HARROW HEALTH, INC.
Form 10-K
March 12, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

OR

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

For the transition period from to

Commission File Number: 001-35814

HARROW HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware	**45-0567010**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

12264 El Camino Real, Suite 350

San Diego, CA 92130

(Address of Principal Executive Offices)(Zip Code)

(858) 704-4040

(Registrant's telephone number, including area code)

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, $0.001 par value per share	The NASDAQ Capital 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 Section 15(d) of the Exchange 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 (§ 229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). **Yes** [X] **No** [ ]

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

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. (Check one):

Large accelerated filer [ ] Accelerated filer [ ]
Non-accelerated filer [ ] Smaller reporting company [X]
Emerging growth company [ ]

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

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

As of June 29, 2018, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately $42 million, based on the closing price of $2.20 for the registrant's common stock as quoted on The NASDAQ Capital Market on that date. For purposes of this calculation, it has been assumed that shares of common stock held by each director, each officer and each person who owns 10% or more of the outstanding common stock of the registrant are held by affiliates of the registrant. The treatment of these persons as affiliates for purposes of this calculation is not conclusive as to whether such persons are affiliates of the registrant for any other purpose.

As of March 11, 2019, there were 24,685,594 shares of the registrant's common stock outstanding.

Portions of the registrant's definitive proxy statement for its 2019 Annual Meeting of Stockholders (Proxy Statement) are incorporated by reference in Part III of this annual report on Form 10-K (Annual Report), to the extent stated herein.

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As used in this Annual Report, unless indicated or the context requires otherwise, the terms the "Company", "Harrow", "we", "us" and "our" refer to Harrow Health, Inc. and its consolidated subsidiaries.

In addition to historical information, the following discussion contains forward-looking statements regarding future events and our future performance. In some cases, you can identify forward-looking statements by terminology such as "will", "may", "should", "expects", "plans", "anticipates", "believes", "estimates", "predicts", "forecasts", "potential" or "continue" or the negative of these terms or other comparable terminology. All statements made in this Annual Report other than statements of historical fact are forward-looking statements. These forward-looking statements involve risks and uncertainties and reflect only our current views, expectations and assumptions with respect to future events and our future performance. If risks or uncertainties materialize or assumptions prove incorrect, actual results or events could differ materially from those expressed or implied by such forward-looking statements. Risks that could cause actual results to differ from those expressed or implied by the forward-looking statements we make include, among others, risks related to: our ability to successfully implement our business plan, develop and commercialize our proprietary formulations in a timely manner or at all, identify and acquire additional proprietary formulations, manage our pharmacy operations, service our debt, obtain financing necessary to operate our business, recruit and retain qualified personnel, manage any growth we may experience and successfully realize the benefits of our prior acquisitions of ImprimisRx NJ, LLC dba ImprimisRx ("RxNJ"), Park Compounding, Inc ("Park") and any other acquisitions and collaborative arrangements we may pursue; competition from pharmaceutical companies, outsourcing facilities and pharmacies; general economic and business conditions; regulatory and legal risks and uncertainties related to our pharmacy operations and the pharmacy and pharmaceutical business in general; physician interest in and market acceptance of our current and any future formulations and compounding pharmacies generally; our limited operating history; and the other risks and uncertainties described under the heading "Risk Factors" in Part I, Item 1A of this Annual Report. You should not place undue reliance on forward-looking statements. Forward-looking statements speak only as of the date they are made and, except as required by law, we undertake no obligation to revise or publicly update any forward-looking statement for any reason.

We have registered trademarks, copyrights and/or pending trademark and copyright applications for a number of proprietary names in the United States, including, but not limited to: Imprimis®, ImprimisRx®, Harrow Health™, Dropless®, LessDrops®, Dropless Cataract Surgery®, Dropless Cataract Therapy®, Dropless Therapy®, MKO Melt™, and Simple Drops™. We may choose to pursue trademark protection in other jurisdictions for one or more of these or other marks in the future. All other trademarks, service marks and trade names included or incorporated by reference into this Annual Report, are the property of their respective owners.

PART I

ITEM 1. BUSINESS

Overview

Our business specializes in the development, production and sale of innovative medications that offer unique competitive advantages and serve unmet needs in the marketplace. Prior to 2017, the Company's business was primarily focused on its ImprimisRx business, the nation's leading ophthalmology pharmaceutical compounding business, and Park Compounding, Inc. ("Park"), a leading health and wellness compounding business. Since 2017, in addition to ImprimisRx and Park, we also have founded and have continuing equity positions in Eton Pharmaceuticals, Inc. ("Eton"), Surface Pharmaceuticals, Inc. ("Surface"), and Melt Pharmaceuticals, Inc. ("Melt"). In 2018, the Company also founded the subsidiaries Mayfield Pharmaceuticals, Inc. ("Mayfield") and Radley Pharmaceuticals, Inc. ("Radley"). The Company owns royalty rights in certain 505(b)(2) drug candidates being developed by Eton, Surface, Melt, Radley and Mayfield. Harrow intends to continue to pursue its operations through subsidiaries for, and royalty rights in, new businesses that commercialize drug candidates that are internally developed or otherwise acquired or licensed from third parties.

Pharmaceutical Compounding Businesses

Pharmaceutical Compounding

Pharmaceutical compounding is the science of combining different active pharmaceutical ingredients (APIs), all of which are approved by the U.S. Food and Drug Administration ("FDA") (either as a finished form product or as a bulk drug ingredient) and excipients, to create specialized pharmaceutical preparations. Physicians and healthcare institutions use compounded drugs when commercially available drugs do not optimally treat a patient's needs. In many cases, compounded drugs, such as ours, have wide market utility and may be clinically appropriate for large patient populations. Examples of compounded formulations include medications with alternative dosage strengths or unique dosage forms, such as topical creams or gels, suspensions, or solutions with more tolerable drug delivery vehicles.

