions of product licenses and product lines from a third party, in relation to any Material Contract or any other Acquisition made prior to the date of this Agreement, (v) non-cash expenses relating to equity-based compensation or purchase accounting, and (vi) other non-recurring and/or non-cash expenses or charges approved by the Agent.

Elapsed Period has the meaning set forth in Section 2.9.1(a).

EM-100 means the preservative-free formulation of ketotifen in ophthalmic solution form indicated for the treatment of allergic conjunctivitis which is the subject of Borrower's Abbreviated New Drug Application No. 208158, submitted on January 19, 2016, with the U.S. FDA.

EM-100 Term Loan means the Term Loan made to the Borrower pursuant to Section 2.2.2, if any.

EM-100 Term Loan Conditions means the satisfaction of each of the following: (a) EM-100 has received FDA approval in accordance with the FDA Law and Regulations for EM-100, (b) Borrower shall have issued to SWK Funding LLC, a warrant, substantially similar in form and substance to the Closing Date Warrant, for an amount of common shares of Borrower equivalent to six percent (6%) of the principal amount funded under the EM-100 Term Loan (as calculated based on the Borrower's average share price for the trailing ten (10) Business Day period prior to the funding of the EM-100 Term Loan), (c) the Subsequent Term Loan has not been made, (d) the one year anniversary of the Closing Date has not occurred.

Environmental Claims means all claims, however asserted, by any Governmental Authority or other Person alleging potential liability or responsibility for violation of any Environmental Law, or for release or injury to the environment or any Person or property.

Environmental Laws means all present or future foreign, federal, state or local laws, statutes, common law duties, rules, regulations, ordinances and codes, together with all administrative orders, directed duties, requests, licenses, authorizations and permits of, and agreements with, any Governmental Authority, in each case relating to any matter arising out of or relating to the effect of the environment on health and safety, or pollution or protection of the environment or workplace, including any of the foregoing relating to the presence, use, production, generation, handling, transport, treatment, storage, disposal, distribution, discharge, release, control or cleanup of any Hazardous Substance.

Equity Interests means, with respect to any Person, its equity ownership interests, its common stock, par value $0.001 per share ("Common Stock") and any other capital stock or other equity ownership units of such Person authorized from time to time, and any other shares, options, interests, participations or other equivalents (however designated) of or in such Person, whether voting or nonvoting, including, without limitation, Common Stock, options, warrants, preferred stock, phantom stock, membership units (common or preferred), stock appreciation rights, membership unit appreciation rights, convertible notes or debentures, stock purchase rights, membership unit purchase rights and all securities convertible, exercisable or exchangeable, in whole or in part, into any one or more of the foregoing.

Event of Default means any of the events described in Section 8.1.

Excluded Taxes has the meaning set forth in Section 3.1(a).

Exempt Accounts means any Deposit Accounts, securities accounts or other similar accounts (i) into which there are deposited no funds other than those intended solely to cover compensation to employees of the Loan Parties (and related contributions to be made on behalf of such employees to health and benefit plans) plus balances for outstanding checks for compensation and such contributions from prior periods; or (ii) constituting employee withholding accounts that contain only funds deducted from pay otherwise due to employees for services rendered to be applied toward the tax obligations of such Person or its employees.

Exit Fee shall have the meaning set forth in Section 2.7(c).

Fair Valuation shall mean the determination of the value of the consolidated assets of a Person on the basis of the amount which may be realized by a willing seller within a reasonable time through collection or sale of such assets at market value on a going concern basis to an interested buyer who is willing to purchase under ordinary selling conditions in an arm's length transaction.

FATCA means Sections 1471 through 1474 of the IRC and any current or future regulations thereunder or official interpretations thereof.

FD&C Act means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq., as amended.

FDA means the Food and Drug Administration of the United States of America.

FDA Law and Regulation means the provisions of the FD&C Act and all applicable regulations promulgated by the FDA.

FDA Products means any finished products sold by Borrower or any of the other Loan Parties for itself or for a third party that are subject to applicable Health Care Laws.

Federal Funds Effective Rate means, for any day, the greater of (a) the rate calculated by the Federal Reserve Bank of New York based on such day's Federal funds transactions by depositary institutions (as determined in such manner as the Federal Reserve Bank of New York shall set forth on its public website from time to time) and published on the next succeeding day on which commercial banks are open for commercial banking business in New York, New York, by the Federal Reserve Bank of New York as the Federal funds effective rate and (b) 2.0%.

Fiscal Quarter means a calendar quarter of a Fiscal Year.

Fiscal Year means the fiscal year of Borrower and its Subsidiaries, which period shall be the twelve (12) month period ending on December 31 of each year.

Foreign Lender means any Lender that is not a "United States person" within the meaning of Section 7701(a)(30) of the IRC.

FRB means the Board of Governors of the Federal Reserve System or any successor thereto.

GAAP means generally accepted accounting principles in effect in the United States of America set forth from time to time in the opinions and pronouncements of the Accounting Principles Board and the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board (or agencies with similar functions of comparable stature and authority within the U.S. accounting profession), which are applicable to the circumstances as of the date of determination.

Governmental Authority means any nation or government, any state or other political subdivision thereof, and any agency, branch of government, department or Person exercising executive, legislative, judicial, regulatory or administrative functions of or pertaining to government and any corporation or other Person owned or controlled (through stock or capital ownership or otherwise) by any of the foregoing, whether domestic or foreign. Governmental Authority shall include any agency, branch or other governmental body charged with the responsibility and/or vested with the authority to administer and/or enforce any Health Care Laws.

Guarantee and Collateral Agreement means the Guarantee and Collateral Agreement dated as of the Closing Date executed by each Loan Party signatory thereto in favor of Agent for the benefit of Agent and Lenders.

Hazardous Substances means hazardous waste, pollutant, contaminant, toxic substance, oil, hazardous material, chemical or other substance regulated by any Environmental Law.

Health Care Laws mean all foreign, federal and state fraud and abuse laws relating to the regulation of healthcare products, pharmaceutical products, laboratory facilities and services, healthcare providers, healthcare professionals, healthcare facilities, clinical research facilities or healthcare payors, including but not limited to (i) the federal Anti-Kickback Statute (42 U.S.C. (§1320a-7b(b))), the Stark Law (42 U.S.C. §1395nn and §1395(q)), the civil False Claims Act (31 U.S.C. §3729 et seq.), TRICARE (10 U.S.C. Section 1071 et seq.), Section 1320a-7 and 1320a-7a of Title 42 of the United States Code and the regulations promulgated pursuant to such statues; (ii) the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191), as amended by the Health Information, Technology for Economic and Clinical Health Act of 2009 (collectively, "HIPAA"), and the regulations promulgated thereunder, (iii) Medicare (Title XVIII of the Social Security Act) and the regulations promulgated thereunder; (iv) Medicaid (Title XIX of the Social Security Act) and the regulations promulgated thereunder; (v) the FD&C Act and all applicable requirements, regulations and guidances issued thereunder by the FDA (including FDA Law and Regulation); (vi) the Controlled Substances Act, as amended, and all applicable requirements, regulations and guidances issued thereunder by the DEA; (vii) CLIA, as amended, and all applicable requirements, regulations, and guidance issued thereunder by the applicable Governmental Authority; (viii) quality, safety and accreditation standards and requirements of all applicable foreign and domestic federal, provincial or state laws or regulatory bodies; (ix) all applicable licensure laws and regulations; (x) all applicable professional standards regulating healthcare providers, healthcare professionals, healthcare facilities, clinical research facilities or healthcare payors; and (xi) any and all other applicable health care laws (whether foreign or domestic), regulations, manual provisions, policies and administrative guidance, including those related to the corporate practice of medicine, fee-splitting, state anti-kickback or self-referral prohibitions, each of clauses (i) through (xi) as may be amended from time to time.

Hedging Obligation means, with respect to any Person, any liability of such Person under any interest rate, currency or commodity swap agreement, cap agreement or collar agreement, and any other agreement or arrangement designed to protect a Person against fluctuations in interest rates, currency exchange rates or commodity prices. The amount of any Person's obligation in respect of any Hedging Obligation shall be deemed to be the incremental obligation that would be reflected in the financial statements of such Person in accordance with GAAP.

Indemnified Taxes has the meaning set forth in Section 3.1(a).

Intellectual Property shall mean all present and future: trade secrets, know-how and other proprietary information; Trademarks and Trademark Licenses (as defined in the Guarantee and Collateral Agreement), internet domain names, service marks, trade dress, trade names, business names, designs, logos, slogans (and all translations, adaptations, derivations and combinations of the foregoing) indicia and other source and/or business identifiers, and the goodwill of the business relating thereto and all registrations or applications for registrations which have heretofore been or may hereafter be issued thereon throughout the world; Copyrights (including Copyrights for computer programs, but excluding commercially available off-the-shelf software and any Intellectual Property rights relating thereto) and Copyright Licenses (as defined in the Guarantee and Collateral Agreement) and all tangible and intangible property embodying the Copyrights, unpatented inventions (whether or not patentable); Patents and Patent Licenses (as defined in the Guarantee and Collateral Agreement); Mask Works (as defined in the Guarantee and Collateral Agreement); industrial design applications and registered industrial designs; license agreements related to any of the foregoing and income therefrom, books, records, writings, computer tapes or disks, flow diagrams, specification sheets, computer software, source codes, object codes, executable code, data, databases and other physical manifestations, embodiments or incorporations of any of the foregoing; customer lists and customer information, the right to sue for all past, present and future infringements of any of the foregoing; all other intellectual property; and all common law and other rights throughout the world in and to all of the foregoing.

Interest Expense means for any Person and its Subsidiaries for any period the consolidated interest expense of such Person and its Subsidiaries for such period (including all imputed interest on Capital Leases).

Interest Only Extension Condition means the satisfaction of each of the following: (a) Borrower shall have received at least $8,000,000 in Raised Cash since the Closing Date, and (b) the nine month anniversary of the Closing Date has not occurred.

Inventory has the meaning set forth in the Guarantee and Collateral Agreement as the context requires.

Investment means, with respect to any Person, (a) the purchase of any debt or equity security of any other Person, (b) the making of any loan or advance to any other Person, (c) becoming obligated with respect to a Contingent Obligation in respect of obligations of any other Person (other than travel and similar advances to employees in the ordinary course of business), or (d) the making of an Acquisition.

IP Security Agreement means the Intellectual Property Security Agreement dated on or about the Closing Date by each Loan Party signatory thereto in favor of Agent for the benefit of Agent and Lenders.

IRC means the Internal Revenue Code of 1986, as amended.

IRS means the United States Internal Revenue Service.

Keyman Life Insurance Policy has the meaning assigned in Section 6.3(e) hereof.

Key Person means Sean Brynjelsen.

Key Person Event means, unless such actions are consented to in advance in writing by Agent, a Key Person shall no longer serve in his respective, current executive capacity with Borrower, unless such Key Person is replaced within ninety (90) days with (in each case) a person of like qualification and experience to assume the respective responsibilities of such departing Key Person and which has been approved in writing by Agent to assume such responsibility and capacity of the applicable departing Key Person, which approval shall not be unreasonably withheld.

Legal Costs means, with respect to any Person, all reasonable, duly documented, out-of-pocket fees and charges of any counsel, accountants, auditors, appraisers, consultants and other professionals to such Person, and all court costs and similar legal expenses.

Lenders has the meaning set forth in the Preamble.

LIBOR Rate means a fluctuating rate per annum equal to the rate which appears on the Bloomberg Page BBAM1 (or on such other substitute Bloomberg page that displays rates at which U.S. Dollar deposits are offered by leading banks in the London interbank deposit market), as the offered rate for loans in Dollars for a three (3) month period, rounded upwards, if necessary, to the nearest 1/8 of 1%. The rate is set by the ICE Benchmark Administration as of 11:00 a.m. (London time) as determined two (2) Business Days prior to each Payment Date, and effective on the Payment Date immediately following such determination date and continuing to but not including the next succeeding Payment Date. If Bloomberg Professional Service (or another nationally-recognized rate reporting source acceptable to Agent) no longer reports the LIBOR Rate or Agent determines in good faith that the rate so reported no longer accurately reflects the rate available to Agent in the London Interbank Market or if such index no longer exists or if page USD-LIBOR-BBA (ICE) no longer exists or accurately reflects the rate available to Agent in the London Interbank

Market, Agent may select a replacement index that approximates as near as possible such prior index. Notwithstanding the foregoing, (i) if at any time Agent determines (which determination shall be conclusive absent manifest error) that the LIBOR Rate is no longer available for determining interest rates for loans or notes similar to the Loans, then Agent shall, in consultation with Borrower, endeavor to establish an alternate rate of interest to the LIBOR Rate that gives due consideration to the then prevailing market convention for determining a rate of interest for loans or notes similar to the Loans in the United States at such time, and, if requested by Agent, Agent and Lenders at such time party hereto and the Borrower shall enter into an amendment to this Agreement to reflect such alternate rate of interest and such other related changes to this Agreement as may be applicable, and (ii) in no event shall the "LIBOR Rate" or any such alternate rate of interest to the LIBOR Rate ever be less than two percent (2%).

Lien means, with respect to any Person, any interest granted by such Person in any real or personal property, asset or other right owned or being purchased or acquired by such Person which secures payment or performance of any obligation and shall include any mortgage, lien, encumbrance, charge or other security interest of any kind, whether arising by contract, as a matter of law, by judicial process or otherwise.

Loan or Loans means, individually and collectively the Term Loan and any other advances made by Agent and Lenders in accordance with the Loan Documents.

Loan Documents means this Agreement, any Notes, the Collateral Documents and all documents, instruments and agreements delivered in connection with the foregoing.

Loan Party means Borrower and each of its Subsidiaries.

Margin Stock means any "margin stock" as defined in Regulation T, U or X of the FRB.

Material Adverse Effect means (a) a material adverse change in, or a material and adverse effect upon, the condition (financial or otherwise), operations, assets, business, prospects or properties of the Loan Parties taken as a whole, (b) a material impairment of the ability of any Loan Party to perform any of its payment Obligations under any Loan Document, or (c) a material and adverse effect upon any material portion of the Collateral under the Collateral Documents or upon the legality, validity, binding effect or enforceability against any Loan Party of any material Loan Document.

Material Contract has the meaning assigned in Section 5.21 hereof.

Multiemployer Pension Plan means a multiemployer plan, as defined in Section 4001(a)(3) of ERISA, to which Borrower or any member of the Controlled Group may have any liability.

Net Cash Proceeds means, with respect to any Disposition, the aggregate cash proceeds (including cash proceeds received pursuant to policies of insurance and by way of deferred payment of principal pursuant to a note, installment receivable or otherwise, but only as and when received) received by any Loan Party pursuant to such Disposition net of (i) the reasonable direct costs relating to such Disposition (including sales commissions and legal, accounting and investment banking fees, commissions and expenses), (ii) any portion of such proceeds deposited in an escrow account pursuant to the documentation relating to such Disposition (*provided* that such amounts shall be treated as Net Cash Proceeds upon their release from such escrow account to and receipt by the applicable Loan Party), (iii) taxes and other governmental costs and expenses paid or reasonably estimated by a Loan Party to be payable as a result thereof (after taking into account any available tax credits or deductions and any tax sharing arrangements), (iv) amounts required to be applied to the repayment of any Debt (together with any interest thereon, premium or penalty and any other amount payable with respect thereto) secured by a Lien that has priority over the Lien, if any, of Agent on the asset subject to such Disposition, (v) reserves for purchase price

adjustments and retained liabilities reasonably expected to be payable by the Loan Parties in connection therewith established in accordance with GAAP (*provided* that upon the final determination of the amount paid in respect of such purchase price adjustments and retained liabilities, the actual amount of purchase price adjustments and retained liabilities paid is less than such reserves, the difference shall, at such time, constitute Net Cash Proceeds), and (vi)(A) with respect to any Disposition described in clauses (a), (b) or (c) of the definition thereof, all money actually applied within one-hundred eighty (180) days to replace such assets or otherwise added to the working capital of the business of Borrower and the Subsidiaries, and (B) with respect to any Disposition, all money actually applied within one-hundred eighty (180) days to repair or replace the assets in question or to repair or reconstruct damaged property or property affected by loss, destruction, damage, condemnation, expropriation, confiscation, requisition, seizure or taking.

Net Sales means the gross amount billed or invoiced by Borrower and its Subsidiaries for Services and for the sale of Products (including products and services ancillary thereto) to independent customers, less deductions for (a) quantity, trade, cash or other discounts, allowances, bad debts, write-offs, credits or rebates (including customer rebates) actually allowed or taken, (b) amounts deducted, repaid or credited by reason of rejections or returns of goods and government mandated rebates, or because of chargebacks or retroactive price reductions, and (c) taxes, tariffs, duties or other governmental charges or assessments (including any sales, value added or similar taxes other than an income tax) levied, absorbed or otherwise imposed on or with respect to the production, sale, transportation, delivery or use of pharmaceutical products. A Product or Service shall be considered sold and/or provided when billed or invoiced. To the extent applicable, components of Net Sales shall be determined in the ordinary course of business in accordance with historical practice and using the accrual method of accounting in accordance with GAAP. For the purposes of calculating Net Sales, Lenders and Agent understand and agree that (i) Affiliates of a Borrower shall not be regarded as independent customers and (ii) Net Sales shall not include Products distributed for product development purposes, including for use in pre-clinical trials.

Note means a promissory note substantially in the form of Exhibit C.

Obligations means all liabilities, indebtedness and obligations (monetary (including post-petition interest, allowed or not) or otherwise) of any Loan Party under this Agreement, any other Loan Document or any other document or instrument executed in connection herewith or therewith which are owed to any Lender or Affiliate of a Lender, in each case howsoever created, arising or evidenced, whether direct or indirect, absolute or contingent, now or hereafter existing, or due or to become due. For the avoidance of doubt, "Obligations" shall include Borrower's obligation to pay any amounts due under Sections 2.7 and 2.8.2 and payable on such date of determination.

OFAC shall mean the U.S. Department of Treasury's Office of Foreign Asset Control.

Origination Fee shall have the meaning set forth in Section 2.7(a).

Paid in Full, Pay in Full or Payment in Full means, with respect to any Obligations, the payment in full in cash of all such Obligations (other than contingent indemnification obligations, yield protection and expense reimbursement to the extent no claim giving rise thereto has been asserted in respect of contingent indemnification obligations, and to the extent no amounts therefor have been asserted, in the case of yield protection and expense reimbursement obligations).

Patents shall mean all of each Loan Party's (or if referring to another Person, such other Person's) now existing or hereafter acquired right, title and interest in and to: (i) all patents, patent applications, inventions, invention disclosures and improvements, and all applications, registrations and recordings relating to the foregoing as may at any time be filed in the United States Patent and Trademark Office or in any similar office or agency of the United States, any state thereof or any political subdivision thereof, or

in any other country, and all research and development relating to the foregoing; and (ii) the reissues, divisions, continuations, renewals, re-examinations, extensions and continuations-in-part of any of the foregoing.

Payment Date means the fifteenth (15th) day of each of February, May, August and November (or the next succeeding Business Day to the extent such 15th day is not a Business Day), commencing with February 17, 2020.

PBGC means the Pension Benefit Guaranty Corporation and any entity succeeding to any or all of its material functions under ERISA.

Pension Plan means a "pension plan," as such term is defined in Section 3(2) of ERISA, which is subject to Title IV of ERISA (other than a Multiemployer Pension Plan), and to which Borrower or any member of the Controlled Group may have any liability, including any liability by reason of having been a substantial employer within the meaning of Section 4063 of ERISA at any time during the preceding five years, or by reason of being deemed to be a contributing sponsor under Section 4069 of ERISA.

Permit means, with respect to any Person, any permit, approval, clearance, authorization, license, registration, certificate, concession, grant, franchise, variance or permission from, and any other contractual obligations with, any Governmental Authority, in each case whether or not having the force of law and applicable to or binding upon such Person or any of its property or Products or to which such Person or any of its property or Products is subject, including without limitation all registrations with Governmental Authorities.

Permitted Liens means Liens permitted by Section 7.2.

Person means any natural person, corporation, partnership, trust, limited liability company, association, Governmental Authority or unit, or any other entity, whether acting in an individual, fiduciary or other capacity.

Prior Debt means the Debt listed on Schedule 4.1.

Pro Rata Term Loan Share means, with respect to any Lender, the applicable percentage (as adjusted from time to time in accordance with the terms hereof) specified opposite such Lender's name on Annex I which percentage represents the aggregate percentage of the Term Loan Commitment held by such Lender, which percentage shall be with respect to the outstanding balance of the Term Loan as of any date of determination after the Term Loan Commitment has terminated.

Product means any products manufactured, sold, developed, tested or marketed by Borrower or any of its Subsidiaries, including, without limitation, those products set forth on Schedule 5.18(b) (as updated from time to time in accordance with Section 6.1.2); *provided, however*, that if Borrower shall fail to comply with the obligations under Section 6.1.2 to give notice to Agent and update Schedule 5.18(b) prior to manufacturing, selling, developing, testing or marketing any new Product, any such undisclosed Product shall be deemed to be included in this definition; and *provided, further*, that products manufactured by Borrower for unaffiliated third parties shall not be deemed "Products" hereunder.

Raised Cash means net cash proceeds resulting from the issuance by Borrower of additional Equity Interests on terms and conditions satisfactory to Agent in its commercially-reasonable discretion other than a public offering of Common Stock registered under the Securities Act of 1933, as amended.

Registered Intellectual Property means all applications, registrations and recordings for or of Patents, Trademarks or Copyrights filed by a Loan Party with any Governmental Authority, all internet domain name registrations owned by a Loan Party, and all proprietary software owned by a Loan Party.

Required Lenders means Lenders having an aggregate Pro Rata Term Loan Share in excess of fifty percent (50%), collectively.

Required Permit means a Permit (a) required under applicable law for the business of Borrower or any of its Subsidiaries or necessary in the manufacturing, importing, exporting, possession, ownership, warehousing, marketing, promoting, sale, labeling, furnishing, distribution or delivery of goods or services under any laws applicable to the business of Borrower or any of its Subsidiaries (including, without limitation, any Health Care Laws) or any Drug Application (including without limitation, at any point in time, all licenses, approvals and permits issued by the FDA, CMS, or any other applicable Governmental Authority necessary for the testing, manufacture, marketing or sale of any Product by Borrower or any of its Subsidiaries as such activities are being conducted by Borrower or its Subsidiaries with respect to such Product at such time), and (b) required by any Person from which Borrower or any of its Subsidiaries have received an accreditation.

Responsible Officer shall mean the president, vice president or secretary of a Person, or any other officer having substantially the same authority and responsibility; or, with respect to compliance with financial covenants or delivery of financial information, the chief financial officer, or the treasurer of a Person, or any other officer having substantially the same authority and responsibility, and in all cases such person shall be listed on an incumbency certificate delivered to Agent, in form and substance acceptable to Agent in its sole discretion.

Revenue-Based Payment has the meaning set forth in Section 2.9.1(a).

Royalties means the amount of any and all royalties, license fees and any other payments or income of any type recognized as revenue in accordance with GAAP by Borrower and its Subsidiaries with respect to the sale of Products or the provision of services by independent licensees of Borrower and/or its Subsidiaries, including any such payments characterized as a share of net profits, any up-front or lump sum payments, any milestone payments, commissions, fees or any other similar amounts, less deductions for amounts deducted, repaid or credited by reason of adjustments to the sales upon which royalty amounts are based, regardless of the reason for such adjustment to such sales. For the purposes of calculating Royalties, Lenders and Agent understand and agree that Affiliates of Borrower shall not be regarded as independent licensees.

Services means services provided by Borrower or any Affiliate of Borrower to un-Affiliated Persons, including without limitation any sales, laboratory analysis, testing, consulting, marketing, commercialization and any other healthcare-related services.

Solvent means, as to any Person at any time, that (a) the fair value of the property of such Person is greater than the amount of such Person's liabilities (including disputed, contingent, unmatured and unliquidated liabilities); (b) the present fair saleable value of the property of such Person is not less than the amount that will be required to pay the probable liability of such Person on its debts as they become due; (c) such Person is able to pay its debts and other liabilities (including subordinated, disputed, contingent, unmatured and unliquidated liabilities) as they become due in the normal course of business; and (d) such Person does not intend to, and does not believe that it will, incur debts or liabilities beyond such Person's ability to pay such debts and liabilities as they become due.

Subordinated Debt means any Debt incurred by Borrower and/or any other Loan Party upon terms acceptable to Agent in its commercially-reasonable discretion and that is subordinated to the Obligations pursuant to a subordination agreement acceptable to Agent in its commercially-reasonable discretion entered into between Agent, any applicable Loan Party and the subordinated creditor(s).

Subsidiary means, with respect to any Person, a corporation, partnership, limited liability company or other entity of which such Person owns, directly or indirectly, such number of outstanding shares or other equity interests as to have more than fifty percent (50%) of the ordinary voting power for the election of directors or other managers of such corporation, partnership, limited liability company or other entity. Unless the context otherwise requires, each reference to Subsidiaries herein shall be a reference to direct and indirect Subsidiaries of Borrower.

Subsequent Term Loan means the Term Loan made to the Borrower pursuant to Section 2.2.3, if any.

Subsequent Term Loan Conditions means the satisfaction of each of the following: (a) Borrower shall have provided Agent evidence that Borrower has received FDA approval in accordance with the FDA Law and Regulations for a second Product developed by Borrower, other than EM-100, (b) Borrower shall have issued to SWK Funding LLC, a warrant, substantially similar in form and substance to the Closing Date Warrant, for an amount of common shares of Borrower equivalent to six percent (6%) of the principal amount funded under the Subsequent Term Loan (as calculated based on the Borrower's average share price for the trailing ten (10) Business Day period prior to the funding of the Subsequent Term Loan), (c) Borrower and Agent shall have agreed upon and implemented additional financial covenants with respect to minimum Aggregate Revenue and minimum EBITDA in accordance with Section 6.14(a), and (d) the one year anniversary of the Closing Date has not occurred.

SWK has the meaning set forth in the Preamble.

Taxes has the meaning set forth in Section 3.1(a).

Term Loan has the meaning set forth in Section 2.1, and shall, for the avoidance of doubt, include the EM-100 Term Loan, if any, and the Subsequent Term Loan, if any.

Term Loan Commitment means $10,000,000.

Term Loan Maturity Date means November 13, 2024.

Termination Date means the earlier to occur of (a) the Term Loan Maturity Date, or (b) the date upon which the Loan and all other Obligations are Paid in Full, whether as a result of (i) the prepayment of the Term Loan and all Obligations through any other mandatory or voluntary prepayment of the Term Loan in full, (ii) the contractual acceleration of the Loan hereunder, (iii) the acceleration of the Loan by Agent in accordance with this Agreement, or (iv) otherwise.

Trademarks shall mean all of each Loan Party's (or if referring to another Person, such other Person's) now existing or hereafter acquired right, title, and interest in and to: (i) all of such Loan Party's (or if referring to another Person, such other Person's) trademarks, trade names, corporate names, company names, business names, fictitious business names, trade styles, service marks, logos, other business identifiers, all applications, registrations and recordings relating to the foregoing as may at any time be filed in the United States Patent and Trademark Office or in any similar office or agency of the United States, or in any other country, and all research and development and the goodwill of the business relating to the foregoing; (ii) all renewals thereof; and (iii) all designs and general intangibles of a like nature.

Uniform Commercial Code means the Uniform Commercial Code as in effect in the State of New York; *provided* that if perfection or the effect of perfection or non-perfection or the priority of any security interest in any Collateral is governed by the Uniform Commercial Code as in effect in a jurisdiction other than the State of New York, "Uniform Commercial Code" means the Uniform Commercial Code as in effect from time to time in such other jurisdiction for purposes of the provisions hereof relating to such perfection, effect of perfection or non-perfection or priority.