Almost all of our sales revenue is derived from making, selling and dispensing our compounded prescription drug formulations as cash pay transactions between us and our end-user customer. As such, the majority of our commercial transactions do not involve distributors, wholesalers, insurance companies, pharmacy benefit managers or other middle parties. By not being reliant on insurance company formulary inclusion and pharmacy benefit manager payment clawbacks, we are able to simplify the prescription transaction process. We believe the outcome of our business model is a simple transaction, involving a patient-in-need, a physician's diagnosis and a fair price and great service for a quality pharmaceutical product. We sell our products through a network of employees and independent contractors and we dispense our formulations in all 50 states, Puerto Rico and in selected markets outside the United States.

Our Compounding Facilities

Pharmaceutical compounding businesses are governed by Sections 503A and 503B of the Federal Food Drug and Cosmetic Act (the "FDCA"). Section 503A of the FDCA provides that a pharmacy is only permitted to compound a drug for an individually identified patient based on a prescription for a patient, and is only permitted to distribute the drug interstate if the pharmacy is licensed to do so in the states where it is compounded and where the medication is received.

Section 503B of the FDCA provides that a pharmacy engaged in preparing sterile compounded drug formulations may voluntarily elect to register as an "outsourcing facility." Outsourcing facilities are permitted to compound large quantities of drugs without a prescription and distribute them out of state with certain limitations such as the formulation appearing on the FDA's drug shortage list or the bulk drug substances contained in the formulations appearing on the FDA's "clinical need" list. Entities voluntarily registering with FDA as outsourcing facilities are subject to additional requirements that do not apply to compounding pharmacies (operating under Section 503A of the FDCA), including adhering to standards such as current good manufacturing practices (cGMP) or other FDA guidance documents and being subject to regular FDA inspection.

We operate three compounding facilities. Our New Jersey operations are comprised of two separate entities and facilities, one of which is registered with the FDA as an outsourcing facility ("NJOF") under Section 503B of the FDCA. The other New Jersey facility ("RxNJ"), and Park Compounding, Inc. ("Park"), our California based pharmacy, are both licensed pharmacies operating under Sections 503A of the FDCA. All products that we sell, produce and dispense are made in the United States of America.

We believe that, with our current compounding pharmacy facilities and licenses and the successful completion and FDA registration of NJOF, we have the infrastructure to scale our business appropriately under the current regulatory landscape and meet the potential growth in demand we are targeting. We plan to invest in one or more of our pharmacies to further their capacity and efficiencies. Also, we may seek to access greater pharmacy and production related redundancy and markets through acquisitions, partnerships or other strategic transactions.

ImprimisRx

ImprimisRx is our ophthalmology focused pharmaceutical compounding business. We offer to over 3,000 physician customers and their patients critical medicines to meet their needs that are unmet by commercially available drugs. We make our formulations available at prices that are, in most cases, lower than non-customized commercial drugs. Our current ophthalmology formulary includes over twenty compounded formulations, many of which are patented or

patent-pending, and are customizable for the specific needs of a patient. Some examples of our compounded medications are various combinations of drugs formulated into one bottle and numerous preservative free formulations. Depending on the formulation, the regulations of a specific state and ultimately the needs of the patient, ImprimisRx products may be dispensed as patient-specific medications from our 503A pharmacies, or for in-office use, made according to current good manufacturing practices (or cGMPs) or other FDA guidance documents, in our FDA-registered NJOF outsourcing facility.

Ophthalmology Market

The three largest markets in the ophthalmology market in the U.S. are ocular surgery, glaucoma and dry eye disease.

For any ocular procedure, a surgeon may require drugs for sedation, dilation, and inflammation and infection prevention. The cataract surgery market continues to experience significant growth. According to a 2018 iData report , 3.7 million cataract surgeries were performed in the U.S. in 2017. The National Eye Institute estimates that over 24 million Americans currently have cataracts and that this number will grow to 38 million by 2030 and reach more than 50 million by 2050. In addition to the 3.7 million cataract surgeries performed annually in the U.S., the American Academy of Ophthalmology (AAO) estimates that over one-half of Americans require some form of vision correction and 43 million of these individuals are candidates for refractive surgery. Nearly 96 percent of the refractive surgery procedures performed are LASIK (laser in situ keratomileusis) surgeries, an outpatient surgical procedure used to treat nearsightedness, farsightedness, and astigmatism. According to Statista, an estimated 600,000 LASIK procedures were performed in the U.S. in 2015.

According to the Glaucoma Research Foundation, there are over 3 million Americans with glaucoma but only half are aware they have it. Open-angle glaucoma (the most common type of glaucoma) is a condition of increased intraocular pressure that causes gradual loss of sight. Glaucoma is incurable, and if not managed can lead to blindness. Generally, the first line of treatment consists of a prostaglandin analogue (PGA) eye drop regimen. As the disease progresses, non-PGA products are generally added as a second line treatment. Topical agents, other than PGAs, include beta blockers, alpha agonists, miotics and steroids. According to a 2013 article in Glaucoma Today, up to 50 percent of glaucoma patients require more than one drug following a few months of initial treatment and there is a direct correlation between the number of glaucoma bottles and decreased adherence; however the FDA has yet to approve a PGA combination product despite combination products including a PGA (Xalacom®, DuoTrav® and Ganfort®) available outside of the U.S. According to a 2017 Market Scope report, the glaucoma pharmaceuticals market is expected to reach $5.3 billion in 2022.

Dry eye occurs when the eye does not produce enough tears, or when the tears are not of the correct consistency and evaporate too quickly. Inflammation of the surface of the eye may also occur. We believe that dry eye disease, or DED, affects over 30 million people in the United States, and a major epidemiological study, the Beaver Dam Offspring Study, published in 2014 in the American Journal of Ophthalmology, reported that in a cohort of over 3,000 patients, DED was self-reported by 14.5% of the patients. According to a 2017 Market Scope report, the global dry eye treatments market is expected to grow from $3.7 billion in 2017 to $4.9 billion in 2022. Dry eye is among the most common conditions seen by eye care professionals.

Park Compounding

Park, our wholly owned subsidiary pharmacy based in Irvine, California, is focused on primarily on health and wellness related, customizable pharmaceutical compounding. Park dispenses sterile and non-sterile compounded medications prescribed by licensed practitioners when commercially available choices do not meet a patient's needs. Park also produces and dispenses certain of our ophthalmology-based formulations.

Pharmaceutical Development Businesses

We have ownership positions in Eton, Surface, Melt, and Mayfield and hold royalty interests in certain of their drug candidates. These companies are pursuing market approval for their drug candidates under the FDCA, including under the abbreviated pathway described in Section 505(b)(2) which permits the submission of a new drug application (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. In 2018, we formed our Radley and Mayfield subsidiaries We intend to pursue our business strategies though subsidiaries and royalty interests that will focus on the development and FDA approval of certain proprietary drug formulations that we currently own, will in-license/acquire and/or otherwise develop.

Eton Pharmaceuticals, Inc.

Eton is a pharmaceutical company focused on developing and commercializing innovative products utilizing the FDA's 505(b)(2) regulatory pathway. Its pipeline includes seven products in various stages of development across a variety of dosage forms. Eton's pipeline is focused on innovative 505(b)(2) products and obtaining FDA marketing approval for currently marketed but unapproved drugs.

In May 2017, we entered into two asset purchase and license agreements (the "Eton License Agreements") with our then wholly owned subsidiary, Eton. Pursuant to the terms of the Eton License Agreements, we assigned and licensed to Eton certain intellectual property and related rights to develop, formulate, make, sell, and sub-license our proprietary formulations including synthetic corticotropin (Eton drug candidate CT-100) (collectively, the "Harrow Products"). Eton, by itself or through a development partner, intends to seek FDA approval for the commercialization of CT-100 through the Section 505(b)(2) regulatory pathway. If approved by the FDA, Eton is required to make royalty payments to us on CT-100. In addition to CT-100, Eton has acquired several additional drug candidates and ones that qualify under the Drug Efficacy Study Implementation (DESI) program which it plans to develop and commercialize. Harrow is only eligible to receive royalties on CT-100 (corticotropin) and will not receive royalties on any other drug candidates currently being developed by Eton.

In June 2017, Eton closed an offering of its Series A Preferred Stock at $3.00 a share for gross proceeds of approximately $20 million (the "Series A Round"). At the time of closing we lost our controlling interest, and deconsolidated Eton from our consolidated financial statements. In November 2018, Eton closed on an initial public offering of 4,140,000 shares of its common stock at $6.00 a share for gross proceeds of approximately $24.8 million (the "Eton IPO"). Following the close of the Eton IPO, all shares of the Eton Series A Preferred Stock converted to Eton common stock. As of the date of this Annual Report, we own 3.5 million shares of Eton common stock, which we estimate is approximately 19.98% of the equity and voting interests issued and outstanding of Eton following the close of the Eton IPO. Eton's common stock currently trades on the NASDAQ Global Market exchange under the ticker symbol "ETON". Our CEO Mark Baum serves on the board of directors of Eton.

Surface Pharmaceuticals, Inc.

Surface is a development-stage pharmaceutical company focused on development and commercialization of innovative therapeutics for ocular surface diseases and is seeking FDA approval for the commercialization of its drug candidates through the Section 505(b)(2) regulatory pathway under the FDCA. In 2017 and amended in April 2018, Harrow entered into asset purchase and license agreements (the "Surface License Agreements") and transferred to Surface its current drug pipeline, which consists of three proprietary drug candidates. Surface's patent-pending topical eye drop drug candidates, SURF-100 and SURF-200, utilize a patented delivery vehicle known as Klarity Drops ("Klarity"), that was invented by Harrow board member and Surface's chairman of the board and renowned ophthalmologist Dr. Richard Lindstrom. Klarity is designed to protect and rehabilitate the ocular surface pathology for patients with DED. Surface's drug candidate SURF-300 is a patent-pending oral capsule that will target patients also suffering from DED signs and symptoms.

In May and in July 2018, Surface closed on an offering of its Series A Preferred Stock at $3.30 a share for proceeds of approximately $21 million (the "Surface Series A Round"). At that time, we lost our controlling interest and deconsolidated Surface from our consolidated financial statements, and currently own approximately 30% of the issued and outstanding voting interests in Surface. Our CEO Mark Baum, and director, Richard Lindstrom serve on the board of directors of Surface.

Melt Pharmaceuticals, Inc.

Melt is a development-stage pharmaceutical company focused on the development and commercialization of proprietary non-intravenous (or IV) sedation and anesthesia therapeutics for human medical procedures in hospital, outpatient, and in-office settings. Melt intends to seek regulatory approval through the FDA's 505(b)(2) regulatory pathway for its proprietary technologies, where possible. In December 2018, Harrow entered into an Asset Purchase Agreement with Melt (the "Melt Asset Purchase Agreement"), and Harrow assigned to Melt the underlying intellectual property for Melt's current pipeline, including its lead drug candidate MELT-100. The core intellectual property Melt owns is a patented series of combination non-opioid sedation drug formulations that we believe to have multitudinous applications. Pursuant to the terms of the Melt Asset Purchase Agreement, Melt is required to make royalty payments to the Company up to eight percent (8%) of net sales of products described in the Melt Asset Purchase Agreement, while any patent rights remain outstanding, as well as other conditions.