U.S. Lender means any Lender that is a "United States person" within the meaning of Section 7701(a)(30) of the IRC.

Wholly-Owned Subsidiary means, as to any Person, another Person all of the Equity Interests of which (except directors' qualifying shares) are at the time directly or indirectly owned by such Person and/or another Wholly-Owned Subsidiary of such Person.

1.2 Interpretation.

(a) In the case of this Agreement and each other Loan Document, (i) the meanings of defined terms are equally applicable to the singular and plural forms of the defined terms; (ii) Annex, Exhibit, Schedule and Section references are to such Loan Document unless otherwise specified; (iii) the term "including" is not limiting and means "including but not limited to;" (iv) in the computation of periods of time from a specified date to a later specified date, the word "from" means "from and including;" the words "to" and "until" each mean "to but excluding," and the word "through" means "to and including;" (v) unless otherwise expressly provided in such Loan Document, (A) references to agreements and other contractual instruments shall be deemed to include all subsequent amendments, restatements and other modifications thereto, but only to the extent such amendments, restatements and other modifications are not prohibited by the terms of any Loan Document, and (B) references to any statute or regulation shall be construed as including all statutory and regulatory provisions amending, replacing, supplementing or interpreting such statute or regulation; (vi) this Agreement and the other Loan Documents may use several different limitations, tests or measurements to regulate the same or similar matters, all of which are cumulative and each shall be performed in accordance with its terms and (vii) this Agreement and the other Loan Documents are the result of negotiations among and have been reviewed by counsel to Agent, Borrower, Lenders and the other parties hereto and thereto and are the products of all parties; accordingly, they shall not be construed against Borrower, Agent or Lenders merely because of Borrower's, Agent's or Lenders' involvement in their preparation. Except where otherwise expressly provided in the Loan Documents, in any instance where the approval, consent or the exercise of Agent's judgment is required, the granting or denial of such approval or consent and the exercise of such judgment shall be (*x*) within the reasonable discretion of Agent and/or Lenders; and (*y*) deemed to have been given only by a specific writing intended for such purpose executed by Agent.

(b) For purposes of converting any amount reported or otherwise denominated in any currency other than Dollars to Dollars under or in connection with the Loan Documents, Agent shall calculate such currency conversion via the applicable exchange rate identified and normally published by Bloomberg Professional Service as the applicable exchange rate as of the close of currency trading on each trading date during the applicable period of measurement, or, if such currency conversion deals exclusively with a particular date of determination, as of the close of currency trading on such date of determination (or the following trading date to the extent no currency trading took place on such date of determination). If Bloomberg Professional Service no longer reports such currency exchange rate, Agent shall select another nationally-recognized currency exchange rate reporting service selected by Agent in good faith.

Section 2 Credit Facility.

2.1 Term Loan Commitments. On and subject to the terms and conditions of this Agreement, each Lender, severally and for itself alone, agrees to make a multi-draw term loan to Borrower (each such loan, individually and collectively, a "Term Loan") in an amount equal to such Lender's applicable Pro Rata Term Loan Share of the Term Loan Commitment. The Commitments of Lenders to make any portion of the Term Loan shall terminate concurrently with the making of such portion of the Term Loan, such portion terminated to equal (i) on the Closing Date, the amount of the initial Term Loan advance set forth in Section 2.2.1, (ii) if the EM-100 Term Loan is made, on the date of the making of the EM-100 Term Loan, the amount of the EM-100 Term Loan, (iii) if the Subsequent Term Loan is made, on the date of the making of the Subsequent Term Loan, the amount of the Subsequent Term Loan, and (iv) on the one year anniversary of the Closing Date, all remaining, unused Term Loan Commitments. The Loan is not a revolving credit facility, and therefore any amount thereof that is repaid or prepaid by Borrower, in whole or in part, may not be re-borrowed.

2.2 Loan Procedures.

2.2.1 Initial Advance.

On the Closing Date, each Lender shall advance to Borrower an amount equal to its Pro Rata Term Loan Share of Five Million and No/100 Dollars ($5,000,000), upon Borrower's satisfaction of the conditions to closing described in Section 4 of this Agreement.

2.2.2 EM-100 Term Loan.

So long as no Material Adverse Effect, Default or Event of Default has occurred and is continuing or would be caused thereby and each of the EM-100 Term Loan Conditions have been satisfied, upon Agent's receipt of a written request from Borrower for a subsequent advance of the Term Loan, each Lender shall make one (1) additional advance (within five (5) Business Days of receipt by Agent of such written request for advance) to Borrower in the amount equal to such lender's Pro Rata Term Loan Share of Two Million and No/100 Dollars ($2,000,000).

2.2.3 Subsequent Term Loan.

So long as no Material Adverse Effect, Default or Event of Default has occurred and is continuing or would be caused thereby and each of the Subsequent Term Loan Conditions have been satisfied, upon Agent's receipt of a written request from Borrower for a subsequent advance of the Term Loan, each Lender shall make one (1) additional advance (within five (5) Business Days of receipt by Agent of such written request for advance) to Borrower in the amount equal to such lender's Pro Rata Term Loan Share of (a) if the EM-100 Term Loan has been made, Three Million and No/100 Dollars ($3,000,000), and (b) if the EM-100 Term Loan has not been made, Five Million and No/100 Dollars ($5,000,000).

2.3 Commitments Several.

The failure of any Lender to make the initial Term Loan on the Closing Date, the EM-100 Term Loan in accordance with Section 2.2.2, or the Subsequent Term Loan in accordance with Section 2.2.3, shall not relieve any other Lender of its obligation (if any) to make its Loan on the applicable date, but no Lender shall be responsible for the failure of any other Lender to make any Term Loan to be made by such other Lender; provided, however, that this Section 2.3 shall not relieve any Lender from liability for a the failure of such Lender to make a Loan required to be made by such Lender.

2.4 Indebtedness Absolute; No Offset; Waiver.

The payment obligations of Borrower hereunder are absolute and unconditional, without any right of rescission, set-off, counterclaim or defense for any reason against Agent and Lenders. As of the Closing Date, the Loan has not been compromised, adjusted, extended, satisfied, rescinded, set-off or modified, and the Loan Documents are not subject to any litigation, dispute, refund, claims of rescission, set-off, netting, counterclaim or defense whatsoever, including but not limited to, claims by or against any Loan Party or any other Person. Payment of the Obligations by Borrower, shall be made only by ACH or wire transfer, in Dollars, and in immediately available funds when due and payable pursuant to the terms of this Agreement and the other Loan Documents, is not subject to compromise, adjustment, extension, satisfaction, rescission, set-off, counterclaim, defense, abatement, suspension, deferment, deductible, reduction, termination or modification, whether arising out of transactions concerning the Loan, or otherwise. Without limitation to the foregoing, to the fullest extent permitted under applicable law and notwithstanding any other term or provision contained in this Agreement or any other Loan Document, Borrower hereby waives (and shall cause each Loan Party to waive) (a) presentment, protest and demand, notice of default (except as expressly required in the Loan Documents), notice of intent to accelerate, notice of acceleration, notice of protest, notice of demand and of dishonor and non-payment of the Obligations, (b) any requirement of diligence or promptness on Agent's part in the enforcement of its rights under the provisions of this Agreement and any other Loan Document, (c) any rights, legal or equitable, to require any marshalling of assets or to require foreclosure sales in a particular order, (d) all notices of every kind and description which may be required to be given by any statute or rule of law except as specifically required hereunder, (e) the benefit of all laws now existing or that may hereafter be enacted providing for any appraisement before sale or any portion of the Collateral, (f) all rights of homestead, exemption, redemption, valuation, appraisement, stay of execution, notice of election to mature or declare due the whole of the Obligations in the event of foreclosure of the Liens created by the Loan Documents, (g) [reserved], and (h) any defense to the obligation to make any payments required under the Loan Documents, including the obligation to pay taxes based on any damage to, defects in or destruction of the Collateral or any other event, including obsolescence of any of the Collateral, it being agreed and acknowledged that such payment obligations are unconditional and irrevocable. Borrower further acknowledges and agrees (i) to any substitution, subordination, exchange or release of any security or the release of any party primarily or secondarily liable for the payment of the Loan; (ii) that Agent shall not be required to first institute suit or exhaust its remedies hereon against others liable for repayment of all or any part of the Loan, whether primarily or secondarily (collectively, the "Obligors"), or to perfect or enforce its rights against any Obligor or any security for the Loan; and (iii) that its liability for payment of the Loan shall not be affected or impaired by any determination that any security interest or lien taken by Agent for the benefit of Agent and Lenders to secure the Loan is invalid or unperfected. Borrower acknowledges, warrants and represents in connection with each waiver of any right or remedy of Borrower contained in any Loan Document, that it has been fully informed with respect to, and represented by counsel of its choice in connection with, such rights and remedies, and all such waivers, and after such advice and consultation, has presently and actually intended, with full knowledge of its rights and remedies otherwise available at law or in equity, to waive or relinquish such rights and remedies to the full extent specified in each such waiver.

2.5 Loan Accounting.

2.5.1 Recordkeeping.

Agent, on behalf of each Lender, shall record in its records the date and amount of the Loan made by each Lender, each prepayment and repayment thereof. The aggregate unpaid principal amount so recorded shall be final, binding and conclusive absent manifest error. The failure to so record any such amount or any error in so recording any such amount shall not, however, limit or otherwise affect

the Obligations of Borrower hereunder or under any Note to repay the principal amount of the Loans hereunder, together with all interest accruing thereon.

2.5.2 Notes.

At the request of any Lender, the Loan of such Lender shall be evidenced by a Note, with appropriate insertions, payable to such Lender in a face principal amount equal to such Lender's Pro Rata Term Loan Share and payable in such amounts and on such dates as are set forth herein.

2.6 Payment of Interest.

2.6.1 Interest Rates.

(a) The outstanding principal balance under the Loan shall bear interest at a per annum rate of interest equal to the Contract Rate (as may be adjusted from time to time in accordance with this Section 2.6.1). Whenever, subsequent to the date hereof, the LIBOR Rate is increased or decreased (as determined on the date that is two (2) Business Days prior to each Payment Date), the Contract Rate, as set forth herein, shall be similarly changed effective as of such subsequent Payment Date, without notice or demand of any kind by an amount equal to the amount of such change in the LIBOR Rate on the date that is two (2) Business Days prior to each such Payment Date. The interest due on the principal balance of the Loan outstanding as of any Payment Date shall be computed for the actual number of days elapsed during the period in question on the basis of a year consisting of three hundred sixty (360) days and shall be calculated by determining the daily principal balance outstanding for each day of such period in question. The daily rate shall be equal to 1/360th times the Contract Rate. If any statement furnished by Agent for the amount of a payment due exceeded the actual amount that should have been paid because the LIBOR Rate decreased and such decrease was not reflected in such statement, Borrower shall make the payment specified in such statement from Agent and Borrower shall receive a credit for the overpayment, which credit shall be applied towards the next subsequent payment due hereunder. If any statement furnished by Agent for the amount of a payment due was less than the actual amount that should have been paid because the LIBOR Rate increased and such increase was not reflected in such statement, Borrower shall make the payment specified in such statement from Agent and Borrower shall be required to pay any resulting underpayment with the next subsequent payment due hereunder.

(b) Borrower recognizes and acknowledges that any default on any payment, or portion thereof, due hereunder or to be made under any of the other Loan Documents, will result in losses and additional expenses to Agent in servicing the Loan, and in losses due to Lenders' loss of the use of funds not timely received. Borrower further acknowledges and agrees that in the event of any such Default, Lenders would be entitled to damages for the detriment proximately caused thereby, but that it would be extremely difficult and impracticable to ascertain the extent of or compute such damages. Therefore, upon the Term Loan Maturity Date and/or upon the occurrence and during the existence of an Event of Default (or upon any acceleration), interest shall automatically accrue hereunder, without notice to Borrower, at the Default Rate. The Default Rate shall be calculated and due from the date that the Default occurred which led to the Event of Default without regard to any grace or cure period as may be applicable and shall be payable upon demand.

(c) Notwithstanding anything herein to the contrary, if at any time the interest rate for any Loan (if applicable), together with all fees, charges and other amounts that are treated as interest on such Loan under applicable law (collectively, "charges"), shall exceed the maximum lawful rate (the "Maximum Rate") that may be contracted for, charged, taken, received or reserved by the Lender holding such Loan in accordance with applicable law, the rate of interest payable in respect of such Loan hereunder (if applicable), together with all charges payable in respect of the Loan, shall be limited to the Maximum

Rate. To the extent lawful, the interest and charges that would have been paid in respect of such Loan but were not paid as a result of the operation of this Section shall be cumulated and the interest (if any) and charges payable to such Lender in respect of other Loans or periods shall be increased (but not above the amount collectible at the Maximum Rate therefor) until such cumulated amount, together with interest thereon at the Federal Funds Effective Rate for each day to the date of repayment, shall have been received by such Lender. Any amount collected by such Lender that exceeds the maximum amount collectible at the Maximum Rate shall be applied to the reduction of the principal balance of such Loan or refunded to the Borrower so that at no time shall the interest (if any) and charges paid or payable in respect of such Loan exceed the maximum amount collectible at the Maximum Rate.

2.6.2 Payments of Interest and Principal.

Borrower shall pay to Lenders all accrued interest on the Loan in arrears on each Payment Date, upon a prepayment of such Loan in accordance with Section 2.8 and at maturity in cash. Any partial prepayment of the Loan shall be applied in inverse order of maturity and so shall not reduce the amount of any quarterly principal amortization payment required pursuant to Section 2.9.1 (but this shall not be construed as permitting any partial prepayment other than as may be expressly permitted elsewhere in this Agreement).

2.7 Fees.

(a) Origination Fee. Borrower shall pay to Agent, for its own account, a fee (the "Origination Fee") in the amount of $100,000, which Origination Fee shall be deemed fully earned and non-refundable on the Closing Date.

(b) Commitment Fee. Borrower shall pay to Agent, a commitment fee (the "Commitment Fee") for the benefit of Lenders, in an amount equal to (*x*) two percent (2.0%) per annum multiplied by (*y*) the average unfunded amount of the Subsequent Term Loan (as such amount may be decreased pursuant to the funding of the EM-100 Term Loan) during each Fiscal Quarter, which Commitment Fee shall be deemed fully earned and non-refundable once paid in accordance with this Section 2.7(b). The Commitment Fee shall accrue quarterly and be calculated based on a year consisting of three hundred sixty (360) days in accordance with the calculation of the interest rate pursuant to Section 2.6.1. Borrower shall pay all accrued and unpaid Commitment Fees, in cash, in arrears, on the Payment Date next following the end of each Fiscal Quarter; provided the Commitment Fee shall terminate (but all accrued and unpaid Commitment Fees shall remain due and payable) upon the earlier to occur of (i) the funding of the Subsequent Term Loan, and (ii) the one year anniversary of the Closing Date.

(c) Exit Fee. Upon the Termination Date, Borrower shall pay an exit fee (the "Exit Fee") to Agent, for the benefit of Lenders, in an amount equal to (*x*) five percent (5.0%) multiplied by (*y*) the aggregate principal amount of all Term Loans advanced hereunder, which Exit Fee shall be deemed fully earned and non-refundable on the Termination Date.

2.8 Prepayment.

2.8.1 Mandatory Prepayment.

(a) Borrower shall prepay the Obligations within three (3) Business Days after the receipt by a Loan Party of any Net Cash Proceeds from any Disposition, in an amount equal to such Net Cash Proceeds.

(b) In connection with any prepayment of the Term Loan made pursuant to this Section 2.8.1, Borrower shall pay to Agent, for the benefit of Lenders, the following amounts (in addition to any such prepayment of the Term Loan and related Obligations) on the date of such prepayment: (i) as it relates to any such prepayment made on or after the first anniversary of the Closing Date, any amounts that would otherwise be due and payable on such date had Borrower voluntarily prepaid the Obligations pursuant to Section 2.8.2; or (ii) as it relates to any such prepayment made on or before the first anniversary of the Closing Date, a prepayment fee equal to five percent (5%) of the aggregate amount of the Term Loan so prepaid.

2.8.2 Voluntary Prepayment.

(a) Subject to clause (b) below and Section 2.8.3 hereof, Borrower may, from time to time, on at least five (5) Business Days' written notice or telephonic notice (followed on the same Business Day by written confirmation thereof) to Agent (which shall promptly advise each Lender thereof) not later than 12:00 noon Dallas time on such day, prepay the Term Loan and all related Obligations in whole or in part at any time on or after the first anniversary of the Closing Date; provided, that, any such partial prepayment of the Obligations shall be in an amount equal to at least $1,000,000 or, if the Net Cash Proceeds of such Disposition is less than $1,000,000, the amount of such Net Cash Proceeds. Such notice to Agent shall specify the amount and proposed date of such prepayment, and the application of such amounts to be prepaid shall be applied in accordance with Section 2.9.1(b) or 2.10.2 (as applicable).

(b) If Borrower makes a prepayment of the Term Loan under Section 2.8.2(a), it shall pay to Agent, for the benefit of Lenders, the following amounts (in addition to any such prepayment of the Term Loan and related Obligations) on the date of such prepayment: (i) if such prepayment is made on or after the first anniversary of the Closing Date but prior to the second anniversary of the Closing Date, five percent (5%) of the aggregate amount of the Term Loan so prepaid; (ii) if such prepayment is made on or after the second anniversary of the Closing Date but prior to the third anniversary of the Closing Date, one percent (1%) of the aggregate amount of the Term Loan so prepaid; and (iii) if such prepayment is made on or after the third anniversary of the Closing Date, zero percent (0%) of the aggregate amount of the Term Loan so prepaid.

(c) For the avoidance of doubt, a permitted payment under this Section 2.8.2 is independent of and in addition to Revenue-Based Payments that are credited toward the principal of the Loans under Section 2.9.1(b). Notwithstanding anything set forth herein or in any other Loan Documents to the contrary, any prepayment of the Loans other than via the application of Revenue-Based Payments made pursuant to Section 2.9.1 or Section 2.10.2, as applicable, or prepayments in accordance with Section 2.8.1 or Section 2.8.3 shall be limited and governed by this Section 2.8.2. Notwithstanding anything in this Section 2.8 to the contrary, after the occurrence and during the continuation of a material default hereunder by a Lender or Agent, Borrower may prepay all or any part of the Loans without the payment of any such prepayment penalty or premium described in this Section 2.8.

2.9 Repayment of Term Loan.

2.9.1 Revenue-Based Payment.

(a) During the period commencing on the date hereof until the Obligations are Paid in Full, Borrower promises to pay to Agent, for the account of each Lender according to its Pro Rata Term Loan Share, an amount based on a percentage of the aggregate of the Net Sales, Royalties and any other income or revenue realized by Borrower and/or its Subsidiaries, on a consolidated basis, in accordance with GAAP (collectively, the "Aggregate Revenue") in each Fiscal Quarter (the "Revenue-Based Payment"), which will be applied to the Obligations as provided in clause (b) below. The Revenue-Based

Payment with respect to each Fiscal Quarter shall be payable on the Payment Date next following the end of such Fiscal Quarter. Commencing with the Fiscal Quarter beginning January 1, 2019, the Revenue-Based Payment with respect to each Fiscal Quarter shall be equal to:

(i) the aggregate Revenue-Based Payments payable during the period commencing as of January 1 of the Fiscal Year of which such Fiscal Quarter is part, through the end of such Fiscal Quarter (such elapsed portion of the Fiscal Year, the "Elapsed Period"), calculated as the net sum of:

(A) One hundred percent (100.00%) of Aggregate Revenue during the Elapsed Period up to and including $10,000,000; plus

(B) Fifty percent (50.00%) of Aggregate Revenue during the Elapsed Period greater than $10,000,000; minus

(ii) the aggregate amount of Revenue-Based Payments, if any, made pursuant to clauses (i) through (iv) of Section 2.9.1(b), with respect to prior Fiscal Quarters in such Fiscal Year; *provided* that the Revenue-Based Payment is payable solely upon Aggregate Revenue in a given Fiscal Year, and will not be calculated on a cumulative, year-over-year basis.

For the avoidance of any doubt, Borrower may calculate the net amount due under this Section 2.9.1(a) and pay to Agent only such net amount due. Borrower is not obligated to pay the entire amounts specified in Sections 2.9.1(a)(i)(A) and (B) to Agent and then have Agent return to Borrower the balance after subtracting the amounts specified in Section 2.9.1(a)(ii).

(b) So long as no Event of Default has occurred and is continuing and until the Obligations have been Paid in Full, each Revenue-Based Payment on each Payment Date will be applied in the following priority:

(i) FIRST, to the payment of all fees, costs, expenses and indemnities due and owing to Agent pursuant to Sections 2.7, 3.1, 3.2, 6.3(d), 10.4 and/or 10.5 under this Agreement or otherwise pursuant to the Collateral Documents, and any other Obligations owing to Agent in respect of sums advanced by Agent to preserve or protect the Collateral or to preserve or protect its security interest in the Collateral;

(ii) SECOND, to the payment of all fees, costs, expenses and indemnities due and owing to Lenders in respect of the Loans and Commitments pursuant to Sections 2.7, 3.1, 3.2, 6.3(d), 10.4 and/or 10.5 under this Agreement or otherwise pursuant to the Collateral Documents, pro rata based on each Lender's Pro Rata Term Loan Share, until Paid in Full;

(iii) THIRD, to the payment of all accrued but unpaid interest in respect of the Loans as of such Payment Date, pro rata based on each Lender's Pro Rata Term Loan Share, until Paid in Full;

(iv) FOURTH,

(1) to the extent that the Interest Only Extension Condition is not satisfied, as it relates to each Payment Date on or after the Payment Date occurring in February 2021, to the payment of all principal of the Loans, pro rata based on each Lender's Pro Rata Term Loan Share, up to an aggregate amount on any Payment Date equal to four

percent (4%) of the aggregate principal amount of Term Loans that have been funded as of such Payment Date; or

(2) to the extent that the Interest Only Extension Condition is satisfied, as it relates to each Payment Date on or after the Payment Date occurring in February 2022, to the payment of all principal of the Loans, pro rata based on each Lender's Pro Rata Term Loan Share, up to an aggregate amount on any Payment Date equal to five and one-half of one percent (5.5%) of the aggregate principal amount of Term Loans that have been funded as of such Payment Date; and

(v) FIFTH, all remaining amounts to the Borrower.

In the event that the amounts distributed under this clause (b) on any Payment Date are insufficient for payment of the amounts set forth in clauses (i) through (iii) above for such Payment Date, Borrower shall pay an amount equal to the extent of such insufficiency, in immediately available funds, within five (5) Business Days of request by Agent.

(c) In the event that Borrower makes any adjustment to Aggregate Revenue after it has been reported to Agent, and such adjustment results in an adjustment to the Revenue-Based Payment due to the Lenders pursuant to this Section 2.9.1, Borrower shall so notify Agent and such adjustment shall be captured, reported and reconciled with the next scheduled report and payment of Revenue-Based Payment hereunder. Notwithstanding the foregoing, Agent and Borrower shall discuss and agree on the amount of any such adjustment prior to it being given effect with respect to future Revenue-Based Payments.

2.9.2 Principal.

Notwithstanding the foregoing, the outstanding principal balance of the Term Loan and all other Obligations then due and owing (including any amounts due pursuant to Section 2.8.2 hereof that may be due and owing on such date) shall be Paid in Full on the Termination Date.

2.10 Payment.

2.10.1 Making of Payments.

Except as set forth in the last sentence of this Section 2.10.1, all payments of principal, interest, fees and other amounts, shall be made in immediately-available funds, via ACH or wire transfer as directed by Agent in writing, not later than 1:00 p.m. Dallas time on the date due, and funds received after that hour shall be deemed to have been received by Agent on the following Business Day. Not later than two (2) Business Days prior to each Payment Date, Agent shall provide to Borrower and each Lender a quarterly statement with the amounts payable by Borrower to Agent on such Payment Date in accordance with Section 2.9.1(b) hereof, which shall include, for additional clarity, Agent's calculation of the Revenue-Based Payment for the prior Fiscal Quarter, which statement shall be binding on Borrower absent manifest error, and Borrower shall be entitled to rely on such quarterly statement in relation to its payment obligations on such Payment Date.

2.10.2 Application of Payments and Proceeds Following an Event of Default.

Following the occurrence and during the continuance of an Event of Default, or if the Obligations have otherwise become or have been declared to become immediately due and payable in accordance with this Agreement, then notwithstanding anything herein or in any other Loan Document to

the contrary, Agent shall apply all or any part of payments in respect of the Obligations and proceeds of Collateral, in each case as received by Agent, to the payment of the Obligations in the order and priority as determined by Agent in its sole discretion.

2.10.3 Set-off.

Borrower agrees that Agent and each Lender and its Affiliates have all rights of set-off and bankers' lien provided by applicable law, and in addition thereto, Borrower agrees that at any time an Event of Default exists, Agent and each Lender may, to the fullest extent permitted by applicable law, apply to the payment of any Obligations of Borrower hereunder then due, any and all balances, credits, deposits, accounts or moneys of Borrower then or thereafter with Agent or such Lender. Notwithstanding the foregoing, no Lender shall exercise any rights described in the preceding sentence without the prior written consent of Agent.

2.10.4 Proration of Payments.

If any Lender shall obtain any payment or other recovery (whether voluntary, involuntary, by application of set-off or otherwise, on account of principal of, interest on or fees in relation to any Loan, but excluding any payment pursuant to Section 3.1, 3.2, 10.5 or 10.8) in excess of its applicable Pro Rata Term Loan Share of payments and other recoveries obtained by all Lenders on account of principal of, interest on or fees in relation to such Term Loan then held by them, then such Lender shall purchase from the other Lenders such participations in the Loans held by them as shall be necessary to cause such purchasing Lender to share the excess payment or other recovery ratably with each of them; *provided* that if all or any portion of the excess payment or other recovery is thereafter recovered from such purchasing Lender, the purchase shall be rescinded and the purchase price restored to the extent of such recovery.

Section 3 Yield Protection.

3.1 Taxes.

(a) All payments of principal and interest on the Loans and all other amounts payable hereunder by or on behalf of Borrower to or for the account of Agent or any Lender shall be made free and clear of and without deduction for any present or future income, excise, stamp, documentary, property or franchise taxes and other taxes, fees, duties, levies, withholdings or other similar charges imposed by any Governmental Authority that is a taxing authority ("Taxes"), excluding (i) taxes imposed on or measured by Agent's or any Lender's net income (however denominated) or gross profits, and franchise taxes, imposed by any jurisdiction (or subdivision thereof) under the laws of which Agent or such Lender is organized or in which Agent or such Lender conducts business or, in the case of any Lender, in which its applicable lending office is located, (ii) any branch profit taxes imposed by the United States of America or any similar tax imposed by any other jurisdiction in which Agent or a Lender is located or conducts business; (iii) in the case of any Foreign Lender, any withholding tax that is imposed on amounts payable to such Foreign Lender at the time such Foreign Lender becomes a party to this Agreement or designates a new lending office; (iv) in the case of any U.S. Lender, any United States federal backup withholding tax; and (v) taxes imposed under FATCA (items in clauses (i) through (v), "Excluded Taxes," and all Taxes other than Excluded Taxes, "Indemnified Taxes"). If any withholding or deduction from any payment to be made by Borrower hereunder is required in respect of any Taxes pursuant to any applicable law, rule or regulation, then Borrower shall: (*w*) make such withholding or deduction; (*x*) pay directly to the relevant Governmental Authority the full amount required to be so withheld or deducted; (*y*) as promptly as practicable forward to Agent the original or a certified copy of an official receipt or other documentation reasonably satisfactory to Agent evidencing such payment to such Governmental Authority; and (*z*) if the withholding or deduction is with respect to Indemnified Taxes, pay to Agent for the account of Lenders

such additional amount or amounts as is necessary to ensure that the net amount actually received by each Lender will equal the full amount such Lender would have received had no such withholding or deduction of Indemnified Taxes been required. To the extent that any amounts shall ever be paid by Borrower in respect of Indemnified Taxes, such amounts shall, for greater certainty, be considered to have accrued and to have been paid by Borrower as interest on the Loans.

(b) Borrower shall indemnify Agent and each Lender for any Indemnified Taxes paid by Agent or such Lender, as applicable, on or with respect to any payment by or on account of any obligation of Borrower hereunder, and any additions to Tax, penalties and interest paid by Agent or such Lender with respect to such Indemnified Taxes; *provided* that Borrower shall not have any obligation to indemnify any party hereunder for any Indemnified Taxes or additions to Tax, penalties or interest with respect thereto that result from or are attributable to such party's own gross negligence or willful misconduct. Payment under this Section 3.1(b) shall be made within thirty (30) days after the date Agent or the Lender, as applicable, makes written demand therefor; *provided*, *however*, that if such written demand is made more than one-hundred eighty (180) days after the earlier of (i) the date on which Agent or the Lender, as applicable, pays such Indemnified Taxes or additions to Tax, penalties or interest with respect thereto and (ii) the date on which the applicable Governmental Authority makes written demand on Agent or such Lender, as applicable, for payment of such Indemnified Taxes or additions to Tax, penalties or interest with respect thereto, then Borrower shall not be obligated to indemnify Agent or such Lender for such Indemnified Taxes or additions to Tax, penalties or interest with respect thereto.

(c) Each Foreign Lender that is a party hereto on the Closing Date or becomes an assignee of an interest under this Agreement under Section 10.8.1 after the Closing Date (unless such Lender was already a Lender hereunder immediately prior to such assignment) shall deliver to Borrower and Agent on or prior to the date on which such Foreign Lender becomes a party to this Agreement:

(i) Two duly completed and executed originals of IRS Form W-8BEN (or IRS Form W-8BENE) claiming exemption from withholding of Taxes under an income tax treaty to which the United States of America is a party;

(ii) two duly completed and executed originals of IRS Form W-8ECI;

(iii) a certificate in form and substance reasonably satisfactory to Agent and Borrower claiming entitlement to the portfolio interest exemption under Section 881(c) of the IRC and certifying that such Foreign Lender is not (*x*) a "bank" within the meaning of Section 881(c)(3)(A) of the IRC, (*y*) a "10 percent shareholder" of Borrower within the meaning of Section 881(c)(3)(B) of the IRC, or (*z*) a "controlled foreign corporation" described in Section 881(c)(3)(C) of the IRC, together with two duly completed and executed originals of IRS Form W-8BEN (or IRS Form W-8BENE); or

(iv) if the Foreign Lender is not the beneficial owner of amounts paid to it hereunder, two duly completed and executed originals of IRS Form W-8IMY, each accompanied by a duly completed and executed IRS Form W-8ECI, IRS Form W-8BEN (or IRS Form W-8BENE), IRS Form W-9 or a portfolio interest certificate described in clause (iii) above from each beneficial owner of such amounts claiming entitlement to exemption from withholding or backup withholding of Taxes.

Each Foreign Lender shall (to the extent legally entitled to do so) provide updated forms to Borrower and Agent on or prior to the date any prior form previously provided under this clause (c) becomes obsolete or expires, after the occurrence of an event requiring a change in the most recent form or certification previously delivered by it pursuant to this clause (c) or from time to time if requested by Borrower or Agent.

Each U.S. Lender shall deliver to Agent and Borrower on or prior to the date on which such Lender becomes a party to this Agreement (and from time to time thereafter upon the request of Borrower or Agent) properly completed and executed originals of IRS Form W-9 certifying that such Lender is exempt from backup withholding. Notwithstanding anything to the contrary contained in this Agreement, Borrower shall not be required to pay additional amounts to or indemnify any Lender pursuant to this Section 3.1 with respect to any Taxes required to be deducted or withheld (or any additions to Tax, penalties or interest with respect thereto) (A) on the basis of the information, certificates or statements of exemption provided by a Lender pursuant to this clause (c), or (B) if such Lender shall fail to comply with the certification requirements of this clause (c).

(d) Without limiting the foregoing, each Lender shall timely comply with any certification, documentation, information or other reporting necessary to establish an exemption from withholding under FATCA and shall provide any documentation reasonably requested by Borrower or Agent sufficient for Borrower and Agent to comply with their obligations under FATCA and to determine that such Lender has complied with such applicable reporting requirements.

(e) If Agent or a Lender determines that it is entitled to or has received a refund of any Taxes for which it has been indemnified by Borrower (or another Loan Party) or with respect to which Borrower (or another Loan Party) shall have paid additional amounts pursuant to this Section 3.1, it shall promptly notify Borrower of such refund, and promptly make an appropriate claim to the relevant Governmental Authority for such refund (if it has not previously done so). If Agent or a Lender receives a refund (whether or not pursuant to such claim) of such Taxes, it shall promptly pay over such refund to Borrower (but only to the extent of indemnity payments made, or additional amounts paid, by Loan Parties under this Section 3.1 with respect to the Taxes giving rise to such refund), net of all out-of-pocket expenses of the Agent or such Lender and without interest (other than any interest paid by the relevant Governmental Authority with respect to such refund); *provided* that Borrower, upon the request of Agent or such Lender, agrees to repay to Agent or such Lender the amount paid over to Borrower in the event Agent or such Lender is required to repay such refund to such Governmental Authority. This Section 3.1(e) shall not be construed to require Agent or any Lender to make available its Tax returns (or any other information relating to its Taxes which it deems confidential) to Borrower or any other Person or to alter its internal practices or procedures with respect to the administration of Taxes.

3.2 Increased Cost.

(a) If, after the Closing Date, the adoption of, or any change in, any applicable law, rule or regulation, or any change in the interpretation or administration of any applicable law, rule or regulation by any Governmental Authority, central bank or comparable agency charged with the interpretation or administration thereof (*provided* that notwithstanding anything herein to the contrary, the Dodd-Frank Wall Street Reform and Consumer Protection Act and all requests, rules, guidelines or directives thereunder or issued in connection therewith shall be considered a change in applicable law, regardless of the date enacted, adopted or issued), or compliance by any Lender with any request or directive (whether or not having the force of law) issued after the Closing Date of any such authority, central bank or comparable agency: (i) shall impose, modify or deem applicable any reserve (including any reserve imposed by the FRB), special deposit or similar requirement against assets of, deposits with or for the account of, or credit extended by any Lender; or (ii) shall impose on any Lender any other condition affecting its ability to make loans based on the LIBOR Rate or its obligation to make loans based on the LIBOR Rate; and the result of anything described in clauses (i) and (ii) above is to increase the cost to (or to impose a cost on) such Lender of making or maintaining any loan based on the LIBOR Rate, or to reduce the amount of any sum received or receivable by such Lender under this Agreement or under its Note with respect thereto, then upon demand by such Lender (which demand shall be accompanied by a statement setting forth the basis for such demand and a calculation of the amount thereof in reasonable detail, a copy

of which shall be furnished to Agent), and without duplication of other payment obligations of Borrower hereunder (including pursuant to Section 3.1), Borrower shall pay directly to such Lender such additional amount as will compensate such Lender for such increased cost or such reduction, so long as such amounts have accrued on or after the day which is one-hundred eighty (180) days prior to the date on which such Lender first made demand therefor; *provided* that if the event giving rise to such costs or reductions has retroactive effect, such one-hundred eighty (180) day period shall be extended to include the period of retroactive effect. For the avoidance of doubt, this clause (a) will not apply to any such increased costs or reductions resulting from Taxes, as to which Section 3.1 shall govern.

(b) If any Lender shall reasonably determine that any change after the Closing Date in, or the adoption or phase-in after the Closing Date of, any applicable law, rule or regulation regarding capital adequacy, or any change after the Closing Date in the interpretation or administration thereof by any Governmental Authority, central bank or comparable agency charged with the interpretation or administration thereof, or the compliance by any Lender or any Person controlling such Lender with any request or directive issued after the Closing Date regarding capital adequacy (whether or not having the force of law) of any such authority, central bank or comparable agency (*provided* that notwithstanding anything herein to the contrary, the Dodd-Frank Wall Street Reform and Consumer Protection Act and all requests, rules, guidelines or directives thereunder or issued in connection therewith shall be considered a change in applicable law, regardless of the date enacted, adopted or issued), has or would have the effect of reducing the rate of return on such Lender's or such controlling Person's capital as a consequence of such Lender's obligations hereunder to a level below that which such Lender or such controlling Person could have achieved but for such change, adoption, phase-in or compliance (taking into consideration such Lender's or such controlling Person's policies with respect to capital adequacy) by an amount deemed by such Lender or such controlling Person to be material, then from time to time, within five (5) Business Days of demand by such Lender (which demand shall be accompanied by a statement setting forth the basis for such demand and a calculation of the amount thereof in reasonable detail, a copy of which shall be furnished to Agent), Borrower shall pay to such Lender such additional amount as will compensate such Lender or such controlling Person for such reduction, so long as such amounts have accrued on or after the day which is one-hundred eighty (180) days prior to the date on which such Lender first made demand therefor; *provided* that if the event giving rise to such costs or reductions has retroactive effect, such one-hundred eighty (180) day period shall be extended to include the period of retroactive effect.

(c) Each Lender agrees that, as promptly as practicable after the officer of such Lender responsible for administering its Loans, becomes aware of the occurrence of an event or the existence of a condition that would entitle such Lender to receive payments under this Section 3.2, it will, to the extent not inconsistent with the internal policies of such Lender and any applicable legal or regulatory restrictions, use reasonable efforts to (i) make, issue, fund or maintain its Loans through another office of such Lender, or (ii) take such other measures as such Lender may deem reasonable, if as a result thereof the additional amounts which would otherwise be required to be paid to such Lender pursuant to this Section 3.2 would be materially reduced and if, as determined by such Lender in its sole discretion, the making, issuing, funding or maintaining of such Loans through such other office or in accordance with such other measures, as the case may be, would not otherwise adversely affect such Loans or the interests of such Lender; *provided* that such Lender will not be obligated to utilize such other office pursuant to this clause (c) unless Borrower agrees to pay all incremental expenses incurred by such Lender as a result of utilizing such other office as described above. A certificate as to the amount of any such expenses payable by Borrower pursuant to this clause (c) (setting forth in reasonable detail the basis for requesting such amount) submitted by such Lender to Borrower (with a copy to Agent) shall be conclusive absent manifest error.

3.3 Funding Losses.

Borrower hereby agrees that upon demand by any Lender (which demand shall be accompanied by a statement setting forth the basis for the amount being claimed, a copy of which shall be furnished to Agent), Borrower will indemnify such Lender against any net loss or expense which such Lender has actually sustained or incurred (including any reasonable, documented net loss or expense incurred by reason of the liquidation or reemployment of deposits or other funds acquired by such Lender to fund or maintain the Term Loan subject to the LIBOR Rate, as reasonably determined by such Lender) as a result of (a) any payment or prepayment of the Term Loan of such Lender on a date other than the Term Loan Maturity Date or (b) any failure of Borrower to borrow any Loan on a date specified therefor in a notice of borrowing pursuant to this Agreement. For the purposes of this Section 3.3, all determinations shall be made as if such Lender had actually funded and maintained the Term Loan through the purchase of deposits having a maturity corresponding to the Loan and bearing an interest rate equal to the LIBOR Rate during such period of time being measured. Nothing in this Section 3.3 shall be interpreted to obligate the Loan Parties to indemnify any Lender for lost profits associated with any event described herein.

3.4 Manner of Funding; Alternate Funding Offices.

Notwithstanding any provision of this Agreement to the contrary, each Lender shall be entitled to fund and maintain its funding of all or any part of its Loans in any manner it may determine at its sole discretion. Each Lender may, if it so elects, fulfill its commitment to make the Term Loan by causing any branch or Affiliate of such Lender to make such Loan; *provided* that in such event for the purposes of this Agreement (other than Section 3.1) such Loan shall be deemed to have been made by such Lender and the obligation of Borrower to repay such Loan shall nevertheless be to such Lender and shall be deemed held by it, to the extent of such Loan, for the account of such branch or Affiliate.

3.5 Conclusiveness of Statements; Survival.

Determinations and statements of any Lender pursuant to Section 3.1, 3.2, 3.3 or 3.4 shall be conclusive absent demonstrable error. Lenders may use reasonable averaging and attribution methods in determining compensation under Sections 3.1 or 3.2, and the provisions of such Sections shall survive repayment of the Loans, cancellation of the Notes and termination of this Agreement.

Section 4 Conditions Precedent.

The obligation of each Lender to make its Loan hereunder is subject to the following conditions precedent, each of which shall be reasonably satisfactory in all respects to Agent.

4.1 Prior Debt.

The Prior Debt, if any, has been (or concurrently with the initial borrowing will be) paid in full and all related Liens, if any, have been (or concurrently with the initial borrowing will be) released.

4.2 Delivery of Loan Documents.

Borrower shall have delivered the following documents in form and substance acceptable to Agent in its sole discretion (and, as applicable, duly executed and dated the Closing Date or an earlier date satisfactory to Agent):

(a) Loan Documents. The Loan Documents to which any Loan Party is a party, each duly executed by a Responsible Officer of each Loan Party and the other parties thereto (except Agent and the Lenders), and each other Person (except Agent and the Lenders) shall have delivered to Agent and

Lenders the Loan Documents to which it is a party, each duly executed and delivered by such Person and the other parties thereto (except Agent and the Lenders).

(b) Financing Statements. Properly completed Uniform Commercial Code financing statements and other filings and documents required by law or the Loan Documents to provide Agent, for the benefit of Agent and Lenders, perfected first priority Liens in the Collateral.

(c) Lien Searches. Copies of Uniform Commercial Code, foreign, state and county search reports listing all effective financing statements filed and other Liens of record against any Loan Party, with copies of any financing statements and applicable searches of the records of the U.S. Patent and Trademark Office and the U.S. Copyright Office performed with respect to each Loan Party, all in each jurisdiction reasonably determined by Agent.

(d) Collateral Access Agreements. Fully executed (except by Agent and the Lenders) Collateral Access Agreements reasonably requested by Agent with respect to the Collateral.

(e) Payoff; Release. Payoff letters with respect to the repayment in full of all Prior Debt, termination of all agreements relating thereto and the release of all Liens granted in connection therewith, with Uniform Commercial Code or other appropriate termination statements and documents effective to evidence the foregoing or authorization to file the same.

(f) Authorization Documents. For each Loan Party, such Person's (i) charter (or similar formation document), certified by the appropriate Governmental Authority, (ii) good standing certificates in its jurisdiction of incorporation (or formation) and in each other jurisdiction reasonably requested by Agent, (iii) bylaws (or similar governing document), (iv) resolutions of its board of directors (or similar governing body) approving and authorizing such Person's execution, delivery and performance of the Loan Documents to which it is party and the transactions contemplated thereby, and (v) signature and incumbency certificates of its officers executing any of the Loan Documents, all certified by its secretary or an assistant secretary (or similar officer) as being in full force and effect without modification, in form and substance reasonably satisfactory to Agent.

(g) Closing Certificate. A certificate executed by a Responsible Officer of Borrower, which shall constitute a representation and warranty by Borrower as of the Closing Date that the conditions contained in this Section 4 have been satisfied.

(h) Opinions of Counsel. Opinions of counsel for each Loan Party in form and substance acceptable to Agent regarding certain closing matters, and Borrower hereby requests such counsel to deliver such opinions and authorizes Agent and Lenders to rely thereon.

(i) Insurance. (a) Certificates or other evidence of insurance in effect as required by Section 6.3(c) and (d), with endorsements naming Agent as lenders' loss payee and/or additional insured, as applicable, and (b) copies of the Keyman Life Insurance Policy, together with any additional documentation necessary to grant Agent a perfected assignment of such Keyman Life Insurance Policy as required by Section 6.3(e).

(j) Solvency Certificate. Agent shall have received a certificate of the chief financial officer (or, in the absence of a chief financial officer, the chief executive officer or manager) of Borrower, in his or her capacity as such and not in his or her individual capacity, in form and substance reasonably satisfactory to Agent, certifying (i) that Borrower is Solvent after giving effect to the transactions and the indebtedness contemplated by the Loan Documents, and (ii) as to Borrower's financial resources and anticipated ability to meet its obligations and liabilities as they become due, to the effect that as of the

Closing Date, and after giving effect to such transaction and indebtedness: (A) the assets of Borrower, individually and on a consolidated basis, at a Fair Valuation, exceed the total liabilities (including contingent, subordinated, unmatured and unliquidated liabilities) of Borrower, and (B) no unreasonably small capital base with which to engage in its anticipated business exists with respect to Borrower.

(k) Financials. The financial statements, projections and pro forma balance sheet described in Section 5.4.

(l) Account Control Agreements. The fully-executed Account Control Agreement in relation to each of the Deposit Accounts set forth on Schedule 7.14 hereto.

(m) Consents. Evidence that all necessary consents, permits and approvals (governmental or otherwise) required for the execution, delivery and performance by each Loan Party of the Loan Documents have been duly obtained and are in full force and effect.

(n) Other Documents. Such other certificates, documents and agreements as Agent or any Lender may reasonably request.

4.3 Fees. The Lenders and Agent shall have received all fees required to be paid, and all expenses for which invoices have been presented (including the Legal Costs), required to be paid under the Loan Documents on or before the Closing Date. All such amounts will be paid with proceeds of the initial advance of the Term Loan and any previous expense deposits made with Agent on or before the Closing Date and will be reflected in the funding instructions given by Borrower to Agent on or before the Closing Date.

4.4 Closing Date Warrant. Agent shall have received the fully executed Closing Date Warrant.

4.5 Representations, Warranties, Defaults. As of the Closing Date, after giving effect to the making of the Loans, (a) all representations and warranties of Borrower set forth in any Loan Document shall be true and correct in all material respects as if made on and as of the Closing Date (except for representations and warranties that specifically refer to an earlier date, which shall be true and correct in all material respects as of such earlier date) and (b) no Default or Event of Default shall exist. The acceptance of the Term Loan by Borrower shall be deemed to be a certification by Borrower that the conditions set forth in this Section 4.5 have been satisfied.

4.6 Diligence. Agent and Lenders shall have completed their due diligence review of the Loan Parties and their Subsidiaries, their assets, business, obligations and the transactions contemplated herein, the results of which shall be satisfactory in form and substance to Lenders, including, without limitation, (i) an examination of (A) Borrower's projected Aggregate Revenue for such periods as required by Lenders, (B) such valuations of Borrower and its assets as Lenders shall require (C) the terms and conditions of all obligations owed by Borrower deemed material by Lenders, the results of which shall be satisfactory in form and substance to Lenders and (D) background checks with respect to the managers, officers and owners of Borrower required by Agent; (ii) an examination of the Collateral, the financial statements and the books, records, business, obligations, financial condition and operational state of Borrower, and Borrower shall have demonstrated to Lender's reasonable satisfaction that (*x*) no operations of Borrower are the subject of any governmental investigation, evaluation or any remedial action which could result in any expenditure or liability deemed material by Lenders, and (*y*) Borrower has no liabilities or obligations (whether contingent or otherwise) that are deemed material by Lenders.

4.7 Corporate Matters. All corporate and other proceedings, documents, instruments and other legal matters in connection with the transactions contemplated by the Loan Documents (including, but not

limited to, those relating to corporate and capital structures of Borrower) shall be reasonably satisfactory to Agent.

4.8 No Felonies or Indictable Offenses. No Loan Party nor, to Borrower's knowledge, any of their respective Affiliates nor any of their officers or key management personnel shall have been charged with or be under active investigation for a felony crime or indictable offense.

4.9 No Material Adverse Effect. There shall not be any Debt or material obligations (other than those permitted pursuant to Section 7.1 hereof or as otherwise set forth in the Schedules to this Agreement) of any nature with respect to any Loan Party which could reasonably be likely to have a Material Adverse Effect.

Section 5 Representations and Warranties.

To induce Agent and Lenders to enter into this Agreement and to induce Lenders to make the Loan hereunder, Borrower represents and warrants to Agent and Lenders, as of the Closing Date, the date of the EM-100 Term Loan made by Lenders pursuant to Section 2.2.2, and the date of the Subsequent Term Loan made by Lenders pursuant to Section 2.2.3 that:

5.1 Organization.

Each Loan Party is validly existing and in good standing under the laws of its state or country of jurisdiction as set forth on Schedule 5.1, and is duly qualified to do business in each jurisdiction set forth on Schedule 5.1, which are all of the jurisdictions in which failure to so qualify could reasonably be likely to have or result in a Material Adverse Effect.

5.2 Authorization; No Conflict.

Each Loan Party is duly authorized to execute and deliver each Loan Document to which it is a party, to borrow or guaranty monies hereunder, as applicable, and to perform its Obligations under each Loan Document to which it is a party. The execution, delivery and performance by each Loan Party of this Agreement and the other Loan Documents to which it is a party, as applicable, and the transactions contemplated therein, do not and will not (a) require any consent or approval of any Governmental Authority (other than any consent or approval which has been obtained and is in full force and effect), (b) conflict with (i) any provision of applicable law (including any Health Care Law), (ii) the charter, by-laws or other organizational documents of such Loan Party or (iii) (except as it relates to the documents governing the Prior Debt, each of which will be terminated and/or paid on the Closing Date) any Material Contract, or any judgment, order or decree, which is binding upon any Loan Party or any of its properties or (c) require, or result in, the creation or imposition of any Lien on any asset of any Loan Party (other than Liens in favor of Agent created pursuant to the Collateral Documents).

5.3 Validity; Binding Nature.

Each of this Agreement and each other Loan Document to which any Loan Party is a party, as applicable, is the legal, valid and binding obligation of such Loan Party, enforceable against such Loan Party in accordance with its terms, subject to bankruptcy, insolvency and similar laws affecting the enforceability of creditors' rights generally and to general principles of equity and concepts of reasonableness.

5.4 Financial Condition.

(a) The audited consolidated financial statements of Borrower for the Fiscal Year 2018 and the unaudited consolidated financial statements of Borrower for the Fiscal Quarter ended June 30, 2019, copies of each of which have been delivered pursuant hereto, were prepared in accordance with GAAP and present fairly in all material respects the consolidated financial condition of Borrower as at such dates and the results of its operations for the periods then ended.

(b) The consolidated financial projections (including an operating budget and a cash flow budget) of Borrower and its Subsidiaries delivered to Agent and Lenders on or prior to the Closing Date (i) were prepared by Borrower in good faith and (ii) were prepared in accordance with assumptions for which Borrower believes it has a reasonable basis, and the accompanying consolidated and consolidating pro forma unaudited balance sheet of Borrower and its Subsidiaries as at the Closing Date, adjusted to give effect to the financings contemplated hereby as if such transactions had occurred on such date, is consistent in all material respects with such projections (it being understood that the projections are not a guaranty of future performance and that actual results during the period covered by the projections may materially differ from the projected results therein).

5.5 No Material Adverse Effect.

Since December 31, 2018, there has been no material adverse change in the financial condition, operations, assets, business or properties of Borrower taken as a whole.

5.6 Litigation.

No litigation (including derivative actions), arbitration proceeding or governmental investigation or proceeding, to Borrower's knowledge, is pending or threatened against any Loan Party that would reasonably be expected to have, either individually or in the aggregate, a Material Adverse Effect. As of the Closing Date, other than any liability incidental to such litigation or proceedings, no Loan Party has any material Contingent Obligations not listed on Schedule 7.1 or disclosed in the financial statements specified in Section 5.4(a).

5.7 Ownership of Properties; Liens.

Borrower and each other Loan Party owns, or leases or licenses, as applicable, all of its material properties and assets, tangible and intangible, of any nature whatsoever that it purports to own, or lease, as applicable (including Intellectual Property), free and clear of all Liens and charges and claims (including infringement claims with respect to Intellectual Property), except Permitted Liens and as set forth on Schedule 5.7.

5.8 Capitalization.

All issued and outstanding Equity Interests of Loan Parties are duly authorized, validly issued, fully paid, non-assessable, and such securities were issued in compliance in all material respects with all applicable state and federal laws concerning the issuance of securities. Schedule 5.8 sets forth the authorized Equity Interests of each Loan Party as of the Closing Date as well as all Persons owning more than ten percent (10%) of the outstanding Equity Interests in each such Loan Party as of the Closing Date.

5.9 Pension Plans.

No Loan Party has, nor to Borrower's knowledge has any Loan Party ever had, a Pension Plan.

5.10 Investment Company Act.

No Loan Party is an "investment company" or a company "controlled" by an "investment company" or a "subsidiary" of an "investment company," within the meaning of the Investment Company Act of 1940.

5.11 No Default.

No Event of Default or Default exists or would result from the incurrence by Borrower of any Debt hereunder or under any other Loan Document or as a result of any Loan Party entering into the Loan Documents to which it is a party.

5.12 Margin Stock.

No Loan Party is engaged principally, or as one of its important activities, in the business of extending credit for the purpose of purchasing or carrying Margin Stock. As of the Closing Date, no portion of the Obligations is secured directly or indirectly by Margin Stock.

5.13 Taxes.

Each Loan Party has filed, or caused to be filed, all federal, state, foreign and other tax returns and reports required by law to have been filed by it and has paid all federal, state, foreign and other taxes and governmental charges thereby shown to be owing, except any such taxes or charges (a) that are not delinquent or (b) that are being diligently contested in good faith by appropriate proceedings and for which adequate reserves in accordance with GAAP have been set aside on its books.

5.14 Solvency.

On the Closing Date, and immediately prior to and after giving effect to the borrowing hereunder and the use of the proceeds hereof, Borrower is, and will be, Solvent.

5.15 Environmental Matters.

The on-going operations of Loan Parties comply in all respects with all applicable Environmental Laws, except for non-compliance which could not (if enforced in accordance with applicable law) reasonably be expected to result in a Material Adverse Effect. Each Loan Party has obtained, and maintained in good standing, all licenses, permits, authorizations and registrations required under any Environmental Law and necessary for its respective ordinary course operations, and each Loan Party is in compliance with all material terms and conditions thereof, except where the failure to do so would not reasonably be expected to result in a Material Adverse Effect. Neither Borrower, any of its Subsidiaries nor any of their respective properties or operations is subject to any outstanding written order from or agreement with any federal, state, or local Governmental Authority, nor subject to any judicial or docketed administrative proceeding, respecting any Environmental Law, Environmental Claim or Hazardous Substance. There are no Hazardous Substances or other conditions or circumstances existing with respect to any property, or arising from operations prior to the Closing Date, of any Loan Party that would reasonably be expected to result in a Material Adverse Effect. No Loan Party has underground storage tanks.

5.16 Insurance.

Loan Parties and their respective properties are insured with financially sound and reputable insurance companies which are not Affiliates of any Loan Party, in such amounts, with such deductibles and covering such risks as are customarily carried by companies engaged in similar businesses and owning similar properties in localities where such Loan Parties operate, as applicable. A true and complete listing of such insurance as of the Closing Date, including issuers, coverages and deductibles, is set forth on Schedule 5.16.

5.17 Information.

All written information heretofore or contemporaneously herewith furnished in writing by Borrower to Agent or any Lender for purposes of or in connection with this Agreement and the transactions contemplated hereby, taken as a whole, is, and all written information hereafter furnished by or on behalf of Borrower to Agent or any Lender pursuant hereto or in connection herewith, taken as a whole, will be true and accurate in every material respect on the date as of which such information, taken as a whole, is dated or certified, and none of such information is or will be incomplete by omitting to state any material fact necessary to make such information not misleading in any material respect in light of the circumstances under which made (it being recognized by Agent and Lenders that any projections and forecasts provided by Borrower are based on good faith estimates and assumptions believed by Borrower to be reasonable as of the date of the applicable projections or assumptions and that actual results during the period or periods covered by any such projections and forecasts may differ from projected or forecasted results).