Melt's lead 505(b)(2) drug candidate is MELT-100, which combines small, fixed doses of midazolam and ketamine in a dissolving tablet form, that is administered sublingually for conscious sedation during cataract surgery. Based on our experience, we believe there is a strong patient preference for sedation medications delivered sublingually as opposed to the traditional route, which is through an IV method. MELT-100 combines small, fixed doses of midazolam and ketamine in a dissolving tablet form, that is administered sublingually for conscious sedation during cataract surgery. MELT-100 is based on Imprimis' existing MKO Melt formulation, which is comprised of the three active ingredients midazolam, ketamine and ondansetron. MKO Melt has an established history of use in cataract surgery, having been dispensed approximately 100,000 times as a compounded drug since 2016. We intend to leverage the real-world evidence generated by ImprimisRx and more than 400 U.S. cataract surgeons to inform and guide the design and execution of MELT-100's clinical and commercial development programs.

Based solely on the more than 4 million cataract surgeries performed in the US in 2017, we believe the potential U.S. market opportunity for MELT-100 will be in excess of $1 billion. This estimate assumes that MELT-100 will be granted transitional pass-through reimbursement status, or be eligible for separate payment from the Centers for Medicare and Medicaid Services, or CMS, code under Medicare Part B. Pass-through status is designed to promote innovation and allows for separate payment (*i.e.*, outside the packaged procedural payment) under Medicare Part B for certain new drugs and other medical technologies when used in hospital outpatient or ambulatory surgery centers and that meet well-established criteria specified by federal law and regulations governing Medicare spending. Pass through reimbursement status generally lasts for three years, and subsequently payment for the product is then included as part of the packaged payment for the associated procedure for Medicare patients. In the recently released 2019 proposed rules for the CMS outpatient prospective payment system (OPPS), CMS indicated that it will separately pay in the ambulatory surgical center, or ASC, setting for non-opioid drugs with an FDA-approved indication for postoperative pain relief. In addition to this proposed rule, an extension of the pass-through reimbursement period to five years was allowed for certain products in October 2018.

In January 2019, Melt completed a Pre-IND meeting with FDA, and intends to begin enrolling patients for clinical studies related to MELT-100 in 2020.

During January 2019, Melt closed on the sale of its Series A Preferred Stock at $5.00 a share for gross proceeds of approximately $11 million (the "Melt Series A Round"). At the time of the closing we lost our controlling interest, and deconsolidated Melt from our consolidated financial statements. We own 3.5 million shares of Melt common stock, which is approximately 44% of the equity and voting interests issued and outstanding of Melt. In addition to our Melt equity position and pursuant to the Melt Asset Purchase Agreement, Harrow is eligible to receive mid-single digit percent royalties on sales of contributed drug candidates. Our CEO Mark Baum, and CFO, Andrew Boll serve on the board of directors of Melt.

Mayfield Pharmaceuticals, Inc.

Mayfield, a consolidated subsidiary of Harrow, is a development-stage women's and men's health focused pharmaceutical company. Mayfield intends to seek regulatory approval through the FDA's 505(b)(2) regulatory pathway for its proprietary drug candidates and technologies, including its lead drug candidates MAY-44 and MAY-66. MAY-44 is non-estrogen topical analgesic gel containing a patented pH-balanced formulation of 3.75% lidocaine and other essential excipients designed for use on mucosal surfaces. If FDA-approved, MAY-44 could become the first topical product indicated for dyspareunia. We believe there are an estimated 32 million women in the U.S. who suffer from moderate-to-severe dyspareunia (Clinical Medicine Insights: Reproductive Health 2014*)*, and 64 million post-menopausal women in the U.S. for whom dyspareunia is common. Other more recent estimates suggest dyspareunia affects greater than one in ten women (BJOG An International Journal of Obstetrics and Gynecology 2017). In a proprietary market research report completed in December 2017, a survey of OB/GYN practices estimated that one in every four patients complained of some level of dyspareunia each month. It was also estimated that two-thirds of women complaining of dyspareunia are post-menopausal and one-third are pre- or peri-menopausal. Mayfield's MAY-66 drug candidate a patented, injectable form of pentoxifylline designed for use in the treatment of symptoms associated with Peyronie's disease.

Mayfield and Harrow acquired the intellectual property associated with MAY-44 in January 2019 from Elle Pharmaceutical LLC (the "Mayfield Asset Purchase Agreement") in exchange for $25,000, with an additional $175,000 due upon third party financing of Mayfield, 1 million shares of Mayfield common stock and a 7.5% royalty rate on sales of the product. Once we have finalized the drug candidate assets Mayfield will seek to develop, we intend to build out the Mayfield management, board and clinical advisory team.

Radley Pharmaceuticals, Inc.

Radley, a consolidated subsidiary of Harrow, is a development-stage pharmaceutical company focused on the development of proprietary 505(b)(2) drug candidates focused on rare diseases. During 2019, and prior to initiating significant development activities and costs related to its drug candidates, we intend to meet with FDA to establish and understand the expected clinical and regulatory path to approval for these drug candidates. We are also pursuing investigator-initiated studies for some of Radley's drug candidates with well-known healthcare institutions. We believe this approach will allow us to better understand and weigh the economic costs, clinical feasibility and potential benefits associated with pursuing development activities associated with these drug candidates.

Section 505(b)(2) New Drug Applications

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

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

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

Sales and Marketing

The focus of our sales and marketing is in the United States. We do, however, believe that our proprietary drug formulations could have commercial appeal in international markets, and we have engaged distributors and entered into out-licensing arrangements for certain of our proprietary formulations in certain non-U.S. markets, including Canada. Our sales and marketing efforts are currently organized into two teams, the larger of which focuses on our ophthalmology pharmaceutical compounding business and the other on our non-ophthalmology pharmaceutical compounding business. Our sales and marketing activities consist primarily of efforts to educate doctors, ambulatory surgery centers, healthcare systems, hospitals and other users throughout the U.S. about our compounded formulations. We expect that we may experience growth in the sales of our proprietary pharmaceutical compounded formulations in future periods, particularly in light of our current and planned launches of new formulations and commercialization campaigns. However, we may not be successful in doing so, whether due to the safety, quality or availability of our proprietary compounded formulations, the size of the markets for such formulations, which could be smaller than we expect, the timing of market entry relative to competitive products, the availability of alternative compounded formulations or FDA-approved drugs, the price of our compounded formulations relative to alternative products or the success of our sales and marketing efforts, which is dependent on our ability to build and grow a qualified and adequate internal sales function.