5.18 Intellectual Property; Products and Services.

(a) Schedule 5.18(a) (as updated from time to time in accordance with Section 6.1.2 hereof) accurately and completely lists all of Loan Parties' Registered Intellectual Property. Each Loan Party owns and possesses or has a license or other right to use all Intellectual Property as is necessary for the conduct of the business of such Loan Party, without any known infringement upon the intellectual property rights of others, except as otherwise set forth on Schedule 5.18(a) hereto.

(b) Schedule 5.18(b) (as updated from time to time in accordance with Section 6.1.2 hereof) accurately and completely lists all Products, Services, and all Required Permits in relation thereto, and Borrower has delivered to Agent a copy of all Required Permits as of the date hereof.

(c) With respect to any Product or Service being tested, manufactured, marketed, sold, and/or delivered by Loan Parties, the applicable Loan Party has received (or the applicable, authorized third parties have received), and such Product or Service is the subject of, all Required Permits needed in connection with the testing, manufacture, marketing, sale, and/or delivery of such Product or Service by or on behalf of Loan Parties as currently conducted. No Loan Party has received any notice from any applicable Governmental Authority, specifically including the FDA and/or CMS, that such Governmental Authority is conducting an investigation or review (other than a normal routine scheduled inspection) of any Loan Party's (*x*) manufacturing facilities, laboratory facilities, the processes for such Product, or any related sales or marketing activities and/or the Required Permits related to such Product, and (*y*) laboratory facilities, the processes for such Services, or any related sales or marketing activities and/or the Required Permits related to such Services. There are no material deficiencies or violations of applicable laws in relation to the manufacturing, processes, sales, marketing, or delivery of such Product or Services and/or the Required Permits related to such Product or Services, no Required Permit has been revoked or withdrawn, nor, to the best of Borrower's knowledge, has any such Governmental Authority issued any order or recommendation stating that the development, testing, manufacturing, sales and/or marketing of

such Product or Services by or on behalf of Loan Parties should cease or be withdrawn from the marketplace, as applicable.

(d) Except as set forth on Schedule 5.18(b), (A) there have been no adverse clinical trial results in respect of any Product since the date on which the applicable Loan Party acquired rights to such Product, and (B) there have been no product recalls or voluntary product withdrawals from any market in respect of any Product since the date on which the applicable Loan Party acquired rights to such Product.

(e) No Loan Party has experienced any significant failures in its manufacturing of any Product which caused any reduction in Products sold.

5.19 Restrictive Provisions.

No Loan Party is a party to any agreement or contract or subject to any restriction contained in its operative documents which would reasonably be expected to have a Material Adverse Effect.

5.20 Labor Matters.

No Loan Party is subject to any labor or collective bargaining agreement. There are no known existing or threatened strikes, lockouts or other labor disputes involving any Loan Party that singly or in the aggregate would reasonably be expected to have a Material Adverse Effect. Hours worked by and payment made to employees of each Loan Party are not in violation in any material respect of the Fair Labor Standards Act or any other applicable law, rule or regulation dealing with such matters. Each Loan Party has fully and timely made any and all social benefits and pension contributions and payments required to be made by such Loan Party according to any applicable law or agreement.

5.21 Material Contracts.

The agreements set forth on Schedule 5.21 constitute all material contracts required to be filed by Borrower with the U.S. Securities and Exchange Commission ("SEC") under the Securities Exchange Act of 1934, as amended (collectively, the "Material Contracts"). Schedule 5.21 sets forth, with respect to each real estate lease agreement to which any Loan Party is a party as of the Closing Date, the address of the subject property. The consummation of the transactions contemplated by the Loan Documents will not give rise to a right of termination in favor of any party to any Material Contract (other than a Loan Party) which would reasonably be expected to have, either individually or in the aggregate, a Material Adverse Effect.

5.22 Compliance with Laws; Health Care Laws.

(a) Laws Generally. Each Loan Party is in material compliance with, and is conducting and has conducted its business and operations in material compliance with the requirements of all applicable laws, rules, regulations, decrees, orders, judgments, licenses and permits except where the failure to be in compliance would not reasonably be expected to have a Material Adverse Effect.

(b) Health Care Laws. Without limiting the generality of clause (a) above:

(i) No Loan Party is in violation of any of the Health Care Laws, except for any such violation which would not reasonably be expected (either individually and taken as a whole with any other violations) to have a Material Adverse Effect.

(ii) Each Loan Party (either directly or through one or more authorized third parties) has (i) all licenses, consents, certificates, permits, authorizations, approvals, franchises, registrations, qualifications and other rights from, and has made all declarations and filings with, all applicable Governmental Authorities and self-regulatory authorities (each, an "Authorization") necessary to engage in the business conducted by it, except for such Authorizations with respect to which the failure to obtain would not reasonably be expected to have a Material Adverse Effect, and (ii) no knowledge that any Governmental Authority is considering limiting, suspending or revoking any such Authorization, except where the limitation, suspension or revocation of such Authorization would not reasonably be expected to have a Material Adverse Effect. All such Authorizations are valid and in full force and effect and such Loan Party is in material compliance with the terms and conditions of all such Authorizations and with the rules and regulations of the regulatory authorities having jurisdiction with respect to such Authorizations, except where failure to be in such compliance or for an Authorization to be valid and in full force and effect could not reasonably be expected to have a Material Adverse Effect.

(iii) Each Loan Party has received and maintains accreditation in good standing and without limitation or impairment by all applicable accrediting organizations, to the extent required by applicable law or regulation (including any foreign law or equivalent regulation), except where the failure to be so accredited and in good standing without limitation would not reasonably be expected to have a Material Adverse Effect.

(iv) Except where any of the following would not reasonably be expected to have a Material Adverse Effect, no Loan Party has been, or has been threatened to be, (i) excluded from U.S. health care programs pursuant to 42 U.S.C. §1320(a)7 or any related regulations, (ii) "suspended" or "debarred" from selling products to the U.S. government or its agencies pursuant to the Federal Acquisition Regulation, relating to debarment and suspension applicable to federal government agencies generally (48 C.F.R. Subpart 9.4), or other applicable laws or regulations, or (iii) made a party to any other action by any Governmental Authority that may prohibit it from selling products to any governmental or other purchaser pursuant to any federal, state or local laws or regulations.

(v) No Loan Party has received any written notice from the FDA, CMS, or any other Governmental Authority with respect to, nor to Borrower's best knowledge is there, any actual or threatened investigation, inquiry, or administrative or judicial action, hearing, or enforcement proceeding by the FDA, CMS, or any other Governmental Authority against any Loan Party regarding any violation of applicable law, except for such investigations, inquiries, or administrative or judicial actions, hearings, or enforcement proceedings which, individually and in the aggregate, could not reasonably be expected to result in a Material Adverse Effect.

5.23 Existing Indebtedness; Investments, Guarantees and Certain Contracts.

Except as set forth on Schedule 7.1, no Loan Party (a) has any outstanding Debt, except Debt under the Loan Documents, or (b) owns or holds any equity or long-term debt investments in, or has any outstanding advances to or any outstanding guarantees for the obligations of, or any outstanding borrowings from, any other Person.

5.24 Affiliated Agreements.

Except as set forth on Schedule 7.7 and employment agreements entered into with employees, managers, officers and directors from time to time in the ordinary course of business, (i) there are no existing or proposed agreements, arrangements, understandings or transactions between any Loan

Party, on the one hand, and such Loan Party's members, managers, managing members, investors, officers, directors, stockholders, other equity holders, employees, or Affiliates or any members of their respective families, on the other hand, and (ii) to Borrower's knowledge, none of the foregoing Persons are directly or indirectly, indebted to or have any direct or indirect ownership or voting interest in, any Affiliate of any Loan Party or any Person with which any Loan Party has a business relationship or which competes with any Loan Party (except that any such Persons may own equity interests in (but not exceeding two percent (2%) of the outstanding equity interests of) any publicly traded company that may compete with Loan Parties).

5.25 Names; Locations of Offices, Records and Collateral; Deposit Accounts.

No Loan Party has conducted business under or used any name (whether corporate, partnership or assumed) other than such names set forth on Schedule 5.25A. Each Loan Party is the sole owner(s) of all of its respective names listed on Schedule 5.25A, and any and all business conducted and invoices issued in such names are such Loan Party's sales, business and invoices. Each Loan Party maintains, and since its formation has maintained, respective places of business only at the locations set forth on Schedule 5.25B, and all books and records of Loan Parties relating to or evidencing the Collateral are located in and at such locations (other than (i) Deposit Accounts, (ii) Collateral in the possession of Agent, for the benefit of Agent and Lenders, and (iii) other locations disclosed to Agent from time to time in writing). Schedule 7.14 lists all of Loan Parties' Deposit Accounts as of the Closing Date. All of the tangible Collateral is located exclusively within the United States.

5.26 Non-Subordination.

The payment and performance of the Obligations by Loan Parties are not subordinated in any way to any other obligations of such Loan Parties or to the rights of any other Person.

5.27 Broker's or Finder's Commissions.

Except as set forth in Schedule 5.27, no broker's, finder's or placement fee or commission will be payable to any broker or agent engaged by any Loan Party or any of its officers, directors or agents with respect to the Loan or the transactions contemplated by this Agreement except for fees payable to Agent and Lenders. Borrower agrees to indemnify Agent and each Lender and hold each harmless from and against any claim, demand or liability for broker's, finder's or placement fees or similar commissions, whether or not payable by Borrower, alleged to have been incurred in connection with such transactions, other than any broker's or finder's fees payable to Persons engaged by Agent and/or Lenders.

5.28 Anti-Terrorism; OFAC.

(a) No Loan Party nor any Person controlling or controlled by a Loan Party, nor, to Borrower's knowledge, any Person having a beneficial interest in a Loan Party, nor any Person for whom a Loan Party is acting as agent or nominee in connection with this transaction (1) is a Person whose property or interest in property is blocked or subject to blocking pursuant to Section 1 of Executive Order 13224 of September 23, 2001, Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism (66 Fed. Reg. 49079 (2001)), (2) engages in any dealings or transactions prohibited by Section 2 of such executive order, or is otherwise associated with any such Person in any manner that violates of Section 2 of such executive order, or (3) is a Person on the list of Specially Designated Nationals and Blocked Persons or is in violation of the limitations or prohibitions under any other OFAC regulation or executive order.

(b) No part of the proceeds of the Loan will be used, directly or indirectly, for any payments to any governmental official or employee, political party, official of a political party, candidate for political office, or anyone else acting in an official capacity, in order to obtain, retain or direct business or obtain any improper advantage, in violation of the United States Foreign Corrupt Practices Act of 1977, as amended.

5.29 Security Interest.

Except for the anti-assignment provisions included in the agreements set forth on Schedule 5.29, hereto, each Loan Party has full right and power to grant to Agent, for the benefit of itself and the other Lenders, a perfected, first priority (subject to Permitted Liens) security interest and Lien on the Collateral pursuant to this Agreement and the other Loan Documents, as applicable, subject to the following sentence. Upon the execution and delivery of this Agreement and the other Loan Documents, and upon the filing of the necessary financing statements and/or appropriate filings and/or delivery of the necessary certificates evidencing any equity interest, control and/or possession, as applicable, without any further action, Agent will have a good, valid and first priority (subject to Permitted Liens) perfected Lien and security interest in the Collateral, for the benefit of Agent and Lenders. Borrower is not party to any agreement, document or instrument that conflicts with this Section 5.29.

5.30 Survival.

Borrower hereby makes the representations and warranties contained herein with the knowledge and intention that Agent and Lenders are relying and will rely thereon. All such representations and warranties will survive the execution and delivery of this Agreement, the closing and the making of the Loan.

Section 6 Affirmative Covenants.

Until all Obligations have been Paid in Full, Borrower agrees that, unless at any time Agent shall otherwise expressly consent in writing, it will:

6.1 Information.

Furnish to Agent (which shall furnish to each Lender):

6.1.1 Annual Report.

Promptly when available and in any event within one hundred twenty (120) days after the close of each Fiscal Year: (a) a copy of the annual audited report of Borrower and its Subsidiaries for such Fiscal Year, including therein (i) a consolidated balance sheet and statement of earnings and cash flows of Borrower and its Subsidiaries as at the end of and for such Fiscal Year, certified without qualification (except for qualifications relating to changes in accounting principles or practices reflecting changes in GAAP and required or approved by Borrower's independent certified public accountants) by independent auditors of recognized standing selected by Borrower and reasonably acceptable to Agent, and (ii) a comparison with the previous Fiscal Year; and (b) upon Agent's reasonable request, a consolidated balance sheet of Borrower and its Subsidiaries as of the end of such Fiscal Year and consolidated statements of earnings and cash flows for Borrower and its Subsidiaries for such Fiscal Year, together with a comparison of actual results for such Fiscal Year with the budget for such Fiscal Year, each certified by the chief financial officer or another executive officer of Borrower.

6.1.2 Interim Reports.

(a) Promptly when available and in any event within forty-five (45) days after the end of each Fiscal Quarter, unaudited consolidated balance sheets of Borrower and its Subsidiaries as of the end of such Fiscal Quarter, together with consolidated statements of earnings and cash flows for such Fiscal Quarter and for the period beginning with the first day of such Fiscal Year and ending on the last day of such Fiscal Quarter, together with a comparison with the corresponding period of the previous Fiscal Year and a comparison with the budget for such period of the current Fiscal Year (which may be in preliminary form), certified by the chief financial officer or other executive officer of Borrower.

(b) Together with each such quarterly report to be delivered pursuant to clause (a) above, Borrower shall provide to Agent (i) a written statement of Borrower's management setting forth a summary discussion of Borrower's financial condition, changes in financial condition and results of operations, and (ii) updated Schedules to this Agreement, as applicable, setting forth any changes to the disclosures set forth in such schedules as most recently provided to Agent.

(c) Promptly when available, copies of all monthly or quarterly sales, production or similar reports prepared by Borrower or otherwise utilized by management of Borrower in the normal course of business.

6.1.3 Monthly Review Meeting.

Borrower and any other Loan Parties as requested by Agent shall be available in person or via teleconference as and when requested by Agent and no less frequent than monthly for a review meeting regarding the status of Borrower, the Collateral and performance of the same.

6.1.4 Revenue-Based Payment Reconciliation.

Upon Agent's request Borrower shall furnish to Agent, a report, in form acceptable to Agent, reconciling the Net Sales, Royalties, and all other revenue reported by Borrower to Agent during any reporting period to the Aggregate Revenue reported by Borrower hereunder for such period and the amount of Revenue-Based Payment(s) made by Borrower in connection with such period(s).

6.1.5 Compliance Certificate.

Contemporaneously with the furnishing of a copy of each annual audit report pursuant to Section 6.1.1 and each set of quarterly statements pursuant to Section 6.1.2, a duly completed Compliance Certificate, with appropriate insertions, dated the date of delivery and corresponding to such annual report or such quarterly statements, and signed by the chief financial officer (or other executive officer) of Borrower, containing computations, if applicable, showing compliance with Section 7.13 and a statement to the effect that such officer has not become aware of any Event of Default or Default that exists or, if there is any such event, describing it and the steps, if any, being taken to cure it.

6.1.6 Reports to Governmental Authorities and Shareholders.

Promptly upon the filing or sending thereof, copies of (a) all regular, periodic or special reports of each Loan Party filed with any Governmental Authority, (b) all registration statements (or such equivalent documents) of each Loan Party filed with any Governmental Authority and (c) all proxy statements or other communications made to the holders of Borrower's Equity Interests generally.

6.1.7 Notice of Default; Litigation.

Promptly upon becoming aware of any of the following, written notice describing the same and the steps being taken by Borrower or the applicable Loan Party affected thereby with respect thereto:

(a) the occurrence of an Event of Default;

(b) any litigation, arbitration or governmental investigation or proceeding not previously disclosed by Borrower to Lenders which has been instituted or, to the knowledge of Borrower, is threatened in writing against Borrower or any other Loan Party or to which any of the properties of any thereof is subject, which in any case would reasonably be expected to have a Material Adverse Effect;

(c) the institution of any steps by any member of the Controlled Group or any other Person to terminate any Pension Plan, or the failure of any member of the Controlled Group to make a required contribution to any Pension Plan (if such failure is sufficient to give rise to a Lien under Section 303(k) of ERISA) or to any Multiemployer Pension Plan, or the taking of any action with respect to a Pension Plan which could result in the requirement that Borrower or any other Loan Party furnish a bond or other security to the PBGC or such Pension Plan, or the occurrence of any event with respect to any Pension Plan or Multiemployer Pension Plan which could result in the incurrence by any member of the Controlled Group of any material liability, fine or penalty (including any claim or demand for withdrawal liability or partial withdrawal from any Multiemployer Pension Plan), or any material increase in the contingent liability of Borrower or any other Loan Party with respect to any post-retirement welfare plan benefit, or any notice that any Multiemployer Pension Plan is in reorganization, that increased contributions may be required to avoid a reduction in plan benefits or the imposition of an excise tax, that any such plan is or has been funded at a rate less than that required under Section 412 of the IRC, that any such plan is or may be terminated, or that any such plan is or may become insolvent;

(d) any cancellation or material adverse change in any insurance maintained by Borrower or any other Loan Party;

(e) any other event (including (i) any violation of any law, including any Environmental Law, or the assertion of any Environmental Claim or (ii) the enactment or effectiveness of any law, rule or regulation) which could reasonably be expected to have a Material Adverse Effect; or

(f) to the extent that it would reasonably be expected to result in a Material Adverse Effect (i) any suspension, revocation, cancellation or withdrawal of an Authorization required for Borrower or any other Loan Party, is threatened or there is any basis for believing that such Authorization will not be renewable upon expiration or will be suspended, revoked, cancelled or withdrawn, (ii) Borrower or any other Loan Party enters into any consent decree or order pursuant to any Health Care Law and Regulation, or becomes a party to any judgment, decree or judicial or administrative order pursuant to any Health Care Law, (iii) receipt of any written notice or other written communication from the FDA, CMS, or any other applicable Governmental Authority alleging non-compliance with CLIA or any other applicable Health Care Law, (iv) the occurrence of any violation of any Health Care Law by Borrower or any of the other Loan Parties in the development or provision of Services, and record keeping and reporting to the FDA or CMS that could reasonably be expected to require or lead to an investigation, corrective action or enforcement, regulatory or administrative action, (v) the occurrence of any civil or criminal proceedings relating to Borrower or any of the other Loan Parties or any of their respective employees, which involve a matter within or related to the FDA's or CMS' jurisdiction, (vi) any officer, employee or agent of Borrower or any of the other Loan Parties is convicted of any crime or has engaged in any conduct for which debarment is mandated or permitted by 21 U.S.C. § 335a, or (vii) any officer, employee or agent

of Borrower or any of the other Loan Parties has been convicted of any crime or engaged in any conduct for which such Person could be excluded from participating in any federal, provincial, state or local health care programs under Section 1128 of the Social Security Act or any similar law or regulation.

6.1.8 Management Report.

Within five (5) Business Days after receipt thereof, copies of all detailed financial and management reports submitted to Borrower or any other Loan Party by independent auditors in connection with each annual or interim audit made by such auditors of the books of Borrower or any other Loan Party.

6.1.9 Projections.

As soon as practicable, and in any event not later than thirty (30) days after the commencement of each Fiscal Year, financial projections on a quarterly basis of revenues and EBITDA for Borrower and the Subsidiaries for such Fiscal Year prepared in a manner consistent with the projections delivered by Borrower to Agent prior to the Closing Date or otherwise in a manner reasonably satisfactory to Agent, accompanied by a certificate of a chief financial officer (or other executive officer) of Borrower on behalf of Borrower to the effect that (a) such projections were prepared by them in good faith, (b) Borrower believes that it has a reasonable basis for the assumptions contained in such projections and (c) such projections have been prepared in accordance with such assumptions.

6.1.10 Updated Schedules to Guarantee and Collateral Agreement.

Contemporaneously with the furnishing of each annual audit report pursuant to Section 6.1.1, updated versions of the Schedules to the Guarantee and Collateral Agreement showing information as of the date of such audit report (it being agreed and understood that this requirement shall be in addition to the notice and delivery requirements set forth in the Guarantee and Collateral Agreement).

6.1.11 Other Information.

Promptly, from time to time as Agent reasonably requests, Borrower shall deliver or shall cause to be delivered to Agent:

(a) copies of any reports, statements or written materials (other than routine communications (electronic or otherwise) between Borrower or its Affiliates and such entities that are not material in nature) in relation to any Material Contract;

(b) such other information concerning Borrower and any other Loan Party as Agent may reasonably request;

(c) copies of all material communication as well as other material documents received by Loan Parties or any of their Subsidiaries from the FDA, CMS, DEA, or any other Governmental Authority; and

(d) copies of (*x*) any notices or other communications relating to any breach, default, or event of default with respect to any Debt listed on Schedule 7.1 and (*y*) any other modifications or amendments entered into in relation to any Debt listed on Schedule 7.1.

6.2 Books; Records; Inspections.

Keep, and cause each other Loan Party to keep, its books and records in accordance with sound business practices sufficient to allow the preparation of financial statements in accordance with GAAP; permit, and cause each other Loan Party to permit (at any reasonable time and with reasonable notice), Agent or any representative thereof to inspect the properties and operations of Borrower or any other Loan Party; and permit, and cause each other Loan Party to permit, at any reasonable time and with reasonable notice (or at any time without notice if an Event of Default exists), Agent (accompanied by any Lender) or any representative thereof to visit any or all of its offices, to discuss its financial matters with its officers and its independent auditors (and Borrower hereby authorizes such independent auditors to discuss such financial matters with any Lender or Agent or any representative thereof), and to examine (and, at the expense of Borrower or the applicable Loan Party, photocopy extracts from) any of its books or other records; and permit, and cause each other Loan Party to permit, (at any reasonable time and with reasonable notice) Agent and its representatives to inspect the Collateral and other tangible assets of Borrower or Loan Party, to perform appraisals of the equipment of Borrower or Loan Party, and to inspect, audit, check and make copies of and extracts from the books, records, computer data, computer programs, journals, orders, receipts, correspondence and other data relating to any Collateral. Notwithstanding the forgoing, prior to the occurrence and continuance of an Event of Default, Agent and Lenders shall conduct no more than one (1) such inspection, examination and or audit described in this Section 6.2 during any Fiscal Quarter.

6.3 Conduct of Business; Maintenance of Property; Insurance.

(a) Borrower shall, and shall cause each other Loan Party to, (i) conduct its business in accordance with its current business practices, (ii) engage principally in the same or similar lines of business substantially as heretofore conducted, (iii) collect the Royalties in the ordinary course of business, (iv) maintain all of its Collateral used or useful in its business in good repair, working order and condition (normal wear and tear excepted and except as may be disposed of in the ordinary course of business and in accordance with the terms of the Loan Documents), (v) from time to time to make all necessary repairs, renewals and replacements to the Collateral; (vi) maintain and keep in full force and effect all material Permits and qualifications to do business and good standing in its jurisdiction of formation and each other jurisdiction in which the ownership or lease of property or the nature of its business makes such Permits or qualification necessary and in which failure to maintain such Permits or qualification could reasonably be expected to be, have or result in a Material Adverse Effect; (vii) remain in good standing and maintain operations in all jurisdictions in which it is currently located, except where the failure to remain in good standing or maintain operations would not reasonably be expected to be, have or result in a Material Adverse Effect, and (viii) maintain, comply with and keep in full force and effect all Intellectual Property and Permits necessary to conduct its business, except in each case where the failure to maintain, comply with or keep in full force and effect could not reasonably be expected to be, have or result in a Material Adverse Effect.

(b) Borrower shall keep, and cause each other Loan Party to keep, all property necessary in the business of Borrower or each other Loan Party in good working order and condition, ordinary wear and tear excepted.

(c) Borrower shall maintain, and cause each other Loan Party to maintain, with responsible insurance companies, such insurance coverage as shall be required by all laws, governmental regulations and court decrees and orders applicable to it and such other insurance, to such extent and against such hazards and liabilities, as is (i) customarily maintained by Persons operating in the same geographical region as Borrower that are (A) subject to CLIA and other applicable Health Care Laws, or (B) otherwise delivering to customers products or services similar to the Services (in each case, as determined by Agent in its reasonable discretion), and (ii) otherwise in form, substance, and amounts acceptable to Agent in its

reasonable discretion; *provided* that in any event, such insurance shall, unless the Agent otherwise agrees, insure against all risks and liabilities of the type insured against as of the Closing Date and shall have insured amounts no less than, and deductibles no higher than, those amounts provided for as of the Closing Date. Upon request of Agent or any Lender, Borrower shall furnish to Agent or such Lender a certificate setting forth in reasonable detail the nature and extent of all insurance maintained by Borrower and each other Loan Party. Borrower shall cause each issuer of an insurance policy to provide Agent with an endorsement (*x*) showing Agent as a lender's loss payee with respect to each policy of property or casualty insurance and naming Agent as an additional insured with respect to each policy of liability insurance promptly upon request by Agent, (*y*) providing that the insurance carrier will endeavor to give at least thirty (30) days' prior written notice to Borrower and Agent (or ten (10) days' prior written notice if the Agent consents to such shorter notice) before the termination or cancellation of the policy prior to the expiration thereof and (*z*) reasonably acceptable in all other respects to Agent.

(d) Unless Borrower provides Agent with evidence of the continuing insurance coverage required by this Agreement, Agent (upon reasonable advance notice to Borrower) may purchase insurance at Borrower's expense to protect Agent's and Lenders' interests in the Collateral. This insurance shall protect Borrower's and each other Loan Party's interests. The coverage that Agent purchases shall pay any claim that is made against Borrower or any other Loan Party in connection with the Collateral. Borrower may later cancel any insurance purchased by Agent, but only after providing Agent with evidence that Borrower has obtained the insurance coverage required by this Agreement. If Agent purchases insurance for the Collateral, as set forth above, Borrower will be responsible for the reasonable costs of that insurance, including interest and any other charges that may be imposed with the placement of the insurance, until the effective date of the cancellation or expiration of the insurance, and such costs of the insurance may be added to the principal amount of the Loans owing hereunder.

(e) In addition to the foregoing, Borrower shall maintain during the term of this Agreement, a life insurance policy on the life of each Key Person with a responsible insurance company, in the aggregate amount of $3,000,000 (the "Keyman Life Insurance Policy") and shall provide and shall cause the issuer of the Keyman Life Insurance Policy to provide Agent with copies of each Keyman Life Insurance Policy and any additional documentation, each in form and substance acceptable to Agent in its commercially-reasonable discretion, necessary to grant Agent a perfected assignment of such Keyman Life Insurance Policy.

6.4 Compliance with Laws; Payment of Taxes and Liabilities.

(a) Comply, and cause each other Loan Party to comply, in all material respects with all applicable laws, rules, regulations, decrees, orders, judgments, licenses and permits, except where failure to comply would not reasonably be expected to have a Material Adverse Effect; (b) without limiting clause (a) above, ensure, and cause each other Loan Party to ensure, that no person who Controls a Loan Party is (i) listed on the Specially Designated Nationals and Blocked Person List maintained by OFAC, and/or any other similar lists maintained by OFAC pursuant to any authorizing statute, Executive Order or regulation or (ii) a Person designated under Section 1(b), (c) or (d) or Executive Order No. 13224 (September 23, 2001), any related enabling legislation or any other similar Executive Orders; (c) without limiting clause (a) above, comply and cause each other Loan Party to comply, with all applicable Bank Secrecy Act and anti-money laundering laws and regulations, (d) file, or cause to be filed, all federal, state, foreign and other tax returns and reports required by law to be filed by any Loan Party, and (e) pay, and cause each other Loan Party to pay, prior to delinquency, all foreign, federal, state and other taxes and other material governmental charges against it or any of its property, as well as material claims of any kind which, if unpaid, could become a Lien (other than a Permitted Lien) on any of its property; *provided* that the foregoing shall not require Borrower or any other Loan Party to pay any such tax, charge or claim so long as it shall contest the validity thereof in good faith by appropriate proceedings and shall set aside on its

books adequate reserves with respect thereto in accordance with GAAP. For purposes of this Section 6.4, "Control" shall mean, when used with respect to any Person, (*x*) the direct or indirect beneficial ownership of fifty-one percent (51%) or more of the outstanding Equity Interests of such Person or (*y*) the power to direct or cause the direction of the management and policies of such Person whether by contract or otherwise.

6.5 Maintenance of Existence.

Maintain and preserve, and (subject to Section 7.4) cause each other Loan Party to maintain and preserve, (a) its existence and good standing in the jurisdiction of its organization and (b) its qualification to do business and good standing in each jurisdiction where the nature of its business makes such qualification necessary, other than any such jurisdiction where the failure to be qualified or in good standing would not reasonably be expected to have a Material Adverse Effect.

6.6 Employee Benefit Plans.

Except to the extent that failure to do so would not be reasonably expected to result in (a) a Material Adverse Effect or (b) liability in excess of $100,000 of any Loan Party, maintain, and cause each other Loan Party to maintain, each Pension Plan (if any) in substantial compliance with all applicable requirements of law and regulations.

6.7 Environmental Matters.

Except to the extent the failure to do so would not be reasonably expected to result in a Material Adverse Effect, if any release or disposal of Hazardous Substances shall occur or shall have occurred on any real property or any other assets of Borrower or any other Loan Party, cause, or direct the applicable Loan Party to cause, the prompt containment and removal of such Hazardous Substances and the remediation of such real property or other assets as is necessary to comply in all material respects with all Environmental Laws and to preserve the value of such real property or other assets. Without limiting the generality of the foregoing, except to the extent the failure to do so would not be reasonably expected to result in a Material Adverse Effect, Borrower shall, and shall cause each other Loan Party to, comply with each valid federal or state judicial or administrative order requiring the performance at any real property by Borrower or any other Loan Party of activities in response to the release or threatened release of a Hazardous Substance.

6.8 Further Assurances.

Take, and cause each other Loan Party to take, such actions as are necessary or as Agent or the Required Lenders may reasonably request from time to time to ensure that the Obligations of Borrower and each other Loan Party under the Loan Documents are secured by a perfected Lien in favor of Agent (subject only to the Permitted Liens) on substantially all of the assets of Borrower and each Subsidiary of Borrower (as well as all equity interests of each Subsidiary of Borrower) and guaranteed by all of the Subsidiaries of Borrower (including, promptly upon the acquisition or creation thereof, any Subsidiary of Borrower acquired or created after the Closing Date), in each case including (a) the execution and delivery of guaranties, security agreements, pledge agreements, mortgages, deeds of trust, financing statements and other documents, and the filing or recording of any of the foregoing; (b) the delivery of certificated securities (if any) and other Collateral with respect to which perfection is obtained by possession but excluding (i) the requirement for the Loan Parties to execute and deliver leasehold mortgages, and (ii) any other Excluded Collateral as defined in the Guarantee and Collateral Agreement; and (c) using commercially reasonable efforts to obtain and deliver executed Collateral Access Agreements in relation to

any foreign and domestic location where a material portion of the Collateral is held or otherwise stored from time to time.

6.9 Compliance with Health Care Laws.

(a) Without limiting or qualifying Section 6.4 or any other provision of this Agreement, Borrower will comply, and will cause each other Loan Party and each Subsidiary of Borrower to comply, in all material respects with all applicable Health Care Laws relating to the operation of such Person's business, except where failure to comply would not reasonably be expected to have a Material Adverse Effect.

(b) Borrower will, and will cause each other Loan Party and each Subsidiary to:

(i) Keep in full force and effect all Authorizations required to operate such Person's business under applicable Health Care Laws and maintain any other qualifications necessary to conduct, arrange for, administer, provide services in connection with or receive payment for all applicable Services, except to the extent such failure to keep in full force and effect or maintain would not reasonably be expected to have a Material Adverse Effect.

(ii) Promptly furnish or cause to be furnished to the Agent, with respect to matters that could reasonably be expected to have a Material Adverse Effect, (w) copies of all material reports of investigational/inspectional observations issued to and received by the Loan Parties or any of their Subsidiaries, and issued by any Governmental Authority relating to such Person's business, (x) copies of all material establishment investigation/inspection reports (including, but not limited to, FDA Form 483's) issued to and received by Loan Parties or any of their Subsidiaries and issued by any Governmental Authority, (y) copies of all material warnings and material untitled letters as well as other material documents received by Loan Parties or any of their Subsidiaries from the FDA, CMS, DEA, or any other Governmental Authority relating to or arising out of the conduct applicable to the business of the Loan Parties or any of their Subsidiaries that asserts past or ongoing lack of compliance with any Health Care Law or any other applicable foreign, federal, state or local law or regulation of similar import and (z) notice of any material investigation or material audit or similar proceeding by the FDA, DEA, CMS, or any other Governmental Authority.

(iii) Promptly furnish or cause to be furnished to the Agent, with respect to matters that would reasonably be expected to have a Material Adverse Effect, (in such form as may be reasonably required by Agent) copies of all non-privileged, reports, correspondence, pleadings and other communications relating to any matter that could lead to the loss, revocation or suspension (or threatened loss, revocation or suspension) of any material Authorization or of any material qualification of any Loan Party or Subsidiary; *provided* that any internal reports to a Person's compliance "hot line" which are promptly investigated and determined to be without merit need not be reported.

(iv) Promptly furnish or cause to be furnished to the Agent notice of all material fines or penalties imposed by any Governmental Authority under any Health Care Law against any Loan Party or any of its Subsidiaries.

(v) Promptly furnish or cause to be furnished to the Agent notice of all material allegations by any Governmental Authority (or any agent thereof) of fraudulent activities of any Loan Party or any of its Subsidiaries in relation to the provision of clinical research or related services.

Notwithstanding anything to the contrary in any Loan Document, no Loan Party or any of its Subsidiaries shall be required to furnish to Agent or any Lender patient-related or other information, the disclosure of which to Agent or such Lender is prohibited by any applicable law.

6.10 Cure of Violations.

If there shall occur any breach of Section 6.9, Borrower shall take such commercially reasonable action as is necessary to validly challenge or otherwise appropriately respond to such fact, event or circumstance within any timeframe required by applicable Health Care Laws, and shall thereafter diligently pursue the same.

6.11 Corporate Compliance Program.

Maintain, and will cause each other Loan Party to maintain on its behalf, reasonable procedures to ensure that its employees and agents (including such Loan Party's sales force) complies with applicable laws and regulations (including, for the avoidance of doubt, any Health Care Laws applicable to such Loan Party). Upon request by Agent, Borrower shall provide Agent with information regarding such procedures.

6.12 Payment of Debt.

Except as otherwise prescribed in the Loan Documents, Borrower shall pay, discharge or otherwise satisfy when due and payable (subject to applicable grace periods and, in the case of trade payables, to ordinary course of payment practices) all of its material obligations and liabilities, except when the amount or validity thereof is being contested in good faith by appropriate proceedings and appropriate reserves shall have been made in accordance with GAAP consistently applied.

6.13 [Reserved].

6.14 Post-Closing Covenants:

(a) Within thirty (30) days after the Closing Date, Borrower shall cause to be delivered to Agent a fully-executed Collateral Access Agreement, each in form and substance reasonable acceptable to Agent, in relation to the following leased properties of Borrower: (i) 85 Oakwood, Lake Zurich, Illinois 60047, and (ii) 21925 W. Field Parkway, Suite 235, Deer Park, IL 60010.

(b) Within thirty (30) days after the Closing Date, Borrower shall have delivered to Agent (i) property and liability insurance certificates and (ii) lender's loss payee and additional insured endorsements in favor of Agent with respect to the Borrower's property and liability insurance policies, as applicable, in form and substance reasonably acceptable to Agent.

(c) Within ninety (90) days after the Closing Date, Borrower shall have delivered to Agent either (i) an Account Control Agreement in favor of Agent, in form and substance reasonably acceptable to Agent, with respect to each Deposit Account of Borrower set forth on Schedule 7.14 that does not constitute an Exempt Account (the "Existing Accounts"), (ii) an Account Control Agreement, in form and substance reasonably acceptable to Agent, with respect to any replacement Deposit Accounts opened by Borrower to replace any such Existing Account (the "Replacement Accounts") and evidence that each such replaced Existing Account, if applicable, has been closed by Borrower, and/or (iii) for any Existing Account not covered by an Account Control Agreement, evidence reasonably satisfactory to Agent that such Existing Account has been closed.

(d) Within one-hundred eighty (180) days after the Closing Date, Borrower and Agent shall collaboratively work to amend this Agreement to implement additional financial covenants related to minimum Aggregate Revenue and minimum EBITDA.

Section 7 Negative Covenants.

Until all Obligations have been Paid in Full, Borrower agrees that, unless at any time Agent shall otherwise expressly consent in writing, in its sole discretion, it will:

7.1 Debt.

Not, and not permit any other Loan Party to, create, incur, assume or suffer to exist any Debt, except:

(a) Obligations under this Agreement and the other Loan Documents;

(b) Subordinated Debt;

(c) Debt secured by Liens permitted by Section 7.2(b), Section 7.2(d) or Section 7.2(o) and extensions, renewals and re-financings thereof; *provided* that the aggregate amount of all such Debt permitted under Section 7.2(d) at any time outstanding shall not exceed $500,000;

(d) Debt with respect to any Hedging Obligations incurred for bona fide hedging purposes and not for speculation;

(e) Debt (i) arising from customary agreements for indemnification related to sales of goods, licensing of intellectual property or adjustment of purchase price or similar obligations in any case incurred in connection with the acquisition or disposition of any business, assets or Subsidiary of Borrower otherwise permitted hereunder, (ii) representing deferred compensation to employees of any Loan Party incurred in the ordinary course of business, or (iii) representing customer deposits and advance payments received in the ordinary course of business from customers for goods purchased in the ordinary course of business;

(f) Debt with respect to cash management obligations and other Debt in respect of automatic clearing house arrangements, netting services, overdraft protection and similar arrangements, in each case incurred in the ordinary course of business;

(g) Debt incurred in connection with surety bonds, performance bonds or letters of credit for worker's compensation, unemployment compensation and other types of social security and otherwise in the ordinary course of business or referred to in Section 7.2(e);

(h) Debt described on Schedule 7.1 as of the Closing Date, and any extension or renewal thereof so long (i) as the principal amount thereof is not increased, (ii) as the terms and conditions of such extension, renewal or refinancing are substantially identical to the original Debt, (iii) as to such extension or renewal, no collateral or other form of security is granted by Borrower in connection therewith; and

(i) unsecured Debt (which for further clarity shall exclude accounts payable and other current liabilities incurred by Loan Parties in the ordinary course of business), in addition to the Debt listed above, in an aggregate outstanding amount not at any time exceeding $100,000.

7.2 Liens.

Not, and not permit any other Loan Party to, create or permit to exist any Lien on any of its real or personal properties, assets or rights of whatsoever nature (whether now owned or hereafter acquired), except:

(a) Liens for taxes or other governmental charges not at the time delinquent or thereafter payable without penalty or being diligently contested in good faith by appropriate proceedings and, in each case, for which it maintains adequate reserves in accordance with GAAP and with respect to which no execution or other enforcement has occurred;

(b) Liens arising in the ordinary course of business (including without limitation (i) Liens of carriers, warehousemen, mechanics, landlords and materialmen and other similar Liens imposed by law and (ii) Liens incurred in connection with worker's compensation, unemployment compensation and other types of social security or in connection with surety bonds, bids, tenders, performance bonds, trade contracts not for borrowed money, licenses, statutory obligations and similar obligations) for sums not overdue or being diligently contested in good faith by appropriate proceedings and not involving any deposits or advances or borrowed money or the deferred purchase price of property or services and, in each case, for which it maintains adequate reserves in accordance with GAAP and with respect to which no execution or other enforcement of which is effectively stayed;

(c) Liens described on Schedule 7.2 as of the Closing Date (other than Liens being released at the closing under this Agreement) and the replacement, extension or renewal of any Lien permitted by this clause (c) upon or in the same property subject thereto arising out of the extension, renewal or replacement of the Debt secured thereby (without increase in the amount thereof);

(d) (i) Liens arising in connection with Capital Leases (and attaching only to the property being leased), (ii) Liens on any property securing debt incurred for the purpose of financing all or any part of the cost of acquiring or improving such property; *provided* that any such Lien attaches to such property within ninety (90) days of the acquisition or improvement thereof and attaches solely to the property so acquired or improved, and (iii) the replacement, extension or renewal of a Lien permitted by one of the foregoing clauses (i) or (ii) in the same property subject thereto arising out of the extension, renewal or replacement of the Debt secured thereby (without increase in the amount thereof);

(e) Liens relating to litigation bonds and attachments, appeal bonds, judgments and other similar Liens arising in connection with any judgment or award that is not an Event of Default hereunder;

(f) easements, rights of way, restrictions, minor defects or irregularities in title and other similar Liens not interfering in any material respect with the ordinary conduct of the business of Borrower or any Subsidiary;

(g) Liens arising under the Loan Documents;

(h) any interest or title of a licensor, sublicensor, lessor or sublessor under any license, lease, sublicense or sublease agreement entered into in the normal course of business, only to the extent limited to the item licensed or leased;

(i) (i) Liens of a collection bank arising under Section 4-210 of the Uniform Commercial Code on items in the course of collection and (ii) customary set off rights of deposit banks

with respect to deposit accounts maintained at such deposit banks or which are contained in standard agreements for the opening of an account with a bank;

(j) Liens arising from precautionary filings of financing statements under the Uniform Commercial Code or similar legislation of any applicable jurisdiction in respect of operating leases permitted hereunder and entered into by a Loan Party in the ordinary course of business;

(k) Liens attaching to cash earnest money deposits in connection with any letter of intent or purchase agreement permitted hereunder or indemnification other post-closing escrows or holdbacks;

(l) Liens incurred with respect to Hedging Obligations incurred for bona fide hedging purposes and not for speculation;

(m) Liens to secure obligations of a Loan Party to another Loan Party; and

(n) Liens arising out of conditional sale, title retention, consignment or similar arrangements for the sale of goods in the ordinary course of business.

7.3 Dividends; Redemption of Equity Interests.

Not (a) declare, pay or make any dividend or distribution on any Equity Interests or other securities or ownership interests, (b) apply any of its funds, property or assets to the acquisition, redemption or other retirement of any Equity Interests or other securities or interests or of any options to purchase or acquire any of the foregoing, (c) otherwise make any payments, dividends or distributions to any member, manager, managing member, stockholder, director or other equity owner in such Person's capacity as such other than in compliance with Section 7.7 hereof, or (d) make any payment of any management, service or related or similar fee to any Affiliate or holder of Equity Interests of Borrower other than in compliance with Section 7.7 hereof.

7.4 Mergers; Consolidations; Asset Sales.

(a) Not be a party to any amalgamation or any other form of Division, merger or consolidation, unless agreed to by Agent in its commercially reasonable discretion, nor permit any other Loan Party to be a party to any Division, amalgamation or any other form of merger or consolidation, unless agreed to by Agent in its reasonable discretion. Notwithstanding the foregoing, in the event that Agent withholds its approval under this Section 7.4 for any reason, Borrower may prepay all of its obligations under this Agreement without the payment of any prepayment penalty or premium described in Section 2.8 of this Agreement and proceed with such transaction.

(b) Not, and not permit any other Loan Party to, sell, transfer, dispose of, convey, lease or license any of its real or personal property assets or Equity Interests, except for (i) sales of Inventory in the ordinary course of business for at least fair market value, (ii) transfers, destruction or other disposition of obsolete or worn-out assets in the ordinary course of business and (iii) any other sales and dispositions of assets (excluding (A) any Equity Interests of Borrower or any Subsidiary or (B) sales of Inventory described in clause (i) above) for at least fair market value (as determined by the Board of Directors of Borrower) so long as the net book value of all assets sold or otherwise disposed of in any Fiscal Year does not exceed $250,000 with respect to sales and dispositions made pursuant to this clause (iii), (iv) sales and dispositions to Loan Parties, (v) leases, licenses, subleases and sublicenses entered into in the ordinary course of business, (vi) sales and exchanges of Cash Equivalent Investments to the extent otherwise permitted hereunder, (vii) Liens expressly permitted under Section 7.2 and transactions expressly permitted

by clause (a) or Section 7.10, (viii) sales or issuances of Equity Interests by Borrower, (ix) issuances of Equity Interests by any Loan Party to any other Loan Party, (x) dispositions in the ordinary course of business consisting of the abandonment of intellectual property rights which, in the reasonable good faith determination of Borrower, are not material to the conduct of the business of the Loan Parties, (xi) a cancellation of any intercompany Debt among the Loan Parties, (xii) a disposition which constitutes an insured event or pursuant to a condemnation, expropriation, "eminent domain" or similar proceeding, (xiii) sales and dispositions among Subsidiaries of Borrower, and (xiv) exchanges of existing equipment for new equipment that is substantially similar to the equipment being exchanged and that has a value equal to or greater than the equipment being exchanged.

(c) Notwithstanding any provision in this Agreement or any other Loan Documents to the contrary, the prior consent of Agent shall not be required in connection with the licensing or sublicensing of Intellectual Property pursuant to collaborations, licenses or other strategic transactions with third parties executed (i) in the ordinary course of a Loan Party's business, (ii) on an arms-length basis and (iii) prior to the occurrence of an Event of Default.

7.5 Modification of Organizational Documents.

Not permit the charter, by-laws or other organizational documents of Borrower or any other Loan Party to be amended or modified in any way which could reasonably be expected to materially and adversely affect the interests of Agent or any Lender. An amendment to Borrower's certificate of incorporation to increase Borrower's authorized capital stock shall not be deemed to adversely affect the interests of Agent or any Lender.

7.6 Use of Proceeds.

Use the proceeds of the Loans solely to refinance the Prior Debt, if any, and otherwise for working capital, for fees and expenses related to the negotiation, execution, delivery and closing of this Agreement and the other Loan Documents and the transactions contemplated hereby and thereby and for other general business purposes of Borrower and its Subsidiaries, and not use any proceeds of any Loan or permit any proceeds of any Loan to be used, either directly or indirectly, for the purpose, whether immediate, incidental or ultimate, of "purchasing or carrying" any Margin Stock.

7.7 Transactions with Affiliates.

Not, and not permit any other Loan Party to, enter into, or cause, suffer or permit to exist any transaction, arrangement or contract with any of its other Affiliates, which is on terms which are less favorable than are obtainable from any Person which is not one of its Affiliates, other than (i) reasonable compensation and indemnities to, benefits for, reimbursement of expenses of, and employment arrangements with, officers, employees and directors in the ordinary course of business, (ii) transactions among Loan Parties and (iii) transactions pursuant to agreements in existence on the Closing Date and set forth on Schedule 7.7.

7.8 Inconsistent Agreements.

Not, and not permit any other Loan Party to, enter into any agreement containing any provision which would (a) be violated or breached by any borrowing by Borrower hereunder or by the performance by Borrower or any other Loan Party of any of its Obligations hereunder or under any other Loan Document, (b) prohibit Borrower or any other Loan Party from granting to Agent and Lenders a Lien on any of its assets or (c) create or permit to exist or become effective any encumbrance or restriction on the ability of any other Loan Party to (i) pay dividends or make other distributions to Borrower or any other

Subsidiary, or pay any Debt owed to Borrower or any other Subsidiary, (ii) make loans or advances to Borrower or any other Loan Party or (iii) transfer any of its assets or properties to Borrower or any other Loan Party, other than, in the cases of clauses (b) and (c), (A) restrictions or conditions imposed by any agreement relating to purchase money Debt, Capital Leases and other secured Debt or to leases and licenses permitted by this Agreement if such restrictions or conditions apply only to the property or assets securing such Debt or the property leased or licensed, (B) customary provisions in leases and other contracts restricting the assignment thereof, (C) restrictions and conditions imposed by law, and (D) customary provisions in contracts for the disposition of any assets; *provided* that the restrictions in any such contract shall apply only to the assets or Subsidiary that is to be disposed of and such disposition is permitted hereunder.

7.9 Business Activities.

Not, and not permit any other Loan Party to, engage in any line of business other than the businesses engaged in on the Closing Date and businesses reasonably related thereto. Not, and not permit any other Loan Party to, issue any Equity Interest other than (a) Equity Interests of Borrower that do not require any cash dividends or other cash distributions to be made prior to the Obligations being Paid in Full, (b) any issuance by a Subsidiary to Borrower or another Subsidiary in accordance with Section 7.4 or Section 7.10, or (c) any issuance of directors' qualifying shares as required by applicable law.

7.10 Investments.

Not, and not permit any other Loan Party to, make or permit to exist any Investment in any other Person, except the following:

(a) The creation of any Wholly-Owned Subsidiary and contributions by Borrower to the capital of any Wholly-Owned Subsidiary of Borrower, so long as the recipient of any such contribution has guaranteed the Obligations and such guaranty is secured by a pledge of all of its equity interests and substantially all of its real and personal property, in each case in accordance with Section 6.8;

(b) Cash Equivalent Investments;

(c) bank deposits in the ordinary course of business;

(d) Investments listed on Schedule 7.10 as of the Closing Date, together with any roll-over or reinvestment of such Investment(s);

(e) any purchase or other acquisition by Borrower or any Wholly-Owned Subsidiary of Borrower of the assets or equity interests of any Subsidiary of Borrower;

(f) transactions among Loan Parties permitted by Section 7.4;

(g) Hedging Obligations permitted under Section 7.1(d);

(h) advances given to employees and directors in existence as of the Closing Date and as listed on Schedule 7.10, which amounts shall not be increased without Agent's prior written consent in its commercially-reasonable discretion;

(i) lease, utility and other similar deposits made in the ordinary course of business and trade credit extended in the ordinary course of business;

(j) Investments consisting of the non-cash portion of the consideration received in respect of Dispositions permitted hereunder;

(k) Investments permitted by Borrower or any Loan Party as a result of the receipt of insurance and/or condemnation or expropriation proceeds in accordance with the Loan Documents; and

(l) Investments (i) received as a result of the bankruptcy or reorganization of any Person or taken in settlement of or other resolution of claims or disputes or (ii) in securities of customers and suppliers received in connection with the bankruptcy or reorganization of, or settlement of delinquent accounts and bona fide disputes with, customers and suppliers, and, in each case, extensions, modifications and renewals thereof.

7.11 Restriction of Amendments to Certain Documents.

Not, nor permit any Loan Party to, amend or otherwise modify in any material manner, or waive any rights under, any provisions of any of the Material Contracts (or any replacements thereof) set forth on Schedule 7.11 hereto (as such schedule may be updated by Agent from time to time to include any material contracts, licenses, agreements or similar arrangements to those described on such Schedule as of the Closing Date that are entered into by a Loan Party from time to time after the Closing Date).

7.12 Fiscal Year.

Not change its Fiscal Year.

7.13 Financial Covenants

7.13.1 Minimum Consolidated Unencumbered Liquid Assets.

Not permit the Consolidated Unencumbered Liquid Assets to be less than $3,000,000 at any time; provided, however, if Borrower shall have received (i) at least $8,000,000 in Raised Cash since the Closing Date, and (ii) FDA approval in accordance with the FDA Law and Regulations for two Products developed by Borrower, then this requirement shall automatically be reduced to $1,000,000.

7.14 Deposit Accounts.

Not, and not permit any other Loan Party, to maintain or establish any new Deposit Accounts other than (a) Exempt Accounts and (b) the Deposit Accounts set forth on Schedule 7.14 (which Deposit Accounts constitute all of the Deposit Accounts, securities accounts or other similar accounts maintained by the Loan Parties as of the Closing Date) without prior written notice to Agent. Borrower or such other applicable Loan Party and the bank or other financial institution at which the account is to be opened after the Closing Date shall promptly enter into an Account Control Agreement, in form and substance reasonably satisfactory to Agent.

7.15 Subsidiaries.

Not, and not permit any other Loan Party to, in each case without the prior written consent of Agent in its sole discretion, establish or acquire any Subsidiary unless (i) no Default or Event of Default has occurred and is continuing or would result therefrom, (ii) such Subsidiary shall have assumed and joined each Loan Document as a Loan Party pursuant to documentation acceptable to Agent in its commercially-resaonable discretion and (iii) all other Loan Parties shall have reaffirmed all Obligations as well as all

representations and warranties under the Loan Documents (except to the extent such representations and warranties specifically relate to a prior date only).

7.16 Regulatory Matters.

To the extent that any of the following would reasonably be expected to result in a Material Adverse Effect, not, and not permit any other Loan Party to, (i) make, and use commercially reasonable efforts to not permit any officer, employee or agent of any Loan Party to make, any untrue statement of material fact or fraudulent statement to the FDA or any Governmental Authority; fail to disclose a material fact required to be disclosed to the FDA or any Governmental Authority; or commit a material act, make a material statement, or fail to make a statement in breach of CLIA or that could otherwise reasonably be expected to provide the basis for CMS or any Governmental Authority to undertake action against such Loan Party, (ii) conduct any clinical studies in the United States or sponsor the conduct of any clinical research in the United States, (iii) introduce into commercial distribution any FDA Products which are, upon their shipment, adulterated or misbranded in violation of 21 U.S.C. § 331, (iv) make, and use commercially reasonable efforts to not permit any officer, employee or agent of any Loan Party to make, any untrue statement of material fact or fraudulent statement to the FDA or any other Governmental Authority; fail to disclose a material fact required to be disclosed to the FDA or any other Governmental Authority; or commit a material act, make a material statement, or fail to make a statement in breach of the FD&C Act or that could otherwise reasonably be expected to provide the basis for the FDA or any other Governmental Authority to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities," as set forth in 56 Fed. Reg. 46191 (September 10, 1991), or (v) otherwise incur any material liability (whether actual or contingent) for failure to comply with Health Care Laws.

7.17 Name; Permits; Dissolution; Insurance Policies; Disposition of Collateral; Taxes; Trade Names.

Borrower shall not, nor shall it permit any Loan Party to, (a) change its jurisdiction of organization or change its corporate name without thirty (30) calendar days prior written notice to Agent, (b) amend, alter, suspend, terminate or make provisional in any material way, any Permit, the suspension, amendment, alteration or termination of which could reasonably be expected to be, have or result in a Material Adverse Effect without the prior written consent of Agent, which consent shall not be unreasonably withheld, (c) wind up, liquidate or dissolve (voluntarily or involuntarily) or commence or suffer any proceedings seeking or that would result in any of the foregoing, (d) amend, modify, restate or change any insurance policy in a manner adverse to Agent or Lenders or otherwise allow its aggregate products liability insurance coverage to be less than an amount that is commercially reasonable and consistent with customary industry practices, (e) engage, directly or indirectly, in any business other than the business it is engaged in on the Closing Date and/or sell all or any material portion of its assets without Agent's prior written approval in its commercially-reasonable discretion, (f) change its federal tax employer identification number or similar tax identification number under the relevant jurisdiction or establish new or additional trade names without providing not less than thirty (30) days advance written notice to Agent, or (g) revoke, alter or amend any Tax Information Authorization (on IRS Form 8821 or otherwise) or other similar authorization mandated by the relevant Governmental Authority given to any Lender.

7.18 Truth of Statements.

Borrower shall not knowingly furnish to Agent or any Lender any certificate or other document that contains any untrue statement of a material fact or that omits to state a material fact necessary to make it not misleading in light of the circumstances under which it was furnished.

Section 8 Events of Default; Remedies.