During 2017 and 2018, we entered various sales and marketing agreements, with certain organizations to provide exclusive sales and marketing representation services to ImprimisRx in select geographies in the U.S., in connection with our ophthalmic compounded formulations. Under the terms of the sales and marketing agreements, we are required to make commission payments to equal to 10% to 14% of net sales for products above and beyond the initial existing sales amounts. In addition, we are required to make periodic milestone payments to certain organizations in shares of the our restricted common stock if net sales in the assigned territory reach certain future levels by the end of their terms, as applicable. We believe these sales and marketing agreements will accelerate launches of our new ophthalmology programs and limit our initial capital requirements commonly associated with new product launches and increased sizes of sales forces.

Competition

The pharmaceutical and pharmacy industries are highly competitive. We compete against branded drug companies, generic drug companies, outsourcing facilities and other compounding pharmacies. We are significantly smaller than some of our competitors, and we may lack the financial and other resources needed to develop, produce, distribute, market and commercialize any of our proprietary formulations or compete for market share in these sectors. The drug products available through branded and generic drug companies with which our formulations compete have been approved for marketing and sale by the FDA and are required to be manufactured in facilities compliant with cGMP standards. Although we prepare some of our compounded formulations in accordance with cGMP standards and our other formulations are produced according to the standards provided by United States Pharmacopoeia (USP) <795> and USP <797> and applicable state and federal law, our proprietary compounded formulations are not required to be, and have not been, approved for marketing and sale by the FDA. As a result, some physicians may be unwilling to prescribe, and some patients may be unwilling to use, our formulations. Additionally, under federal and state laws applicable to our current compounding pharmacy operations operating under Section 503A of the FDCA, we are not permitted to prepare significant amounts of a specific formulation in advance of a prescription, compound quantities for office use or utilize a wholesaler for distribution of our formulations; instead, our compounded formulations must be prepared and dispensed in connection with a physician prescription for an individually identified patient. Pharmaceutical companies, on the other hand, are able to sell their FDA-approved products to large pharmaceutical wholesalers, who can in turn sell to and supply hospitals and retail pharmacies. Even though we have registered NJOF with the FDA, our business may not be scalable on the scope available to our competitors that produce FDA-approved drugs, which may limit our potential for profitable operations. These facets of our operations may subject our business to limitations our competitors offering FDA-approved drugs may not face.

Biotechnology and related pharmaceutical technologies are subject to rapid and significant change. Our future success will depend in large part on our ability to maintain a competitive position with respect to these technologies. Products developed by our competitors, including FDA-approved drugs and compounded formulations created by other pharmacies, could render our products and technologies obsolete or unable to compete. Any products that we develop may become obsolete before we recover expenses incurred in developing the products, which may require that we seek additional funds that may or may not be available to continue our operations. The competitive environment requires an ongoing, extensive search for medical and technological innovations and the ability to develop and market these innovations effectively, and we may not be competitive with respect to these factors. Other competitive factors include the safety and efficacy of a product, the size of the market for a product, the timing of market entry relative to competitive products, the availability of alternative compounded formulations or approved drugs, the price of a product relative to alternative products, the availability of third-party reimbursement, the success of sales and marketing efforts, brand recognition and the availability of scientific and technical information about a product. Although we believe we are positioned to compete favorably with respect to many of these factors, if our proprietary formulations are unable to compete with the products of our competitors, we may never gain market share or achieve profitability.

Factors Affecting Our Performance

We believe the primary factors affecting our performance are our ability to increase revenues of our proprietary compounded formulations and certain non-proprietary products, grow and gain operating efficiencies in our pharmacy operations, optimize pricing and obtain reimbursement options for our proprietary compounded formulations, and continue to pursue development and commercialization opportunities for certain of our ophthalmology and other assets that we have not yet made commercially available as compounded formulations. We believe we have built a tangible and intangible infrastructure that will allow us to scale revenues efficiently in the long-term. All of these activities will require significant costs and other resources, which we may not have or be able to obtain from operations or other sources.

Reimbursement Options and Pricing Optimization

Our proprietary ophthalmic pharmaceutical compounded formulations are primarily available on a cash-pay basis. However, we work with third-party insurers, pharmacy benefit managers and buying groups to offer patient-specific customizable compounded formulations at accessible prices. We may devote time and other resources to seek reimbursement and patient pay opportunities for these and other compounded formulations and we have hired pharmacy billers to process certain existing reimbursement opportunities for certain formulations. However, we may be unsuccessful in achieving these goals, as many third-party payors have imposed significant restrictions on reimbursement for compounded formulations in recent years. Moreover, third-party payors, including Medicare, are increasingly attempting to contain health care costs by limiting coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has not granted formal labeling approval. Further, the Health Reform Law may have a considerable impact on the existing U.S. system for the delivery and financing of health care and could conceivable have a material effect on our business. As a result, reimbursement from Medicare, Medicaid and other third-party payors may never be available for any of our products or, if available, may not be sufficient to allow us to sell the products on a competitive basis and at desirable price points. If government and other third-party payors do not provide adequate coverage and reimbursement levels for our formulations, the market acceptance for our formulations may be limited.

Additionally, we are making efforts to normalize the pricing for our currently available proprietary compounded ophthalmic formulations. An economic study conducted in 2015 by researchers at Andrew Chang & Co, LLC and co-sponsored by us demonstrated that, assuming the cost of Dropless Therapy is $100 per dose, our formulations may provide collective savings to Medicare, Medicaid and patients of up to $13 billion, with a most likely savings estimate of $8.7 billion, over a 10-year period. Based on this research, we believe optimized pricing for certain of our compounded formulations could be greater than $100 per dose. Any efforts to attain optimized pricing for these or any of our other proprietary formulations could fail, which could make our products less attractive or unavailable to some patients or could reduce our margins.

Intellectual Property

Our success and ability to compete depends upon our ability to protect our intellectual property. We conduct a fulsome analysis of the intellectual property landscape prior to acquiring rights to formulations and filing patent applications. In addition, as of February 28, 2019, we owned and/or licensed nine U.S. issued patents, two international issued patents, and 32 U.S. patent applications, including 29 utility (including continuation, continuation-in-part and divisional) and three provisional patent applications, and we owned seven international patent applications filed under the Patent Cooperation Treaty and 42 foreign patent applications. We presently have 14 U.S. and 13 foreign patent applications pending that relate to our SSP Technology. We expect to file additional patent applications in the U.S. and pursue patent protection for certain of our formulations in other important international jurisdictions in the future.

As of February 28, 2019, we had worldwide 180 issued trademarks, pending trademark and copyright applications, or registered copyright and/or trademarks including, but not limited to: Imprimis®, ImprimisRx®, Harrow Health™, Dropless®, LessDrops®, Dropless Cataract Surgery®, Dropless Cataract Therapy®, Dropless Therapy®, MKO Melt™, and Simple Drops™. We may choose to pursue trademark protection in other jurisdictions for any one or more of these or other marks in the future.

We also rely on unpatented trade secrets and know-how and continuing technological innovation in order to develop our formulations, which we seek to protect, in part, by confidentiality agreements with our employees, consultants, collaborators and others, including certain service providers. We also have invention or patent assignment agreements with our current employees and certain consultants. However, our employees and consultants may breach these agreements and we may not have adequate remedies for any breach, or our trade secrets may otherwise become known or be independently discovered by competitors. In addition, inventions relevant to us could be developed by a person not bound by an invention assignment agreement with us, in which case we may have no rights to use the applicable invention.

Governmental Regulation

Our business is subject to federal, state and local laws, regulations, and administrative practices, including, among others: federal, state and local licensure and registration requirements concerning the operation of pharmacies and the practice of pharmacy; the Health Insurance Portability and Accountability Act (HIPAA); the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2012 (collectively, the Health Reform Law); statutes and regulations of the FDA, the U.S. Federal Trade Commission, the U.S. Drug Enforcement Administration and the U.S. Consumer Product Safety Commission, as well as regulations promulgated by comparable state agencies concerning the sale, advertisement and promotion of the products we sell. The regulatory and quality compliance environment for compounded drugs has become significantly more rigorous, complex and strict since the passage of The Drug Quality and Security Act of 2013. The complexity of the current state and federal regulatory environment, as well as the expected continued evolution of state and federal laws governing pharmaceutical compounding, have and will continue to present potentially significant challenges to our business model and the fulfillment of our mission as a company. Below are descriptions of some of the various federal and

state laws and regulations which may govern or impact our current and planned operations.

Pharmacy Regulation

Our pharmacy operations are regulated by both individual states and the federal government. Every state has laws and regulations addressing pharmacy operations, including regulations relating specifically to compounding pharmacy operations. These regulations generally include licensing requirements for pharmacists, pharmacy technicians and pharmacies, as well as regulations related to compounding processes, safety protocols, purity, sterility, storage, controlled substances, recordkeeping and regular inspections, among other things. State rules and regulations are updated periodically, generally under the jurisdiction of individual state boards of pharmacy. Failure to comply with the state pharmacy regulations of a particular state could result in a pharmacy being prohibited from operating in that state, financial penalties and/or becoming subject to additional oversight from that state's board of pharmacy. In addition, many states are considering imposing, or have already begun to impose, more stringent requirements on compounding pharmacies. If our pharmacy operations become subject to additional licensure requirements, are unable to maintain their required licenses or if states place burdensome restrictions or limitations on pharmacies, our ability to operate in some states could be limited.

Federal law limits compounding pharmacies from engaging in the practice of anticipatory compounding, which involves preparing compounded medications before the actual receipt of a prescription or practitioner's order, unless the compounding pharmacy has a history of filling certain prescriptions for a customer. In such cases, it is acceptable to engage in anticipatory compounding or the preparation of larger batches so that medications will be ready when they are needed. Anticipatory compounding also reduces the cost of compounded medications, as economies of scale can be realized by producing larger batches. Anticipatory compounding also leads to less wasted chemicals, dilutions, fillers, and other associated products are produced, and greater accuracy and uniformity in finished medications, as larger batches decrease the variation caused by preparing multiple, smaller batches. Based on our history of meeting the needs of our customers, we are able to anticipatorily compound batches of our formulations for our customers, per the applicable regulations.

Many of the states into which we deliver pharmaceuticals have laws and regulations that require out-of-state pharmacies to register with, or be licensed by, the boards of pharmacy or similar regulatory bodies in those states. These states generally permit the dispensing pharmacy to follow the laws of the state within which the dispensing pharmacy is located. However, various state pharmacy boards have enacted laws and/or adopted rules or regulations directed at restricting or prohibiting the operation of out-of-state pharmacies by, among other things, requiring compliance with all laws of the states into which the out-of-state pharmacy dispenses medications, whether or not those laws conflict with the laws of the state in which the pharmacy is located, or requiring the pharmacist-in-charge to be licensed in that state. To the extent that such laws or regulations are found to be applicable to our operations, we believe we comply with them.