8.1 Events of Default.

Each of the following shall constitute an Event of Default under this Agreement:

8.1.1 Non-Payment of Credit.

(a) Default in the payment when due of all outstanding Obligations on the Termination Date; (b) default in the payment of any Revenue-Based Payment on or before the applicable Payment Date; or (c) without duplication of clause (b) hereof, default, and continuance thereof for five (5) Business Days, in the payment when due of any interest, fee, or other amount payable by any Loan Party hereunder or under any other Loan Document.

8.1.2 Default Under Other Debt.

Any default shall occur under the terms applicable to any Debt of any Loan Party (excluding the Obligations) in an aggregate principal amount (for all such Debt so affected and including undrawn committed or available amounts and amounts owing to all creditors under any combined or syndicated credit arrangement) exceeding $250,000.

8.1.3 Bankruptcy; Insolvency.

(a) Any Loan Party shall (i) be unable to pay its debts generally as they become due, (ii) file a petition under any insolvency statute, (iii) make a general assignment for the benefit of its creditors, (iv) commence a proceeding for the appointment of a receiver, trustee, liquidator or conservator of itself or of the whole or any substantial part of its property or shall otherwise be dissolved or liquidated, or (v) make an application or commence a proceeding seeking reorganization or liquidation or similar relief under any Debtor Relief Law or any other applicable law; or

(b) (i) a court of competent jurisdiction shall (A) enter an order, judgment or decree appointing a custodian, receiver, trustee, liquidator or conservator of any Loan Party or the whole or any substantial part of any of Loan Party's properties, which shall continue unstayed and in effect for a period of ninety (90) calendar days, (B) approve a petition or claim filed against any Loan Party seeking reorganization, liquidation, appointment of a receiver, interim receiver, liquidator, conservator, trustee or special manager or similar relief under the any Debtor Relief Law or any other applicable law, which is not dismissed within ninety (90) calendar days or, (C) under the provisions of any Debtor Relief Law or other applicable law or statute, assume custody or control of any Loan Party or of the whole or any substantial part of any of Loan Party's properties, which is not irrevocably relinquished within ninety (90) calendar days, or (ii) there is commenced against any Loan Party any proceeding or petition seeking reorganization, liquidation or similar relief under any Debtor Relief Law or any other applicable law or statute, which (A) is not unconditionally dismissed within ninety (90) calendar days after the date of commencement, or (B) is with respect to which Borrower takes any action to indicate its approval of or consent.

8.1.4 Non-Compliance with Loan Documents.

(a) Any failure by Borrower to comply with or to perform any covenant set forth in Section 7; or (b) failure by any Loan Party to comply with or to perform any other provision of this Agreement or any other Loan Document applicable to it (and not constituting an Event of Default under any other provision of this Section 8) and continuance of such failure described in this clause (b) for thirty (30) days

after the earlier of any Loan Party becoming aware of such failure or notice thereof to Borrower from Agent or any Lender.

8.1.5 Representations; Warranties.

Any representation or warranty made by any Loan Party herein or any other Loan Document is false or misleading in any material respect when made, or any schedule, certificate, financial statement, report, notice or other writing furnished by any Loan Party to Agent or any Lender in connection herewith is false or misleading in any material respect on the date as of which the facts therein set forth are stated or certified.

8.1.6 Pension Plans.

(a) Institution of any steps by any Person to terminate a Pension Plan if as a result of such termination any Loan Party or any member of the Controlled Group could be required to make a contribution to such Pension Plan, or could incur a liability or obligation to such Pension Plan, in excess of $250,000; (b) a contribution failure occurs with respect to any Pension Plan sufficient to give rise to a Lien under Section 303(k) of ERISA securing obligations in excess of $250,000; or (c) there shall occur any withdrawal or partial withdrawal from a Multiemployer Pension Plan and the withdrawal liability (without un-accrued interest) to Multiemployer Pension Plans as a result of such withdrawal (including any outstanding withdrawal liability that Borrower or any other Loan Party or any member of the Controlled Group have incurred on the date of such withdrawal) exceeds $250,000.

8.1.7 Judgments.

Final judgments which exceed an aggregate of $250,000 (to the extent not adequately covered by insurance as to which the insurance company has not disclaimed liability (provided that customary "reservation of rights" letters shall not be deemed to be disclaimers of liability)) shall be rendered against any Loan Party and shall not have been paid, discharged or vacated or had execution thereof stayed pending appeal within thirty (30) calendar days after entry or filing of such judgments.

8.1.8 Invalidity of Loan Documents or Liens.

(a) Any Loan Document shall cease to be in full force and effect otherwise in accordance with its express terms that results in a material diminution of the rights and remedies afforded to Agent and/or Lenders or any other secured parties thereunder; (b) any Loan Party (or any Person by, through or on behalf of any Loan Party) shall contest in any manner the validity, binding nature or enforceability of any Loan Document; or (c) any Lien created pursuant to any Loan Document ceases to constitute a valid first priority perfected Lien (subject to Permitted Liens) on any material portion of the Collateral in accordance with the terms thereof, or Agent ceases to have a valid perfected first priority security interest (subject to Permitted Liens) in any material portion of the Collateral pledged to Agent, for the benefit of Agent and Lenders, pursuant to the Collateral Documents.

8.1.9 Invalidity of Subordination Provisions.

Any subordination provision in any intercreditor agreement shall cease to be in full force and effect, or any Loan Party shall contest in any manner the validity, binding nature or enforceability of any such provision.

8.1.10 Change of Control.

A Change of Control not otherwise permitted pursuant to Section 7.4 above shall occur that does not result in the payment in full of all Obligations hereunder in accordance with Section 2.8.3.

8.1.11 Certificate Withdrawals, Adverse Test or Audit Results, and Other Matters.

(a) The institution of any proceeding by FDA, CMS, or any other Governmental Authority to order the withdrawal of any Product or Product category or Service or Service category from the market or to enjoin Borrower or any of its Affiliates from manufacturing, marketing, selling, distributing, or otherwise providing any Product or Product category or Service or Service category that could reasonably be expected to have a Material Adverse Effect, (b) the institution of any action or proceeding by DEA, FDA, CMS, or any other Governmental Authority to revoke, suspend, reject, withdraw, limit, or restrict any Required Permit held by Borrower or any of its Affiliates or any of their representatives, which, in each case, could reasonably be expected to have a Material Adverse Effect, (c) the commencement of any enforcement action against Borrower or any of its Affiliates by DEA, FDA, CMS, or any other Governmental Authority that could reasonably be expected to have a Material Adverse Effect, (d) the recall of any Products or Service from the market, the voluntary withdrawal of any Products or Service from the market, or actions to discontinue the sale of any Products or Service that could reasonably be expected to have a Material Adverse Effect, (e) the occurrence of adverse test, audit, or inspection results in connection with a Product or Service which could reasonably be expected to have a Material Adverse Effect, or (f) the occurrence of any event described in clauses (a) through (e) above that would otherwise cause Borrower to be excluded from participating in any federal, provincial, state or local health care programs under Section 1128 of the Social Security Act or any similar law or regulation.

8.1.12 Material Adverse Effect.

Any Material Adverse Effect shall occur that is not otherwise provided for in this Section 8.1.

8.2 Remedies.

(a) If any Event of Default described in Section 8.1.3 shall occur, the Loan and all other Obligations shall become immediately due and payable without presentment, demand, protest or notice of any kind; and, if any other Event of Default shall occur and be continuing, Agent may, and upon the written request of Required Lenders shall, declare all or any part of the Loans and other Obligations to be due and payable, whereupon the Loans and other Obligations (including without limitation the Exit Fee and any amounts due pursuant to Section 2.8.2 hereof, payable with respect thereto) shall become immediately due and payable (in whole or in part, as applicable), all without presentment, demand, protest or notice of any kind. Agent shall use commercially reasonable efforts to promptly advise Borrower of any such declaration, but failure to do so shall not impair the effect of such declaration.

(b) In addition to the acceleration provisions set forth in Section 8.2(a) above, upon the occurrence and continuation of an Event of Default, Agent may (or shall at the request of Required Lenders) exercise any and all rights, options and remedies provided for in any Loan Document, under the Uniform Commercial Code, any other applicable foreign or domestic laws or otherwise at law or in equity, including, without limitation, the right to (i) apply any property of Borrower held by Agent to reduce the Obligations, (ii) foreclose the Liens created under the Loan Documents, (iii) realize upon, take possession of and/or sell any Collateral or securities pledged, with or without judicial process, (iv) exercise all rights and powers with respect to the Collateral as Borrower might exercise, (v) collect and send notices regarding

the Collateral, with or without judicial process, (vi) by its own means or with judicial assistance, enter any premises at which Collateral and/or pledged securities are located, or render any of the foregoing unusable or dispose of the Collateral and/or pledged securities on such premises without any liability for rent, storage, utilities, or other sums, and Borrower shall not resist or interfere with such action, (vii) at Borrower's expense, require that all or any part of the Collateral be assembled and made available to Agent, for the benefit of Agent and Lenders, or Required Lenders at any place reasonably designated by Required Lenders in their sole discretion and/or relinquish or abandon any Collateral or securities pledged or any Lien thereon.

(c) The enumeration of any rights and remedies in any Loan Document is not intended to be exhaustive, and all rights and remedies of Agent and Lenders described in any Loan Document are cumulative and are not alternative to or exclusive of any other rights or remedies which Agent and Lenders otherwise may have. The partial or complete exercise of any right or remedy shall not preclude any other further exercise of such or any other right or remedy.

(d) Notwithstanding any provision of any Loan Document, Agent, in its sole discretion shall have the right, but not any obligation, at any time that Loan Parties fail to do so, subject to any applicable cure periods permitted by or otherwise set forth in the Loan Documents, and from time to time, without prior notice, to: (i) discharge (at Borrower's expense) taxes or Liens affecting any of the Collateral that have not been paid in violation of any Loan Document or that jeopardize Agent's Lien priority in the Collateral; or (ii) make any other payment (at Borrower's expense) for the administration, servicing, maintenance, preservation or protection of the Collateral (each such advance or payment set forth in clauses (i) and (ii) herein, a "Protective Advance"). Agent shall be reimbursed for all Protective Advances pursuant to Section 2.9.1(b) and/or Section 2.10, as applicable, and any Protective Advances shall bear interest at the Default Rate from the date such Protective Advance is paid by Agent until it is repaid. No Protective Advance by Agent shall be construed as a waiver by Agent, or any Lender of any Default, Event of Default or any of the rights or remedies of Agent or any Lender under any Loan Document.

Section 9 Agent.

9.1 Appointment; Authorization.

Each Lender hereby irrevocably appoints, designates and authorizes Agent to take such action on its behalf under the provisions of this Agreement and each other Loan Document and to exercise such powers and perform such duties as are expressly delegated to it by the terms of this Agreement or any other Loan Document, together with such powers as are reasonably incidental thereto. Notwithstanding any provision to the contrary contained elsewhere in this Agreement or in any other Loan Document, Agent shall not have any duty or responsibility except those expressly set forth herein, nor shall Agent have or be deemed to have any fiduciary relationship with any Lender, and no implied covenants, functions, responsibilities, duties, obligations or liabilities shall be read into this Agreement or any other Loan Document or otherwise exist against Agent.

9.2 Delegation of Duties.

Agent may execute any of its duties under this Agreement or any other Loan Document by or through agents, employees or attorneys-in-fact and shall be entitled to advice of counsel concerning all matters pertaining to such duties. Agent shall not be responsible for the negligence or misconduct of any agent or attorney-in-fact that it selects with reasonable care.

9.3 Limited Liability.

None of Agent or any of its Affiliates, directors, officers, employees or agents shall (a) be liable for any action taken or omitted to be taken by any of them under or in connection with this Agreement or any other Loan Document or the transactions contemplated hereby (except to the extent resulting from its own gross negligence or willful misconduct as determined by a court of competent jurisdiction), or (b) be responsible in any manner to any Lender for any recital, statement, representation or warranty made by any Loan Party or Affiliate of any Loan Party, or any officer thereof, contained in this Agreement or in any other Loan Document, or in any certificate, report, statement or other document referred to or provided for in, or received by Agent under or in connection with, this Agreement or any other Loan Document, or the validity, effectiveness, genuineness, enforceability or sufficiency of this Agreement or any other Loan Document (or the creation, perfection or priority of any Lien or security interest therein), or for any failure of any Loan Party or any other party to any Loan Document to perform its Obligations hereunder or thereunder. Agent shall not be under any obligation to any Lender to ascertain or to inquire as to the observance or performance of any of the agreements contained in, or conditions of, this Agreement or any other Loan Document, or to inspect the properties, books or records of any Loan Party or Affiliate of any Loan Party.

9.4 Reliance.

Agent shall be entitled to rely, and shall be fully protected in relying, upon any writing, resolution, notice, consent, certificate, affidavit, letter, telegram, facsimile, telex or telephone message, statement or other document believed by it to be genuine and correct and to have been signed, sent or made by the proper Person or Persons, and upon advice and statements of legal counsel (including counsel to any Loan Party), independent accountants and other experts selected by Agent. Agent shall be fully justified in failing or refusing to take any action under this Agreement or any other Loan Document unless it shall first receive such advice or concurrence of Required Lenders (or all Lenders if expressly required hereunder) as it deems appropriate and, if it so requests, confirmation from Lenders of their obligation to indemnify Agent against any and all liability and expense which may be incurred by it by reason of taking or continuing to take any such action. Agent shall in all cases be fully protected in acting, or in refraining from acting, under this Agreement or any other Loan Document in accordance with a request or consent of Required Lenders (or all Lenders if expressly required hereunder) and such request and any action taken or failure to act pursuant thereto shall be binding upon each Lender.

9.5 Notice of Default.

Agent shall not be deemed to have knowledge or notice of the occurrence of any Event of Default or Default except with respect to defaults in the payment of principal, interest and fees required to be paid to Agent for the account of Lenders, unless Agent shall have received written notice from a Lender or Borrower referring to this Agreement, describing such Event of Default or Default and stating that such notice is a "notice of default." Agent will notify Lenders of its receipt of any such notice or any such default in the payment of principal, interest and fees required to be paid to Agent for the account of Lenders. Agent shall take such action with respect to such Event of Default or Default as may be requested by Required Lenders in accordance with Section 8.2; *provided* that unless and until Agent has received any such request, Agent may (but shall not be obligated to) take such action, or refrain from taking such action, with respect to such Event of Default or Default as it shall deem advisable or in the best interest of Lenders.

9.6 Credit Decision.

Each Lender acknowledges that Agent has not made any representation or warranty to it, and that no act by Agent hereafter taken, including any review of the affairs of Borrower and the other Loan

Parties, shall be deemed to constitute any representation or warranty by Agent to any Lender. Each Lender represents to Agent that it has, independently and without reliance upon Agent and based on such documents and information as it has deemed appropriate, made its own appraisal of and investigation into the business, prospects, operations, property, financial and other condition and creditworthiness of Borrower, and made its own decision to enter into this Agreement and to extend credit to Borrower hereunder. Each Lender also represents that it will, independently and without reliance upon Agent and based on such documents and information as it shall deem appropriate at the time, continue to make its own credit analysis, appraisals and decisions in taking or not taking action under this Agreement and the other Loan Documents, and to make such investigations as it deems necessary to inform itself as to the business, prospects, operations, property, financial and other condition and creditworthiness of the Loan Parties. Except for notices, reports and other documents expressly herein required to be furnished to Lenders by Agent, Agent shall not have any duty or responsibility to provide any Lender with any credit or other information concerning the business, prospects, operations, property, financial or other condition or creditworthiness of any Loan Party which may come into the possession of Agent.

9.7 Indemnification.

Whether or not the transactions contemplated hereby are consummated, each Lender shall indemnify upon demand Agent and its Affiliates, directors, officers, employees and agents (to the extent not reimbursed by or on behalf of Borrower and without limiting the obligation of Borrower to do so), based on such Lender's Pro Rata Term Loan Share, from and against any and all actions, causes of action, suits, losses, liabilities, damages and expenses, including Legal Costs, except to the extent any thereof result from the applicable Person's own gross negligence or willful misconduct, as determined by a court of competent jurisdiction. Without limitation of the foregoing, each Lender shall reimburse Agent upon demand for its ratable share of any costs or out-of-pocket expenses (including Legal Costs) incurred by Agent in connection with the preparation, execution, delivery, administration, modification, amendment or enforcement (whether through negotiations, legal proceedings or otherwise) of, or legal advice in respect of rights or responsibilities under, this Agreement, any other Loan Document, or any document contemplated by or referred to herein, to the extent that Agent is not reimbursed for such expenses by or on behalf of Borrower. The undertaking in this Section 9.7 shall survive repayment of the Loans, cancellation of the Notes, any foreclosure under, or modification, release or discharge of, any or all of the Collateral Documents, termination of this Agreement and the resignation or replacement of Agent.

9.8 Agent Individually.

SWK and its Affiliates may make loans to, issue letters of credit for the account of, accept deposits from, acquire equity interests in and generally engage in any kind of banking, trust, financial advisory, underwriting or other business with any Loan Party and any Affiliate of any Loan Party as though SWK were not Agent hereunder and without notice to or consent of any Lender. Each Lender acknowledges that, pursuant to such activities, SWK or its Affiliates may receive information regarding Loan Parties or their Affiliates (including information that may be subject to confidentiality obligations in favor of any such Loan Party or such Affiliate) and acknowledge that Agent shall be under no obligation to provide such information to them. With respect to their Loans (if any), SWK and its Affiliates shall have the same rights and powers under this Agreement as any other Lender and may exercise the same as though SWK were not Agent, and the terms "Lender" and "Lenders" include SWK and its Affiliates, to the extent applicable, in their individual capacities.

9.9 Successor Agent.

Agent may resign as Agent at any time upon 30 days' prior notice to Lenders and Borrower (unless during the existence of an Event of Default such notice is waived by Required Lenders). If Agent

resigns under this Agreement, Required Lenders shall, with (so long as no Event of Default exists) the consent of Borrower (which shall not be unreasonably withheld or delayed), appoint from among Lenders a successor agent for Lenders. If no successor agent is appointed prior to the effective date of the resignation of Agent, Agent may appoint, on behalf of, and after consulting with Lenders and (so long as no Event of Default exists) Borrower, a successor agent. Upon the acceptance of its appointment as successor agent hereunder, such successor agent shall succeed to all the rights, powers and duties of the retiring Agent and the term "Agent" shall mean such successor agent, and the retiring Agent's appointment, powers and duties as Agent shall be terminated. After any retiring Agent's resignation hereunder as Agent becomes effective, the provisions of this Section 9 and Sections 10.4 and 10.5 shall continue to inure to its benefit as to any actions taken or omitted to be taken by it while it was Agent under this Agreement. If no successor agent has accepted appointment as Agent by the date which is thirty (30) days following a retiring Agent's notice of resignation, the retiring Agent's resignation shall nevertheless thereupon become effective and Lenders shall perform all of the duties of Agent hereunder until such time, if any, as Required Lenders appoint a successor agent as provided for above; *provided* that in the case of any collateral security held by Agent for the benefit of Agent and Lenders under any of the Loan Documents, the retiring Agent shall continue so to hold such collateral security until such time as a successor Agent is appointed and the provisions of this Section 9 and Sections 10.4 and 10.5 shall continue to inure to its benefit so long as retiring Agent shall continue to so hold such collateral security. Upon the acceptance of a successor's appointment as Agent hereunder, the retiring Agent shall be discharged from all of its duties and obligations hereunder or under the other Loan Documents in respect of the Collateral.

9.10 Collateral and Guarantee Matters.

Lenders irrevocably authorize Agent, at its option and in its discretion, (a) to release any Lien granted to or held by Agent under any Collateral Document (i) when all Obligations have been Paid in Full; (ii) constituting property sold or to be sold or disposed of as part of or in connection with any sale or other disposition permitted hereunder (including by consent, waiver or amendment and it being agreed and understood that Agent may conclusively rely without further inquiry on a certificate of an officer of Borrower as to the sale or other disposition of property being made in compliance with this Agreement); or (iii) subject to Section 10.1, if approved, authorized or ratified in writing by Required Lenders; (b) notwithstanding Section 10.1(a)(ii) hereof to release any party from its guaranty under the Guarantee and Collateral Agreement (i) when all Obligations have been Paid in Full or (ii) if such party was sold or is to be sold or disposed of as part of or in connection with any disposition permitted hereunder (including by consent, waiver or amendment and it being agreed and understood that Agent may conclusively rely without further inquiry on a certificate of an officer of Borrower as to the sale or other disposition being made in compliance with this Agreement); or (c) to subordinate its interest in any Collateral to any holder of a Lien on such Collateral which is permitted by Section 7.2(d) (it being understood that Agent may conclusively rely on a certificate from Borrower in determining whether the Debt secured by any such Lien is permitted by Section 7.1). Upon request by Agent at any time, Lenders will confirm in writing Agent's authority to release, or subordinate its interest in, particular types or items of Collateral pursuant to this Section 9.10.

Agent shall release any Lien granted to or held by Agent under any Collateral Document (i) when all Obligations have been Paid in Full, (ii) in respect of property sold or to be sold or disposed of as part of or in connection with any sale or other disposition permitted hereunder (it being agreed and understood that Agent may conclusively rely without further inquiry on a certificate of an officer of Borrower as to the sale or other disposition of property being made in compliance with this Agreement) or (iii) subject to Section 10.1, if directed to do so in writing by Required Lenders.

In furtherance of the foregoing, Agent agrees to execute and deliver to Borrower, at Borrower's expense, such termination and release documentation as Borrower may reasonably request to evidence a Lien release that occurs pursuant to terms of this Section 9.10.

9.11 Intercreditor Agreements.

Each Lender hereby irrevocably appoints, designates and authorizes Agent to enter into one or more intercreditor agreements in relation to any other Debt of Borrower entered into in accordance with this Agreement or as otherwise approved by Required Lenders, on its behalf and to take such action on its behalf under the provisions of any such agreement (subject to the last sentence of this Section 9.11). Each Lender further agrees to be bound by the terms and conditions of any such intercreditor agreement. Each Lender hereby authorizes Agent to issue blockages notices in connection with any such Debt of Borrower and such intercreditor agreement, or any replacement intercreditor agreement, in its discretion or, at the direction of Required Lenders.

9.12 Actions in Concert.

For the sake of clarity, each Lender hereby agrees with each other Lender that no Lender shall take any action to protect or enforce its rights arising out of this Agreement, the Notes or any other Loan Document (including exercising any rights of set-off) without first obtaining the prior written consent of Agent and Required Lenders, it being the intent of Lenders that any such action to protect or enforce rights under this Agreement, the Notes and the other Loan Documents shall be taken in concert and at the direction or with the consent of Agent or Required Lenders.

Section 10 Miscellaneous.

10.1 Waiver; Amendments.

(a) Except as otherwise expressly provided in this Agreement, no amendment, modification or waiver of, or consent with respect to, any provision of this Agreement or any of the other Loan Documents shall in any event be effective unless the same shall be in writing and signed by Borrower (with respect to Loan Documents to which Borrower is a party), by Lenders having aggregate Pro Rata Term Loan Shares of not less than the aggregate Pro Rata Term Loan Shares expressly designated herein with respect thereto or, in the absence of such express designation herein, by Required Lenders, and then any such amendment, modification, waiver or consent shall be effective only in the specific instance and for the specific purpose for which given; *provided*, *however*, that:

(i) no such amendment, modification, waiver or consent shall, unless in writing and signed by all of the Lenders directly affected thereby, in addition to Required Lenders and Borrower, do any of the following: (A) increase any of the Commitments (*provided* that only the Lenders participating in any such increase of the Commitments shall be considered directly affected by such increase), (B) extend the date scheduled for payment of any principal of (except as otherwise expressly set forth below in clause (C)) or interest on the Loans or any fees or other amounts payable hereunder or under the other Loan Documents, or (C) reduce the principal amount of any Loan, the amount or rate of interest thereon (*provided* that Required Lenders may rescind an imposition of default interest pursuant to Section 2.6.1), or any fees or other amounts payable hereunder or under the other Loan Documents; and

(ii) no such amendment, modification, waiver or consent shall, unless in writing and signed by all of the Lenders in addition to Borrower (with respect to Loan Documents to which Borrower is a party), do any of the following: (A) release any material guaranty under the Guarantee and Collateral Agreement or release all or substantially all of the Collateral granted under the Collateral Documents, except as otherwise specifically provided in this Agreement or the other Loan Documents, (B) change the definition of Required Lenders, (C) change any provision of this Section 10.1, (D) amend the provisions of Section 2.10.2 or Section 2.10.4, or (E) reduce

the aggregate Pro Rata Term Loan Shares required to effect any amendment, modification, waiver or consent under the Loan Documents.

(b) No amendment, modification, waiver or consent shall, unless in writing and signed by Agent, in addition to Borrower and Required Lenders (or all Lenders directly affected thereby or all of the Lenders, as the case may be, in accordance with the provisions above), affect the rights, privileges, duties or obligations of Agent (including without limitation under the provisions of Section 9), under this Agreement or any other Loan Document.

(c) No delay on the part of Agent or any Lender in the exercise of any right, power or remedy shall operate as a waiver thereof, nor shall any single or partial exercise by any of them of any right, power or remedy preclude other or further exercise thereof, or the exercise of any other right, power or remedy.

10.2 Notices.

All notices hereunder shall be in writing (including via electronic mail) and shall be sent to the applicable party at its address shown on Annex II or at such other address as such party may, by written notice received by the other parties, have designated as its address for such purpose. Notices sent by electronic mail transmission shall be deemed to have been given when sent if sent during regular business hours on a Business Day, otherwise, such deemed delivery will be effective as of the next Business Day; notices sent by mail shall be deemed to have been given five (5) Business Days after the date when sent by mail, first class postage prepaid; and notices sent by hand delivery, registered or certified mail, or overnight courier service shall be deemed to have been given when received. Borrower, Agent and Lenders each hereby acknowledge that, from time to time, Agent, Lenders and Borrower may deliver information and notices using electronic mail.

10.3 Computations.

Unless otherwise specifically provided herein, any accounting term used in this Agreement shall have the meaning customarily given such term in accordance with GAAP, and all financial computations hereunder shall be computed in accordance with GAAP consistently applied. The explicit qualification of terms or computations by the phrase "in accordance with GAAP" shall in no way be construed to limit the foregoing. Notwithstanding any other provision contained herein, all terms of an accounting or financial nature used herein shall be construed, and all computations of amounts and ratios referred to herein shall be made, without giving effect to any election under Statement of Financial Accounting Standards 159 (Codification of Accounting Standards 825-10) to value any Debt or other liabilities of any Loan Party or any Subsidiary at "fair value", as defined therein.

10.4 Costs; Expenses.

Borrower agrees to pay on demand the reasonable, out-of-pocket costs and expenses of (a) Agent (including Legal Costs) in connection with (i) the preparation, execution, syndication and delivery (including perfection and protection of Collateral) of this Agreement, the other Loan Documents and all other documents provided for herein or delivered or to be delivered hereunder or in connection herewith; provided Borrower's reimbursement obligations for Agent's costs and expenses incurred prior to the Closing Date shall not exceed $125,000, (ii) the administration of the Loans and the Loan Documents, and (iii) any proposed or actual amendment, supplement or waiver to any Loan Document, and (b) Agent and Lenders (including Legal Costs) in connection with the collection of the Obligations and enforcement of this Agreement, the other Loan Documents or any such other documents. In addition, Borrower agrees to pay and to save Agent and Lenders harmless from all liability for, any fees of Borrower's auditors in

connection with any reasonable exercise by Agent and Lenders of their rights pursuant to and to the extent provided in Section 6.2. All Obligations provided for in this Section 10.4 shall survive repayment of the Loans, cancellation of the Notes, and termination of this Agreement.