Further, under federal law, Section 503A of the FDCA seeks to limit the amount of compounded products that a pharmacy can distribute interstate. The interpretation and enforcement of this provision is dependent on the FDA entering into a standard Memorandum of Understanding ("MOU") with each state setting forth limits on shipments of

interstate compounding. In January of 2018, the FDA released a "2018 Compounding Policy Priorities Plan" (the "2018 Compounding Plan") which provided an overview of the key priorities the FDA plans to focus on in 2018 in connection with compounding regulations. One of the priorities outlined in the 2018 Compounding Plan addressed the FDA's plan to release a revised MOU (the "Revised MOU"). Pursuant to the statements in the Compounding Plan, the Revised MOU would consider amounts shipped interstate by a compounder to be inordinate amounts if the "number of prescriptions of compounded drugs distributed interstate during any calendar month is greater than 50 percent." Importantly, instead of that number serving as a "hard limit, for state action," the 50% target would trigger certain additional reporting requirements. The Revised MOU will also provide states more time to report to the FDA, and flexibility on identifying when amounts are inordinate, considering the size and scope of compounding operations. Until the Revised MOU is issued and presented to states to consider, the extent of interstate distribution restrictions imposed by Section 503A is unknown. However, the FDA has continued to state its position that it does not intend to enforce the 5% out of state distribution limit set forth in the law for compounders until a final MOU is made available for a state's signature. The FDA has proposed a 180 day grace period for states to agree to the final MOU after the final version is presented, which to date has not occurred, before it would begin to enforce the 5% rule. If the final Revised MOU contains a 50% limit on interstate distribution, dependent on the additional reporting requirements to be outlined in the Revised MOU, our pharmacy operations could be materially limited.

Certain provisions of the FDCA govern the preparation, handling, storage, marketing and distribution of pharmaceutical products. The Drug Quality and Security Act of 2013 (DQSA) clarifies and strengthens the federal regulatory framework governing compounding pharmacies. Title 1 of the DQSA, the Compounding Quality Act, modifies provisions of the Section 503A of the FDCA that were found to be unconstitutional by the U.S. Supreme Court in 2002. In general, Section 503A provides that pharmacies are exempt from the provisions of the FDCA requiring compliance with cGMP, labeling with adequate directions for use and FDA approval prior to marketing if the pharmacy complies with certain other requirements. Among other things, to comply with Section 503A, a compounded drug must be compounded by a licensed pharmacist for an identified individual patient on the basis of a valid prescription. Pharmacies may only compound in limited quantities before receipt of a prescription for an individual patient and are subject to limitations on anticipatory compounding for distribution, which generally permit anticipatory compounding only based on historical prescription volumes.

The DQSA also contained new Section 503B of the FDCA, which established an outsourcing facility as a new form of entity that is permitted to compound larger quantities of drug formulations without a prescription, thus permitting the practice of anticipatory compounding, and distributing them out of state without limitation, if the drug formulations appear on the FDA's drug shortage list or the bulk drug substances contained in the formulations appear on a "clinical need" list to be established by the FDA. Entities voluntarily registering as outsourcing facilities are subject to cGMP requirements and regular FDA inspection, among other requirements. As described above, our current pharmacy operations in NJ and CA are governed by Section 503A of the FDCA, and our NJ based outsourcing facility is governed by Section 503B of the FDCA.

In a recent California federal court ruling in *Allergan USA, Inc. v. Prescribers Choice, Inc.* the Court made a ruling which could impact 503B facilities. It determined that while the FDA's interim policies do not override the statutory obligations of the DQSA, the Court supported the FDA's authority and flexibility as it determines what clinical needs exist and finalizes the bulk drug substances list. The Court did not wish to set a policy that limits the ability of the FDA to determine whether there is a clinical need for particular drugs, while simultaneously allowing the compounding of certain drugs to meet health needs. The Court went on to note that acting "in good faith" in complying with FDA guidelines and processes, means the facility has not run afoul of the DQSA as it relates to California's Sherman Food, Drug and Cosmetic Law.

Confidentiality, Privacy and HIPAA

Our pharmacy operations involve the receipt, use and disclosure of confidential medical, pharmacy and other health-related information. In addition, we use aggregated and blinded (anonymous) data for research and analysis purposes. The federal privacy regulations under HIPAA are designed to protect the medical information of a healthcare patient or health plan enrollee that could be used to identify the individual. Among other things, HIPAA limits certain uses and disclosures of protected health information and requires compliance with federal security regulations regarding the storage, utilization and transmission of and access to electronic protected health information. The requirements imposed by HIPAA are extensive. In addition, most states have enacted privacy and security laws that protect identifiable patient information that is not health-related. Further, several states have enacted more protective and comprehensive pharmacy-related privacy legislation that not only applies to patient records but also prohibits the transfer or use for commercial purposes of pharmacy data that identifies prescribers. These regulations impose substantial requirements on covered entities and their business associates regarding the storage, utilization and transmission of and access to personal health and non-health information. Many of these laws apply to our business.

Medicare and Medicaid Reimbursement

Medicare is a federally funded program that provides health insurance coverage for qualified persons age 65 or older and for some disabled persons with certain specific conditions. State-funded Medicaid programs provide medical

benefits to groups of low-income and disabled individuals, some of whom may have inadequate or no medical insurance. Currently, most of our commercially available formulations are sold in cash transactions and the customers decide whether or not to seek reimbursement opportunities from Medicare, Medicaid and other third parties. We work with third-party insurers, pharmacy benefit managers and buying groups to offer patient-specific customizable compounded formulations at accessible prices. We plan to continue to devote time and other resources to seek reimbursement and patient pay opportunities for these and other compounded formulations, and we have hired pharmacy billers to process certain existing reimbursement opportunities for certain formulations. However, we may be unsuccessful in achieving these goals, as many third-party payors have imposed significant restrictions on reimbursement for compounded formulations in recent years. Moreover, third-party payors, including Medicare, are increasingly attempting to contain health care costs by limiting coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. Further, the Health Reform Law may have a considerable impact on the existing U.S. system for the delivery and financing of health care and could conceivable have a material effect on our business. As a result, reimbursement from Medicare, Medicaid and other third-party payors may never be available for any of our products or, if available, may not be sufficient to allow us to sell the products on a competitive basis and at desirable price points.