10.5 Indemnification by Borrower.

In consideration of the execution and delivery of this Agreement by Agent and Lenders and the agreement to extend the Commitments provided hereunder, Borrower hereby agrees to indemnify, exonerate and hold Agent, each Lender and each of the officers, directors, employees, Affiliates and agents of Agent and each Lender (each a "Lender Party") free and harmless from and against any and all actions, causes of action, suits, losses, liabilities, damages and expenses, including Legal Costs (collectively, the "Indemnified Liabilities"), incurred by Lender Parties or any of them as a result of, or arising out of, or relating to any Loan Party or any of their respective officers, directors or agents, including, without limitation, (a) any tender offer, merger, purchase of equity interests, purchase of assets or other similar transaction financed or proposed to be financed in whole or in part, directly or indirectly, with the proceeds of any of the Loans, (b) the use, handling, release, emission, discharge, transportation, storage, treatment or disposal of any Hazardous Substance at any property owned or leased by Borrower or any other Loan Party, (c) any violation of any Environmental Laws with respect to conditions at any property owned or leased by any Loan Party or the operations conducted thereon, (d) the investigation, cleanup or remediation of offsite locations at which any Loan Party or their respective predecessors are alleged to have directly or indirectly disposed of Hazardous Substances, (e) the execution, delivery, performance or enforcement of this Agreement or any other Loan Document by any Lender Party, except to the extent any such Indemnified Liabilities result solely from the applicable Lender Party's own gross negligence or willful misconduct as finally determined by a court of competent jurisdiction in a non-appealable judgment, or (f) such Person's general operation of its business including all product liability out of or in connection with such Person's or any of its Affiliates or licensees manufacture use or sale of a Product or the provision of a Service. If and to the extent that the foregoing undertaking may be unenforceable for any reason, Borrower hereby agrees to make the maximum contribution to the payment and satisfaction of each of the Indemnified Liabilities which is permissible under applicable law. All Obligations provided for in this Section 10.5 shall survive repayment of the Loans, cancellation of the Notes, any foreclosure under, or any modification, release or discharge of, any or all of the Collateral Documents and termination of this Agreement.

10.6 Marshaling; Payments Set Aside.

Neither Agent nor any Lender shall be under any obligation to marshal any assets in favor of Borrower or any other Person or against or in payment of any or all of the Obligations. To the extent that Borrower makes a payment or payments to Agent or any Lender, or Agent or any Lender enforces its Liens or exercises its rights of set-off, and such payment or payments or the proceeds of such enforcement or set-off or any part thereof are subsequently invalidated, declared to be fraudulent or preferential, set aside or required (including pursuant to any settlement entered into by Agent or any Lender in its discretion) to be repaid to a trustee, receiver or any other party in connection with any bankruptcy, insolvency or similar proceeding, or otherwise, then (a) to the fullest extent permitted by applicable law, to the extent of such recovery, the obligation hereunder or part thereof originally intended to be satisfied shall be revived and continued in full force and effect as if such payment had not been made or such enforcement or set-off had not occurred and (b) each Lender severally agrees to pay to Agent upon demand its ratable share of the total amount so recovered from or repaid by Agent to the extent paid to such Lender.

10.7 Nonliability of Lenders.

The relationship between Borrower on the one hand and Lenders and Agent on the other hand shall be solely that of borrower and lender. Neither Agent nor any Lender shall have any fiduciary

responsibility to Borrower. Neither Agent nor any Lender undertakes any responsibility to Borrower to review or inform Borrower of any matter in connection with any phase of Borrower's business or operations. To the fullest extent permitted under applicable law, execution of this Agreement by Borrower constitutes a full, complete and irrevocable release of any and all claims which Borrower may have at law or in equity in respect of all prior discussions and understandings, oral or written, relating to the subject matter of this Agreement and the other Loan Documents. Neither Agent nor any Lender shall have any liability with respect to, and Borrower hereby, to the fullest extent permitted under applicable law, waives, releases and agrees not to sue for, any special, indirect, punitive or consequential damages or liabilities. Nothing set forth in this Agreement shall be deemed a waiver by Borrower in relation to Agent's and Lenders' general duty of good faith and fair dealing to Loan Parties.

10.8 Assignments.

10.8.1 Assignments.

(a) Any Lender may at any time assign to one or more Persons (other than a Loan Party and their respective Affiliates) (any such Person, an "Assignee") all or any portion of such Lender's Loans and Commitments, with the prior written consent of Agent, and, so long as no Default or Event of Default has occurred and is continuing, Borrower (which consents shall not be unreasonably withheld or delayed), provided, however, that no such consent(s) shall be required:

(i) from Borrower for an assignment by a Lender (i) to another Lender or an Affiliate of a Lender or an Approved Fund of a Lender or (ii) to any finance company, insurance company or other financial institution that invests in commercial loans similar to the financing transaction(s) contemplated in this Agreement in the ordinary course of its business, but, in each case, such Lender will give written notice to Borrower of any such assignment;

(ii) from Agent for an assignment by a Lender to an Affiliate of a Lender or an Approved Fund of a Lender;

(iii) from Borrower or Agent for an assignment by SWK Funding LLC, as a Lender, to any Person for which SWK Advisors LLC acts as an investment advisor (or any similar type of representation or agency) pursuant to a written agreement, but SWK Funding LLC will give written notice to Borrower of any such assignment;

(iv) from Borrower or Agent for an assignment by a Lender of its Loans and its Note as collateral security to a Federal Reserve Bank or, as applicable, to such Lender's trustee for the benefit of its investors (but no such assignment shall release any Lender from any of its obligations hereunder); or

(v) from Borrower, Agent or any Lender for (A) the assignment of SWK's Loans and Commitments to a Permitted Assignee (as defined below) or (B) a collateral assignment by SWK of, and the grant by SWK of a security interest in, all of SWK's right, title and interest in, to and under each of the Loan Documents, including, without limitation, all of SWK's rights and interests in, to and under this Agreement, the Obligations and the Collateral (collectively, the "Assigned Rights"), to a Permitted Assignee, provided that no such collateral assignment shall release SWK from any of its obligations under any of the Loan Documents. In connection with any enforcement of or foreclosure upon its security interests in any of the Assigned Rights, a Permitted Assignee, upon notice to Borrower, SWK and the other Lenders, shall be entitled to substitute itself, or its designee, for SWK as a Lender under this Agreement. For purposes hereof, the term "Permitted Assignee" shall mean any lender to or funding source of SWK or its Affiliate,

together with its successors, assigns or designees (including, without limitation, any purchaser or other assignee of the Assigned Rights from such Person). Effective immediately upon the replacement of SWK as a Lender under this Agreement by a Permitted Assignee in accordance with this clause (v), SWK shall automatically be deemed to have resigned as Agent pursuant to Section 9.9 of this Agreement (without the need for Agent giving advance written notice of such resignation as required pursuant to such Section 9.9), and Required Lenders shall appoint a successor Agent in accordance with Section 9.9 of this Agreement.

(b) From and after the date on which the conditions described above have been met, (i) such Assignee shall be deemed automatically to have become a party hereto and, to the extent that rights and obligations hereunder have been assigned to such Assignee pursuant to such Assignment Agreement, shall have the rights and obligations of a Lender hereunder and (ii) the assigning Lender, to the extent that rights and obligations hereunder have been assigned by it pursuant to such Assignment Agreement, shall be released from its rights (other than its indemnification rights) and obligations hereunder. Upon the request of the Assignee (and, as applicable, the assigning Lender) pursuant to an effective Assignment Agreement, Borrower shall execute and deliver to Agent for delivery to the Assignee (and, as applicable, the assigning Lender) a Note in the principal amount of the Assignee's Pro Rata Term Loan Share (and, as applicable, a Note in the principal amount of the Pro Rata Term Loan Share retained by the assigning Lender). Each such Note shall be dated the effective date of such assignment. Upon receipt by the assigning Lender of such Note, the assigning Lender shall return to Borrower any prior Note held by it.

(c) Agent, acting solely for this purpose as an agent of Borrower, shall maintain at one of its offices in the United States a copy of each Assignment Agreement delivered to it and a register for the recordation of the names and addresses of each Lender, and the Commitments of, and principal amount of the Loans owing to, such Lender pursuant to the terms hereof. The entries in such register shall be, in the absence of manifest error, conclusive, and Borrower, Agent and Lenders may treat each Person whose name is recorded therein pursuant to the terms hereof as a Lender hereunder for all purposes of this Agreement, notwithstanding notice to the contrary. Such register shall be available for inspection by Borrower and any Lender, at any reasonable time upon reasonable prior notice to Agent.

(d) Notwithstanding the foregoing provisions of this Section 10.8.1 or any other provision of this Agreement, any Lender may at any time assign all or any portion of its Loans and its Note (i) as collateral security to a Federal Reserve Bank or, as applicable, to such Lender's trustee for the benefit of its investors (but no such assignment shall release any Lender from any of its obligations hereunder) and (ii) to (*w*) an Affiliate of such Lender which is at least fifty percent (50%) owned (directly or indirectly) by such Lender or by its direct or indirect parent company, (*x*) its direct or indirect parent company, (*y*) to one or more other Lenders or (*z*) to an Approved Fund.

10.9 Participations.

Any Lender may at any time sell to one or more Persons participating interests in its Loans, Commitments or other interests hereunder (any such Person, a "Participant"). In the event of a sale by a Lender of a participating interest to a Participant, (a) such Lender's obligations hereunder shall remain unchanged for all purposes, (b) Borrower and Agent shall continue to deal solely and directly with such Lender in connection with such Lender's rights and obligations hereunder and (c) all amounts payable by Borrower shall be determined as if such Lender had not sold such participation and shall be paid directly to such Lender. No Participant shall have any direct or indirect voting rights hereunder except with respect to any event described in Section 10.1 expressly requiring the unanimous vote of all Lenders or, as applicable, all affected Lenders. Each Lender agrees to incorporate the requirements of the preceding sentence into each participation agreement which such Lender enters into with any Participant. Borrower

agrees, to the fullest extent permitted by applicable law, that if amounts outstanding under this Agreement are due and payable (as a result of acceleration or otherwise), each Participant shall be deemed to have the right of set-off in respect of its participating interest in amounts owing under this Agreement to the same extent as if the amount of its participating interest were owing directly to it as a Lender under this Agreement; *provided* that such right of set-off shall be subject to the obligation of each Participant to share with Lenders, and Lenders agree to share with each Participant, as provided in Section 2.10.4. Borrower also agrees that each Participant shall be entitled to the benefits of Section 3 as if it were a Lender (*provided* that a Participant shall not be entitled to such benefits unless such Participant agrees, for the benefit of Borrower, to comply with the documentation requirements of Section 3.1(c) as if it were a Lender and complies with such requirements, and *provided*, *further*, that no Participant shall receive any greater compensation pursuant to Section 3 than would have been paid to the participating Lender if no participation had been sold). Any such Lender transferring a participation shall, as an agent for Borrower, maintain in the United States a register to record the names, address, and interest, principal and other amounts owing to, each Participant. The entries in such register shall be, in the absence of manifest error, conclusive, and Borrower, Agent and the Lenders may treat each Person whose name is recorded therein pursuant to the terms hereof as a Participant hereunder for all purposes of this Agreement, notwithstanding notice to the contrary. Such participation register shall be available for inspection by the Agent or Borrower, at any reasonable time upon reasonable prior written notice from Agent or Borrower.

10.10 Confidentiality.

Borrower, Agent and each Lender agree to use commercially reasonable efforts (equivalent to the efforts Borrower, Agent or such Lender applies to maintain the confidentiality of its own confidential information) to maintain as confidential all information (including, without limitation, any information provided by Borrower pursuant to Sections 6.1, 6.2 and 6.9) provided to them by any other party hereto and/or any other Loan Party, as applicable, except that Agent and each Lender may disclose such information (a) to Persons employed or engaged by Agent or such Lender or any of their Affiliates (including collateral managers of Lenders) in evaluating, approving, structuring or administering the Loans and the Commitments (*provided* that such Persons have been informed of the covenants contained in this Section 10.10); (b) to any assignee or participant or potential assignee or participant that has agreed to comply with the covenants contained in this Section 10.10 (and any such assignee or participant or potential assignee or participant may disclose such information to Persons employed or engaged by them as described in clause (a) above); (c) as required or requested by any federal or state regulatory authority or examiner, or any insurance industry association, or as reasonably believed by Agent or such Lender to be compelled by any court decree, subpoena or legal or administrative order or process; (d) as, on the advice of Agent's or such Lender's counsel, is required by law; (e) in connection with the exercise of any right or remedy under the Loan Documents or in connection with any litigation to which Agent or such Lender is a party; (f) to any nationally recognized rating agency or investor of a Lender that requires access to information about a Lender's investment portfolio in connection with ratings issued or investment decisions with respect to such Lender; (g) that ceases to be confidential through no fault of Agent or any Lender; (h) to a Person that is an investor or prospective investor in a Securitization that agrees that its access to information regarding Borrower and the Loans and Commitments is solely for purposes of evaluating an investment in such Securitization and who agrees to treat such information as confidential; or (i) to a Person that is a trustee, collateral manager, servicer, noteholder or secured party in a Securitization in connection with the administration, servicing and reporting on the assets serving as collateral for such Securitization. For purposes of this Section, "Securitization" means a public or private offering by a Lender or any of its Affiliates or their respective successors and assigns, of securities which represent an interest in, or which are collateralized, in whole or in part, by the Loans or the Commitments. In each case described in clauses (c), (d) and (e) (as such disclosure in clause (e) pertains to litigation only), where the Agent or Lender, as applicable, is compelled to disclose a Loan Party's confidential information, promptly after such disclosure the Agent or such Lender, as applicable, shall notify Borrower of such disclosure *provided*, *however*, that

neither the Agent nor any Lender shall be required to notify Borrower of any such disclosure (i) to any federal or state banking regulatory authority conducting an examination of the Agent or such Lender, or (ii) to the extent that it is legally prohibited from so notifying Borrower. Notwithstanding the foregoing, Agent reserves the right to provide to industry trade organizations information necessary and customary for inclusion in league table measurements.

10.11 Captions.

Captions used in this Agreement are for convenience only and shall not affect the construction of this Agreement.

10.12 Nature of Remedies.

All Obligations of Borrower and rights of Agent and Lenders expressed herein or in any other Loan Document shall be in addition to and not in limitation of those provided by applicable law. No failure to exercise and no delay in exercising, on the part of Agent or any Lender, any right, remedy, power or privilege hereunder, shall operate as a waiver thereof; nor shall any single or partial exercise of any right, remedy, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power or privilege.

10.13 Counterparts.

This Agreement may be executed in any number of counterparts and by the different parties hereto on separate counterparts and each such counterpart shall be deemed to be an original, but all such counterparts shall together constitute but one and the same Agreement. Receipt by facsimile machine or in ".pdf" format through electronic mail of any executed signature page to this Agreement or any other Loan Document shall constitute effective delivery of such signature page. This Agreement and the other Loan Documents to the extent signed and delivered by means of a facsimile machine or other electronic transmission (including ".pdf"), shall be treated in all manner and respects and for all purposes as an original agreement or amendment and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. No party hereto or to any such other Loan Document shall raise the use of a facsimile machine or other electronic transmission to deliver a signature or the fact that any signature or agreement or amendment was transmitted or communicated through the use of a facsimile machine or other electronic transmission as a defense to the formation or enforceability of a contract and each such party forever waives any such defense.

10.14 Severability.

The illegality or unenforceability of any provision of this Agreement or any instrument or agreement required hereunder shall not in any way affect or impair the legality or enforceability of the remaining provisions of this Agreement or any instrument or agreement required hereunder.

10.15 Entire Agreement.

This Agreement, together with the other Loan Documents, embodies the entire agreement and understanding among the parties hereto and supersedes all prior or contemporaneous agreements and understandings of such Persons, verbal or written, relating to the subject matter hereof and thereof.

10.16 Successors; Assigns.

This Agreement shall be binding upon Borrower, Lenders and Agent and their respective successors and assigns, and shall inure to the benefit of Borrower, Lenders and Agent and the successors and assigns of Lenders and Agent. No other Person shall be a direct or indirect legal beneficiary of, or have any direct or indirect cause of action or claim in connection with, this Agreement or any of the other Loan Documents. Borrower may not assign or transfer any of its rights or Obligations under this Agreement without the prior written consent of Agent and each Lender.

10.17 Governing Law.

THIS AGREEMENT AND EACH NOTE SHALL BE A CONTRACT MADE UNDER AND GOVERNED BY THE INTERNAL LAWS OF THE STATE OF NEW YORK APPLICABLE TO CONTRACTS MADE AND TO BE PERFORMED ENTIRELY WITHIN SUCH STATE, WITHOUT REGARD TO CONFLICT OF LAWS PRINCIPLES (OTHER THAN SECTION 5-1401 AND SECTION 5-1402 OF THE NEW YORK GENERAL OBLIGATIONS CODE).

10.18 Forum Selection; Consent to Jurisdiction.

ANY LITIGATION BASED HEREON, OR ARISING OUT OF, UNDER, OR IN CONNECTION WITH THIS AGREEMENT OR ANY OTHER LOAN DOCUMENT, SHALL BE BROUGHT AND MAINTAINED EXCLUSIVELY IN THE COURTS OF THE STATE OF NEW YORK OR IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK; *PROVIDED* THAT ANY SUIT SEEKING ENFORCEMENT AGAINST ANY COLLATERAL OR OTHER PROPERTY MAY BE BROUGHT, AT AGENT'S OPTION, IN THE COURTS OF ANY JURISDICTION WHERE SUCH COLLATERAL OR OTHER PROPERTY MAY BE FOUND. EACH PARTY HEREBY EXPRESSLY AND IRREVOCABLY SUBMITS TO THE JURISDICTION OF THE COURTS OF THE STATE OF NEW YORK AND OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK FOR THE PURPOSE OF ANY SUCH LITIGATION AS SET FORTH ABOVE. EACH PARTY FURTHER IRREVOCABLY CONSENTS TO THE SERVICE OF PROCESS BY REGISTERED MAIL, U.S. FIRST CLASS POSTAGE PREPAID, OR BY PERSONAL SERVICE WITHIN OR WITHOUT THE STATE OF NEW YORK. EACH PARTY HEREBY EXPRESSLY AND IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED UNDER APPLICABLE LAW, ANY OBJECTION WHICH IT MAY NOW OR HEREAFTER HAVE TO THE LAYING OF VENUE OF ANY SUCH LITIGATION BROUGHT IN ANY SUCH COURT REFERRED TO ABOVE AND ANY CLAIM THAT ANY SUCH LITIGATION HAS BEEN BROUGHT IN AN INCONVENIENT FORUM.

10.19 Waiver of Jury Trial.

EACH OF BORROWER, AGENT AND EACH LENDER, TO THE FULLEST EXTENT PERMITTED UNDER APPLICABLE LAW, HEREBY WAIVES ANY RIGHT TO A TRIAL BY JURY IN ANY ACTION OR PROCEEDING TO ENFORCE OR DEFEND ANY RIGHTS UNDER THIS AGREEMENT, ANY NOTE, ANY OTHER LOAN DOCUMENT AND ANY AMENDMENT, INSTRUMENT, DOCUMENT OR AGREEMENT DELIVERED OR WHICH MAY IN THE FUTURE BE DELIVERED IN CONNECTION HEREWITH OR THEREWITH OR ARISING FROM ANY LENDING RELATIONSHIP EXISTING IN CONNECTION WITH ANY OF THE FOREGOING, AND AGREES THAT ANY SUCH ACTION OR PROCEEDING SHALL BE TRIED BEFORE A COURT AND NOT BEFORE A JURY.

10.20 Patriot Act.

Each Lender that is subject to the USA Patriot Act (Title III of Pub. L. 107-56 (signed into law October 26, 2001)) (the "Patriot Act"), and Agent (for itself and not on behalf of any Lender), hereby notifies each Loan Party that, pursuant to the requirements of the Patriot Act, such Lender and Agent are required to obtain, verify and record information that identifies each Loan Party, which information includes the name and address of each Loan Party and other information that will allow such Lender or Agent, as applicable, to identify each Loan Party in accordance with the Patriot Act.

10.21 Independent Nature of Relationship.

Nothing herein contained shall constitute any Loan Party and SWK as a partnership, an association, a joint venture or any other kind of entity or legal form or constitute any party the agent of the other. No party shall hold itself out contrary to the terms of this Section 10.21 and no party shall become liable by any representation, act or omission of the other contrary to the provisions hereof. No Loan Party, Lender, nor SWK has any fiduciary or other special relationship with the other party hereto or any of its Affiliates. The Loan Parties and SWK agree that SWK is not involved in or responsible for the manufacture, marketing or sale of any Product or the provision of any Service.

[*Remainder of page intentionally blank; signature pages follow.*]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed and delivered by their duly authorized officers as of the date first set forth above.

BORROWER:

ETON PHARMACEUTICALS, INC.,
a Delaware corporation

By: 
Name: W. Wilson Troutman
Title: Chief Financial Officer

AGENT AND LENDERS:

SWK FUNDING LLC, a Delaware limited liability company, as Agent and a Lender

By: SWK Holdings Corporation, a Delaware corporation, its sole Manager

By: _____
Name: Winston Black
Title: Chief Executive Officer

ANNEX I

Commitments and Pro Rata Term Loan Shares

Lender	Commitment	Pro Rata Term Loan Share
SWK Funding LLC	$10,000,000	100%

ANNEX II

Addresses

Party	Notice Address
Agent:	SWK Funding LLC 14755 Preston Road, Suite 105 Dallas, Texas 75254 Email: notifications@swkhold.com with a copy to: Holland & Knight LLP 200 Crescent Court, Suite 1600 Dallas, Texas 75201 Attn: Ryan Magee Email: ryan.magee@hklaw.com
Borrower:	Eton Pharmaceuticals, Inc. 21925 W Field Parkway, Suite 235 Deer Park, IL 60010 Attn: Sean Brynjelsen with a copy to: Fairchild Morgan Law 150 S Wacker Dr., Suite 2400 Chicago, IL 60606 Attn: Geoffrey R. Morgan Email: gmorgan@fairchildmorgan.com

EXHIBIT A

Form of Assignment Agreement

This ASSIGNMENT AGREEMENT (the "Assignment Agreement") is entered into as of [_____] [_], 20[__], by and between the Assignor named on the signature page hereto ("Assignor") and the Assignee named on the signature page hereto ("Assignee"). Reference is made to the Credit Agreement dated as of November 13, 2019, (as amended, restated, supplemented, or otherwise modified from time to time, the "Credit Agreement") among ETON PHARMACEUTICALS, INC., a Delaware corporation ("Borrower"), the Lenders party thereto from time to time ("Lenders"), and SWK FUNDING LLC, a Delaware limited liability company, as administrative agent (in such capacity, together with its successors and assigns, the "Agent") on behalf of the Lenders. Capitalized terms used herein and not otherwise defined shall have the meanings assigned to them in the Credit Agreement.

Assignor and Assignee agree as follows:

1. For an agreed consideration, Assignor hereby irrevocably sells and assigns to Assignee, and the Assignee hereby irrevocably purchases and assumes from Assignor, subject to and in accordance with the Credit Agreement, as of the Effective Date (as defined below) (a) all of Assignors' rights and obligations in its capacities as Lender under the Credit Agreement and any other documents or instruments delivered pursuant thereto to the extent related to the amount and percentage interest, as identified on the schedule attached hereto, of all of such outstanding rights and obligations of Assignor under or in relation to the Credit Agreement, and (b) to the extent permitted to be assigned under applicable law, all claims, suits, causes of action and any other right of Assignor (in its capacity as Lender) against any Person, whether known or unknown, arising under or in connection with the Credit Agreement, any other documents or instruments delivered pursuant thereto or the loan transactions governed thereby or in any way based on or related to any of the foregoing, including, but not limited to, contract claims, tort claims, malpractice claims, statutory claims and all other claims at law or in equity related to the rights and obligations sold and assigned pursuant to clause (a) above (the rights and obligations sold and assigned by Assignor to the Assignee pursuant to clauses (a) and (b) above being referred to herein collectively as an "Assigned Interest"). Such sale and assignment is without recourse to Assignor and, except as expressly provided in this Assignment Agreement, without representation or warranty by Assignor.

2. Assignor (a) represents that as of the Effective Date, that it is the legal and beneficial owner of the Assigned Interests free and clear of any adverse claim; (b) represents that, as of the date hereof, the balance of the Loan is $[_____]; (c) makes no other representation or warranty and assumes no responsibility with respect to any statement, warranties or representations made in or in connection with the Credit Agreement or the execution, legality, validity, enforceability, genuineness, sufficiency or value of the Credit Agreement, any other Loan Documents or any other instrument or document furnished pursuant thereto; and (d) makes no representation or warranty and assumes no responsibility with respect to the financial condition of any Loan Party or any other Person or the performance or observance by any Loan Party of its Obligations under the Credit Agreement or the other Loan Documents or any other instrument or document furnished pursuant thereto.

3. Assignee (a) represents and warrants that it has full power and authority, and has taken all action necessary, to execute and deliver this Assignment Agreement and to consummate the transactions contemplated hereby and to become a Lender under the Credit Agreement; (b) confirms that it has received a copy of the Credit Agreement and the other Loan Documents, together with copies of the most recent financial statements delivered pursuant thereto and such other documents and information as it has deemed appropriate to make its own credit analysis and decision to enter into this Assignment Agreement; (c) represents and warrants that it has, independently and without reliance upon Agent or

Assignor or any other Lender and based on such documents and information as it has deemed appropriate, made its own credit analysis and decision to enter into this Assignment Agreement and to purchase such Assigned Interest; (d) agrees that it will, independently and without reliance upon Agent, Assignor or any other Lender and based on such documents and information as it shall deem appropriate at the time, continue to make its own credit decisions in taking or not taking action under the Credit Agreement; (e) appoints and authorizes Agent to take such action as agent on its behalf and to exercise such powers under the Credit Agreement as are delegated to Agent by the terms thereof, together with such powers as are reasonably incidental thereto; (f) hereby represents and warrants that upon the effectiveness of this Assignment Agreement, Assignee will be a Lender under the Credit Agreement and further agrees that it will perform in accordance with their terms all obligations which by the terms of the Credit Agreement are required to be performed by it as a Lender; (g) represents that on the date of this Assignment Agreement it is not presently aware of any facts that would cause it to make a claim under the Credit Agreement; (h) if organized under the laws of a jurisdiction outside the United States, attaches the forms prescribed by the Internal Revenue Service of the United States, which have been duly executed, certifying as to Assignee's exemption from United States withholding taxes with respect to all payments to be made to Assignee under the Credit Agreement or such other documents as are necessary to indicate that all such payments are subject to such tax at a rate reduced by an applicable tax treaty; and (i) represents and warrants that it is sophisticated with respect to decisions to acquire assets of the type represented by the Assigned Interest and either it, or the Person exercising discretion in making its decision to acquire the Assigned Interest, is experienced in acquiring assets of such type.

4. The effective date for this Assignment Agreement shall be as set forth on the schedule attached hereto (the "Effective Date"). Following the execution of this Assignment Agreement, it will be delivered to Agent for acceptance and recording by Agent pursuant to the Credit Agreement.

5. Upon such acceptance and recording, from and after the Effective Date, (a) Assignee shall be a party to the Credit Agreement and, to the extent provided in this Assignment Agreement, have the rights and obligations of a Lender thereunder and (b) Assignor shall, to the extent provided in this Assignment Agreement, relinquish its rights (other than indemnification rights) and be released from its obligations under the Credit Agreement.

6. From and after the Effective Date, Agent shall make all payments in respect of each Assigned Interest (including payments of principal, interest, fees and other amounts) to Assignor for amounts which have accrued to but excluding the Effective Date and to Assignee for amounts which have accrued from and after the Effective Date. Notwithstanding the foregoing, Agent shall make all payments of interest, fees or other amounts paid or payable in kind from and after the Effective Date to Assignee.

7. THIS ASSIGNMENT AGREEMENT SHALL BE A CONTRACT MADE UNDER AND GOVERNED BY THE INTERNAL LAWS OF THE STATE OF NEW YORK APPLICABLE TO CONTRACTS MADE AND TO BE PERFORMED ENTIRELY WITHIN SUCH STATE, WITHOUT REGARD TO CONFLICT OF LAWS PRINCIPLES (OTHER THAN SECTION 5-1401 AND SECTION 5-1402 OF THE NEW YORK GENERAL OBLIGATIONS CODE).

8. This Assignment Agreement shall be binding upon, and inure to the benefit of, the parties hereto and their respective successors and assigns. This Assignment Agreement may be executed in any number of counterparts and by the different parties hereto on separate counterparts and each such counterpart shall be deemed to be an original, but all such counterparts shall together constitute but one and the same Assignment Agreement. Receipt by facsimile, portable document format (.pdf), or other electronic transmission of any executed signature page to this Assignment Agreement shall constitute effective delivery of such signature page.

[*Remainder of page intentionally blank; signature page follows.*]

The parties hereto have caused this Assignment Agreement to be executed and delivered as of the date first written above.

ASSIGNOR:
[_____]

By: _____
Name: _____
Title: _____

ASSIGNEE:
[_____]

By: _____
Name: _____
Title: _____

[Acknowledged and Agreed:

SWK FUNDING LLC,
as Agent

By: SWK Holdings Corporation,
its sole Manager

By: _____
Name: _____
Title: _____][1]

[Acknowledged and Agreed:

ETON PHARMACEUTICALS, INC.,
a Delaware corporation

By: _____
Name: _____
Title: _____][2]

[1] If required pursuant to Section 10.8.1(a) of the Loan Agreement.

[2] If required pursuant to Section 10.8.1(a) of the Loan Agreement.

Schedule to Assignment Agreement

Assignor: _____

Assignee: _____

Effective Date: _____

Credit Agreement: Credit Agreement, dated as of November 13, 2019, among ETON PHARMACEUTICALS, INC., a Delaware corporation, as Borrower, the financial institutions party thereto from time to time as Lenders, and SWK FUNDING LLC, a Delaware limited liability company, as Agent, as it may be amended, restated, supplemented or otherwise modified from time to time

Interests Assigned:

	Term Loan	Aggregate Pro Rata Term Loan Share
Assignor Amounts (pre-assignment)	$[_____]	[___]%
Assignor Amounts (post-assignment)	$	
Amounts Assigned	$	
Assignee Amounts (pre-assignment)	$	
Assignee Amounts (post-assignment)	$	

Assignee Information:

Address for Notices:

_____
_____
Attention: _____
Telephone: _____
Telecopy: _____

Address for Payments:

Bank: _____
ABA #: _____
Account #: _____
Reference: _____

EXHIBIT B

Form of Compliance Certificate

COMPLIANCE CERTIFICATE

[_____] [_], 20[__]

Please refer to the Credit Agreement, dated as of November 13, 2019 (as amended, restated or otherwise modified from time to time, the "Credit Agreement") among ETON PHARMACEUTICALS, INC., a Delaware corporation ("Borrower"), the lenders party thereto from time to time as Lenders, and SWK FUNDING LLC, a Delaware limited liability company, as administrative agent (in such capacity, together with its successors and assigns, the "Agent") on behalf of the Lenders. This certificate (this "Certificate"), together with supporting calculations attached hereto, is delivered to Agent pursuant to the terms of the Credit Agreement. Terms used but not otherwise defined herein are used herein as defined in the Credit Agreement.

Enclosed herewith is a copy of the **[annual audited/quarterly]** financial statements required under the Credit Agreement as at and for the period ending [_____] (the "Computation Date"), which financial statements fairly present in all material respects the financial condition and results of operations of the Persons covered by such financial statements as of the Computation Date and for the period then ended and have been prepared in accordance with GAAP consistently applied (subject to the absence of footnotes and to normal year-end adjustments).

Borrower hereby certifies and warrants that the (i) computations set forth on the schedule attached hereto correspond to the computations required by Section 7.13.1 of the Credit Agreement and such computations are true and correct as of the Computation Date, and (2) schedule attached hereto accurately lists all Exempt Accounts and all amounts on deposit therein as of the date of this certificate.

Borrower further certifies that no Event of Default or Default has occurred and is continuing **[except as set forth on Annex I hereto, which Annex describes such Event of Default or Default and the steps, if any, being taken to cure it]**.

Borrower has caused this Certificate to be executed and delivered by its officer thereunto duly authorized on [_____] [_], 20[__].

ETON PHARMACEUTICALS, INC.,
a Delaware corporation

By: _____
Name: _____
Title: _____

Schedule to Compliance Certificate
Dated as of _____[1]

A. Section 7.13.1 – Consolidated Unencumbered Liquid Assets

1A. any Cash Equivalent Investment owned by Borrower and its Subsidiaries on a consolidated basis which are not the subject of any Lien or other arrangement with any creditor to have its claim satisfied out of the asset (or proceeds thereof) prior to the general creditors of Borrower and such Subsidiaries other than the Lien for the benefit of Agent and Lenders:

(a) any evidence of Debt, maturing not more than one year after such time, issued or guaranteed by the United States Government or any agency thereof $_____

(b) commercial paper, or corporate demand notes, in each case (unless issued by a Lender or its holding company) rated at least "A-1" by Standard & Poor's Ratings Group or "P-1" by Moody's Investors Service, Inc. $_____

(c) any certificate of deposit (or time deposit represented by a certificate of deposit) or banker's acceptance maturing not more than one year after such time, or any overnight Federal Funds transaction that is issued or sold by any Lender (or by a commercial banking institution that is a member of the Federal Reserve System or is a U.S. branch of a foreign banking institution and has a combined capital and surplus and undivided profits of not less than $500,000,000) $_____

(d) any repurchase agreement entered into with any Lender (or commercial banking institution of the nature referred to in Item (c) above) which (i) is secured by a fully perfected security interest in any obligation of the type described in any of Items (a) through (c) above and (ii) has a market value at the time such repurchase agreement is entered into of not less than one-hundred percent (100%) of the repurchase obligation of such Lender (or other commercial banking institution) thereunder $_____

(e) money market accounts or mutual funds which invest exclusively or substantially in assets satisfying the $_____

[1] The descriptions of the calculations set forth in this certificate are sometimes abbreviated for simplicity, but are qualified in their entirety by reference to the full text of the calculations provided in the Credit Agreement.

foregoing requirements

(f) cash $_____

(g) other short term liquid investments approved in writing by Agent $_____

1B. The aggregate amount of Borrower's accounts payable under GAAP that are ninety (90) days or more past due unless the charges for such account payable are being actively disputed by the applicable Loan Party $_____

1C. Total of Items 1(A)(a) through (g) above, minus Item 1(B) above $_____

2A. Minimum Required as of any date of determination:

Has Borrower received (i) at least $8,000,000 in Raised Cash since the Closing Date, and (ii) FDA approval in accordance with the FDA Law and Regulations for two Products developed by Borrower? ___ Yes ___ No

B. If the response to Item 2A is no, is Item 1C equal to or greater than $3,000,000? ___ Yes ___ No

C. If the response to Item 2A is yes, is Item 1C equal to or greater than $1,000,000? ___ Yes ___ No

B. Exempt Accounts and amounts on deposit therein as of the date hereof:

EXHIBIT C

Form of Note

PROMISSORY NOTE

$[_____] **[_____], 20[__]**

FOR VALUE RECEIVED and pursuant to the terms of this PROMISSORY NOTE (as amended, restated, supplemented, or otherwise modified from time to time, this "**Note**"), the undersigned, ETON PHARMACEUTICALS, INC., a Delaware corporation ("**Borrower**"), having an address at 21925 W Field Parkway, Suite 235, Deer Park, IL 60010, promises to pay to the order of **[_____]** (together with all subsequent holders of this Note being hereinafter referred to collectively, as "**Holder**"), at the offices of **SWK FUNDING LLC**, a Delaware limited liability company, as agent (in such capacity, together with its successors and assigns, the "**Agent**"), on behalf of Holder and the other Lenders (defined below), having an address at 14755 Preston Road, Suite 105, Dallas, Texas 75254, or at such other place as Holder hereof may designate in writing, the principal sum of up to **[_____] DOLLARS ($[_____])**, or such lesser amount as may be advanced by Holder pursuant to that certain Credit Agreement, dated as of November 13, 2019 (as amended, restated, supplemented, or otherwise modified from time to time, the "**Credit Agreement**"), among Borrower, the lenders party thereto from time to time (each a "**Lender**" and collectively, the "**Lenders**"), and Agent, together with interest on the unpaid amount from time to time outstanding under this Note at the rate or rates of interest provided therefor in the Credit Agreement. This Note evidences the obligation of Borrower to repay, with interest thereon, the Loans under the Credit Agreement made by Lenders to Borrower pursuant to the Credit Agreement.

DEFINITIONS

Capitalized terms not otherwise defined herein shall have the meanings set forth in the Credit Agreement.

PRINCIPAL AND INTEREST

Principal. Borrower shall make payments on the principal balance of this Note and accrued interest on the principal balance of this Note in accordance with the provisions of the Credit Agreement. If not sooner paid, the entire unpaid principal balance of this Note and all interest thereon shall be paid on the Term Loan Maturity Date.

Interest. Interest on the unpaid balance of this Note will accrue from the date of this Note until final payment thereof in accordance with the applicable provisions of the Credit Agreement.

Prepayments. Borrower may prepay the principal sum outstanding from time to time hereunder as provided in the Credit Agreement, subject to any prepayment premium set forth in the Credit Agreement.

INCORPORATION OF CREDIT AGREEMENT

This Note has been issued pursuant to the Credit Agreement, and all of the terms, covenants and conditions of the Credit Agreement (including all Exhibits and Schedules thereto) and all other instruments evidencing or securing the indebtedness hereunder are hereby made a part of this Note and are deemed incorporated herein in full.

EVENTS OF DEFAULT

Upon the occurrence and during the continuance of an Event of Default, the Holder shall have the rights and remedies set forth in the Credit Agreement and the other Loan Documents, in addition to any other remedies to which the Holder may be entitled.

LAWFUL LIMITS

All agreements between Borrower and Holder are expressly limited so that in no contingency or event whatsoever, whether by reason of advancement of the proceeds hereof, acceleration of maturity of the unpaid principal balance hereof, or otherwise, shall the amount paid or agreed to be paid to Holder for the use, forbearance or detention of the money to be advanced hereunder exceed the highest lawful rate permissible under applicable usury laws. If, from any circumstances whatsoever, fulfillment of any provision hereof, of the Credit Agreement or of any other Loan Documents shall involve transcending the limit of validity prescribed by any law which a court of competent jurisdiction may deem applicable hereto, then, ipso facto, the obligation to be fulfilled shall be reduced to the limit of such validity, and, if from any circumstance Holder shall ever receive as interest an amount which would exceed the highest lawful rate, such amount which would be excessive interest shall be applied to the reduction of the unpaid principal balance due hereunder and not to the payment of interest. This provision shall control every other provision of all agreements between Borrower and Holder.

To the extent that either Chapter 303 or 306, or both, of the Texas Finance Code, as amended from time to time, apply in determining the Maximum Lawful Rate notwithstanding that the parties have chosen the laws of the State of New York (or applicable United States federal law to the extent that it permits Holder to contract for, charge, take, receive or reserve a greater amount of interest than the laws of the State of New York) to govern and control in the enforcement, interpretation and construction of the Loan Documents generally, Holder hereby elects to determine the applicable rate ceiling by using the weekly ceiling from time to time in effect, subject to Holder's right from time to time to change such method in accordance with applicable law, as the same may be amended or modified from time to time, to utilize any other method of establishing the Maximum Lawful Rate under the Texas Finance Code or under other applicable law by giving notice, if required, to Borrower as provided by applicable law now or hereafter in effect. To the extent United States federal law permits Holder to contract for, charge, take, receive or reserve a greater amount of interest than under Texas law, Holder will rely on United States federal law instead of applicable state law for the purpose of determining the Maximum Lawful Rate. As used herein, (*x*) the term "**Maximum Lawful Rate**" shall mean the maximum lawful rate of interest which may be contracted for, charged, taken, received or reserved by Holder in accordance with the applicable law (or applicable United States federal

law to the extent that it permits Holder to contract for, charge, take, receive or reserve a greater amount of interest than under applicable state law), taking into account all Charges made in connection with the transaction evidenced by the Note and the other Loan Documents, and (*y*) the term "**Charges**" shall mean all fees, charges and/or any other things of value, if any, contracted for, charged, received, taken or reserved by Holder in connection with the transactions relating to the Loan Agreement, the Note and the other Loan Documents, which are treated as interest under applicable law.

MISCELLANEOUS

WAIVERS. PRESENTMENT FOR PAYMENT, NOTICE OF NONPAYMENT OR DISHONOR, PROTEST, NOTICE OF PROTEST, DEMAND, NOTICE OF DEMAND, NOTICE OF ACCELERATION OR INTENT TO ACCELERATE AND ALL OTHER NOTICES IN CONNECTION WITH THE DELIVERY, ACCEPTANCE, PERFORMANCE, DEFAULT OR ENFORCEMENT OF THIS NOTE ARE HEREBY IRREVOCABLY WAIVED BY BORROWER.

Exercise of Remedies. No delay on the part of Agent or Holder in the exercise of any right, power or remedy hereunder, under the Credit Agreement or under any other Loan Document shall operate as a waiver thereof, nor shall any single or partial exercise by Agent or Holder of any right, power or remedy hereunder, under the Credit Agreement or under any other Loan Document preclude other or further exercise thereof, or the exercise of any other right, power or remedy. Upon the occurrence and continuance of an Event of Default, Agent and Holder shall at all times have the right to proceed against any portion of the Collateral in such order and in such manner as Agent and Holder may deem fit, subject to and in accordance with the Credit Agreement, Guarantee and Collateral Agreement and IP Security Agreement without waiving any rights with respect to any other security.

Invalid Provisions. The illegality or unenforceability of any provision of this Note shall not in any way affect or impair the legality or enforceability of the remaining provisions of this Note.

Governing Law. THIS NOTE SHALL BE A CONTRACT MADE UNDER AND GOVERNED BY THE INTERNAL LAWS OF THE STATE OF NEW YORK APPLICABLE TO CONTRACTS MADE AND TO BE PERFORMED ENTIRELY WITHIN SUCH STATE, WITHOUT REGARD TO CONFLICT OF LAWS PRINCIPLES (OTHER THAN SECTION 5-1401 AND SECTION 5-1402 OF THE NEW YORK GENERAL OBLIGATIONS CODE).

Definition of Note. All references to "Note" or "Notes" in the Loan Documents shall also include this Note, to the extent not returned to Borrower for cancellation, as the same may be amended, supplemented, modified, divided and/or restated and in effect from time to time.

New Notes. Upon Agent's written request (on behalf of Holder) Borrower shall execute and deliver to Agent new Notes and/or split or divide the Notes, or any of them, in exchange for the then existing Notes, in such smaller amounts or denominations as Agent shall specify; provided, that the aggregate principal amount of such new, split or divided Notes shall not exceed the aggregate principal amount of the Notes outstanding at the time such request is made; and provided, further, that such Notes that are replaced shall then be deemed no longer

outstanding under the Credit Agreement and replaced by such new Notes and returned to Borrower within a reasonable period of time after Agent's receipt of the replacement Notes.

Replacement Notes. Upon receipt of evidence reasonably satisfactory to Borrower of the mutilation, destruction, loss or theft of any Notes and the ownership thereof, Borrower shall, upon the written request of the holder of such Notes, execute and deliver in replacement thereof new Notes in the same form, in the same original principal amount and dated the same date as the Notes so mutilated, destroyed, lost or stolen; and such Notes so mutilated, destroyed, lost or stolen shall then be deemed no longer outstanding under the Credit Agreement. If the Notes being replaced have been mutilated, they shall be surrendered to Borrower; and if such replaced Notes have been destroyed, lost or stolen, such holder shall furnish Borrower with an indemnity in writing to indemnify, defend and save them harmless in respect of such replaced Notes.

[*Remainder of page intentionally blank; signature page follows*].

IN WITNESS WHEREOF, the undersigned has caused this Promissory Note to be executed as of the day and year first written above.

BORROWER:

ETON PHARMACEUTICALS, INC.,
a Delaware corporation

By: _____
Name: _____
Title: _____

DISCLOSURE SCHEDULES

TO THE

Credit Agreement (the "Agreement")

by and among

Eton Pharmaceuticals, Inc.

(the "Borrower"),

SWK Funding LLC

(the "Agent, Sole Lead Arranger and Sole Bookrunner"),

And

The financial institutions party hereto from time to time as Lenders

Dated: November 13, 2019

These Disclosure Schedules (these "***Schedules***" and each, a "***Schedule***") are being delivered in accordance with, and are incorporated and made part of that certain Credit Agreement defined on the cover page to these Schedules (the "***Agreement***"). Capitalized terms used in these Schedules but not otherwise defined herein will have the respective meanings given to them in the Agreement.

These Schedules are arranged corresponding to the numbered and lettered sections of the Agreement, and the disclosures of any section of the these Schedules shall provide information regarding, and qualify only, the corresponding numbered and lettered section of the Agreement, unless and to the extent that (a) cross references to other Sections are set forth in these Schedules or (b) it is reasonably apparent due to the nature of the disclosure that such disclosure qualifies one or more of the numbered or lettered Sections of the Agreement. Each Schedule is qualified in its entirety by reference to a specific representation, warranty, or covenant in the Agreement (as applicable), and is not intended to constitute, and shall not be construed as constituting, any representations, warranties or covenants of the Members, individually or collectively, except as to the extent required by the Agreement. The information in these Schedules shall not be deemed to enlarge or enhance any of the representations or warranties in the Agreement.

The representations and warranties of Borrower set forth in Section 5 of the Agreement are made and given subject to these Schedules and are qualified as set forth herein. These Schedules are incorporated into the Agreement by reference to the Agreement. These Schedules should be read in their entirety.

All identified agreements set forth in these Schedules are between the party listed and the Borrower unless otherwise stated.

Headings have been inserted in these Schedules for convenience of reference only and shall not have the effect of amending or changing the information presented.

Schedule 1.1 – Pending Acquisitions as of the Closing Date

None

Schedule 4.1 – Prior Debt

None

Schedule 5.1 – Jurisdictions of Qualification

- Illinois
- Delaware

Schedule 5.7 – Ownership of Properties; Liens

None

Schedule 5.8 – Capitalization

Eton Pharmaceuticals, Inc.
Capitalization Data
09/30/2019

			Vested, Not Exercised		Unvested
Shareholder	**Issued Shares**	**% Total**	**RSU's**	**NQSO's**	**NQSO's**
Harrow Health, Inc.	3,500,000	19.66%			
Peter Appel	1,294,329	7.27%			
Opaleye Mgmt., Inc.	881,678	4.95%			
Sean Brynjelsen	1,049,940	5.90%		256,250	193,750
Wilson Troutman	8,399	0.05%		113,854	231,146
Mark Baum	794,745	4.46%	25,000	6,250	6,250
Charles Casamento	71,920	0.40%	25,000	6,250	6,250
Paul Maier	59,745	0.34%	25,000	6,250	6,250
Norbert Riedel	59,745	0.34%	25,000	6,250	6,250
Subtotal	**7,720,501**	**43.36%**	**100,000**	**395,104**	**449,896**
All others	10,086,666	56.64%		248,327	785,051
Grand Total	**17,807,167**	**100.00%**	**100,000**	**643,431**	**1,234,947**

Common shares issued as of 11/12/2019	
(Zero treasury Shares)	**17,807,167**
Common shares authorized as of 11/12/2019	
	50,000,000
Preferred shares authorized as of 11/12/2019	
(None outstanding)	**10,000,000**

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.

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 to common stock, 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 $4.79. 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 as the number of shares of common stock issuable upon the exercise of this warrant was not fixed as it could vary by a factor of 1.000 to 1.333 shares of common stock per warrant share in accordance with the IPO price, and the Company had considered the warrant to be a derivative instrument. The $479 amount was recorded as a component of the issuance costs for the Series A Preferred in June 2017, arid subsequent changes in the fair value of this warrant were recorded as a component of other income and expense. As of September 30, 2018, the fair value of the warrant was $1,577, and the $1,057 increase in fair value during the nine months ended September 30, 2018, was recorded as a component of other income and expense. For the three months ended September 30, 2018, the $561 increase in fair value for the warrants was recorded as a component of other income and expense.

In connection with the 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. In June 2019, 67,737 of these warrant shares were exercised on a cashless basis which resulted in the Company issuing 42,034 shares of its common stock.

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 outstanding warrants are summarized in the table below.

Description of Warrants	No. of Shares	Exercise Price
Business Advisory Warrants	600,000	$0.01
Placement Agent Warrants – Series A Preferred	636,447	$3.00
Placement Agent Warrants – IPO	414,000	$7.50
Total	1,650,447	$3.04 (average)

The holders of these warrants or their permitted transferees, are entitled to rights with respect to the registration under the Securities Act of 1933, as amended (the "Securities Act") 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 Eton and the investors.

Schedule 5.16 – Insurance

August 12, 2019

SUMMARY OF INSURANCE

For:

Eton Pharmaceuticals

21925 W. Field Parkway Ste235

Barrington, IL 60010-7208

Prepared By:

PLEXUS
STRATEGIC INSURANCE SOLUTIONS

21805 W. Field Parkway, Suite 300
Deer Park, IL 60010
P 847.307.6100 F 847.307.6199
plexusgroupe.com

POLICY INFORMATION

Policy #	Term	Writing Company	Policy Premium
711-01-59-01-0002	06/19/2019 - 06/19/2020	Atlantic Specialty Insurance Company	$10,938.00

PROPERTY

PREMISES

Loc #	Address
1	21925 W Field Parkway, Suite 235, Deer Park, IL 60010 (Offices)
2	85 Oakwood Road, Lake Zurich, IL 60047 (Lab)

Subject of Insurance	Limit	Deductible
Blanket Business Personal Property Including Tenant Improvements and Betterments	$1,202,000	$1,000
Business Income with Extra Expense	$300,000	24 Hours

GENERAL LIABILITY

Coverage	Limit
General Aggregate	$2,000,000
Per Location Aggregate	
Products/Completed Operations Aggregate	Excluded
Personal & Advertising Injury	$1,000,000
Each Occurrence	$1,000,000
Damage to Premises Rented to You	$1,000,000
Medical Expense	$15,000
Employee Benefits Liability – Claims Made	$1,000,000
Employee Benefits Liability Retroactive Date	06/15/2017

This Summary is provided as an overview of your policy. You must refer to the provisions found in your policy for the details of your coverage, terms, conditions and exclusions that apply.

BUSINESS AUTO

Coverage	Limit	Deductible
Hired and Non-owned Auto Liability	$1,000,000	
Hired Auto Comprehensive	$50,000	$500
	$50,000	$500

CRIME

Coverage	Limit	Deductible
Employee Theft Including ERISA	$25,000	$1,000
Forgery or Alteration	$25,000	$1,000
Inside the Premises – Theft of Money and Securities	$25,000	$1,000
Inside the Premises – Robbery or Safe Burglary of Other Property	$25,000	$1,000
Outside the Premises	$25,000	$1,000
Money Orders and Counterfeit Money	$25,000	$1,000

UMBRELLA

Each Occurrence	General Aggregate	Self-Insured Retention
$4,000,000	$4,000,000	$0

POLICY INFORMATION

Policy #	Term	Writing Company	Policy Premium
36051825	06/19/2019 - 06/19/2020	Federal Insurance Company	$51,828.00

PRODUCTS LIABILITY

Claims Made Coverage	Limit
Products Completed Operations Aggregate	$10,000,000
Products Completed Operations Each Occurrence	$10,000 ,000
Human Trials	Included
Bodily Injury and Property Damage Deductible	$25,000
Retroactive Date	02/15/2018
Medical Expenses	$10,000
Product Withdrawal Expense	$25,000

POLICY INFORMATION

This Summary is provided as an overview of your policy. You must refer to the provisions found in your policy for the details of your coverage, terms, conditions and exclusions that apply.

Policy #	Term	Writing Company	Policy Premium
83WECAB6QK0	06/19/2019 - 06/19/2020	Hartford Casualty Ins Co	$8,129.00

WORKERS' COMPENSATION

PART 1 WORKERS' COMPENSATION STATE INFORMATION

Statutory
IL

PART 2 EMPLOYERS LIABILITY INFORMATION

Coverage	Limit
Each Accident	$1,000,000
Disease-Policy Limit	$1,000,000
Disease-Each Employee	$1,000,000

Schedule 5.18(a) – Borrower's Registered Intellectual Property

- Licenses
    - Biorphen.com: Biorphen trade name is registered to another party, Sintetica, but Eton is granted the right to use it in the United States
    - Eton owns the rights to the website Biorphen.com
- Trademarks
    - Eton, Serial No. 87443236
    - Eton Pharmaceuticals, Serial No. 87443234
- Websites
    - EtonPharma.com
    - Biorphen.com

Schedule 5.18(b) – Products and Required Permits

- Eton is currently working on licensing Biorphen so that it can be sold as an "approved product" throughout the US. Currently, those licenses are in progress. Additionally, there is an approved third-party that Eton is working with to sell Biorphen; that third-party is already licensed which would help cut down on approval and processing times.

Schedule 5.21 – Material Contracts

All material contracts disclosed as in Eton's 10-K filing for the year ending December 31, 2018 and subsequent 10-Q and 8-K filings

Schedule 5.25A - Names

- Eton Pharmaceuticals, Inc.

Schedule 5.25B - Offices

- 21925 W Field Parkway, Suite #235, Deer Park, IL 60010

- 85B Oakwood Drive, Lake Zurich, IL 60047-1566

Schedule 5.27 – Broker's Commissions

None

Schedule 5.29 – Restricted Assignment Agreements

None

Schedule 7.1 – Existing Debt

None

Schedule 7.2 – Existing Liens

None

Schedule 7.7 – Transactions with Affiliates

Certain Relationships and Transactions with Related Parties

The following includes a summary of transactions since January 1, 2018 to which we have been a party, in which the amount involved in the transaction exceeded $120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than five percent of our voting securities or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest. Other than described below, there have not been, nor are there currently any proposed, transactions or series of similar transactions to which we have been or will be a party other than compensation arrangements, which include equity and other compensation, termination, change in control and other arrangements, which are described under "Executive compensation."

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. Set forth below is a tabular presentation of these arrangements:

Licensor/Seller	Product	Mr. Brynjelsen's % Ownership Interest in Licensor/Seller
Andersen Pharma, LLC	DS-100	27%
Eyemax LLC	EM-100	33%
Selenix LLC	DS-200	50%

We are required to pay to the above 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.

Indemnification Agreements

We have entered into agreements to indemnify our directors and executive officers. These agreements will, among other things, require us to indemnify these individuals for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on behalf of our company or that person's status as a member of our board of directors to the maximum extent allowed under Delaware law.

Participation in our initial public offering

Certain of our stockholders, including stockholders affiliated with certain of our directors and officers, purchased an aggregate of $240,000 in shares of our common stock in our initial public offering in 2018 at the initial public offering price (40,000 shares at $6.00 per share). The underwriting discount for the shares sold to such stockholders in the initial public offering was the same as the underwriting discount for the shares sold to the public.

Schedule 7.10 – Existing Investments

None

Schedule 7.11 – Restricted Material Contracts

None

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in Registration Statement Nos. 333-228493 and 333-230572 on Form S-8 and Registration Statement No. 333-235329 on Form S-3 of our report dated March 5, 2020, relating to the financial statements and financial statement schedule of Eton Pharmaceuticals, Inc., appearing in this Annual Report on Form 10-K of Eton Pharmaceuticals, Inc. for the year ended December 31, 2019.

/s/ KMJ Corbin & Company LLP

Costa Mesa, California
March 5, 2020

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 5, 2020

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 5, 2020

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, 2019, 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 5th day of March, 2020.

/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.