To the extent we obtain third-party reimbursement for our compounded formulations, we may become subject to Medicare, Medicaid and other publicly financed health benefit plan regulations prohibiting kickbacks, beneficiary inducement and the submission of false claims.

FDA New Drug Application Process

As discussed in other sections of this report, we are and may continue to, alone or with project partners, pursue FDA approval to market and sell one or more of our formulations through the FDA's NDA process. 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 Orange Book publication. As a condition of approval, the FDA or other regulatory authorities may require further studies, including Phase 4 post-marketing studies, to provide additional data. Other post-marketing studies may be required to gain approval for the use of a product as a treatment for clinical indications other than those for which the product was initially tested and approved. Also, the FDA or other regulatory authorities require post-marketing reporting to monitor the adverse effects of a drug. Results of post-marketing programs may limit or expand the further marketing of a product.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, fines and potential civil and criminal penalties.

International Regulation

If we pursue commercialization of our proprietary formulations in countries other than the United States, then we may need to obtain the approvals required by the regulatory authorities of such foreign countries that are comparable to the FDA and state boards of pharmacy, and we would be subject to a variety of other foreign statutes and regulations comparable to those relating to our U.S. operations. Regulatory frameworks and requirements vary by country and could involve significant additional licensing requirements and product testing and review periods.

Environmental and Other Matters

We are or may become subject to environmental laws and regulations governing, among other things, any use and disposal by us of hazardous or potentially hazardous substances in connection with our research and preparation of our formulations. In addition, we are subject to work safety and labor laws that govern certain of our operations and our employee relations. In each of these areas, as described above, the FDA and other government agencies have broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, licenses or permits, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on our business.

Research and Development Expenses

Our research and development expenses incurred in 2018 and 2017 primarily include expenses related to the development of intellectual property, researcher and investigator-initiated evaluations, and research and formulation development related primarily to our ophthalmic formulations and certain other assets, in addition to costs associated with our 505(b)(2) drug candidate development programs.

During the year ended December 31, 2018, we incurred $825,000 in research and development expenses, as compared to $413,000 during the year ended December 31, 2017.

Financial Information About Segments and Geographic Areas

Beginning on January 1, 2019, the Company began evaluating performance of the Company based on operating segments. Segment performance for its two operating segments will be based on segment contribution. Our reportable segments consist of (i) our commercial stage pharmaceutical compounding business (Pharmaceutical Compounding), generally including the operations of our ImprimisRx and Park Compounding businesses; and (ii) our start-up operations associated with pharmaceutical drug development business (Pharmaceutical Drug Development). Segment contribution for our segments represents net revenues less cost of sales, research and development, selling and marketing expenses, and select general and administrative expenses. The Company does not evaluate the following items at the segment level:

Operating expenses within selling, general and administrative expenses that result from the impact of corporate initiatives. Corporate initiatives primarily include integration, restructuring, acquisition and other shared costs.

Selling, general and administrative expenses that result from shared infrastructure, including certain expenses associated with legal matters, our board of directors and principal executive officers, investor relations and other like shared expenses.

Other select revenues and operating expenses including R&D expenses, amortization, and asset sales and impairments, net as not all such information has been accounted for at the segment level, or such information has not been used by all segments.

Total assets including capital expenditures.

The Company defines segment net revenues as pharmaceutical compounded drug sales, revenues from licenses and other revenue derived from related agreements.

Cost of sales within segment contribution includes direct and indirect costs to manufacture formulations and sell products, including active pharmaceutical ingredients, personnel costs, packaging, storage, royalties, shipping and handling costs, manufacturing equipment and tenant improvements depreciation, the write-off of obsolete inventory and other related expenses.

Selling, general and administrative expenses consist mainly of personnel-related costs, marketing and promotion costs, distribution costs, professional service costs, insurance, depreciation, facilities costs, transaction costs, and professional services costs which are general in nature and attributable to the segment.

See Notes 19 and 20 to our consolidated financial statements included in this Annual Report for more information about our reportable segments.

Employees

As of March 6, 2019, we employed 134 employees. Our employees are engaged in pharmacy operations, sales, marketing, research, development, and general and administrative functions. We expect to add additional employees in all departmental functions as we carry out our business plan in the next 12 months. We are not party to any collective bargaining agreements with any of our employees. We have never experienced a work stoppage, and we believe our employee relations are good. We hire independent contractor labor and consultants on an as-needed basis.

Company Information

We were incorporated in Delaware in January 2006 as Bywater Resources, Inc. In September 2007, we closed a merger transaction with Transdel Pharmaceuticals Holdings, Inc. and changed our name to Transdel Pharmaceuticals, Inc. We changed our name to Imprimis Pharmaceuticals, Inc. in February 2012. We changed the name of our company to Harrow Health, Inc. in December 2018.

On June 26, 2011, we suspended our operations and filed a voluntary petition for reorganization relief under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the Southern District of California, Case No. 11-10497-11. On December 8, 2011, in connection with our entry into a line of credit agreement and securities purchase agreement with a third party, our voluntary petition for reorganization relief was dismissed.

Our executive offices are located at 12264 El Camino Real, Suite 350, San Diego, California 92130 and our telephone number at such office is (858) 704-4040. Our website address is harrowinc.com. Information contained on our website is not deemed part of this Annual Report.

ITEM 1A. RISK FACTORS

You should carefully consider the following risk factors in addition to the other information contained in this Annual Report. Our business, financial condition, results of operations and stock price could be materially adversely affected by any of these risks.

Risks Related to Our Business

Until last year, we have incurred losses in every year of our operations, and we may not be profitable in the future.

Until 2018, we have incurred losses in every year of our operations, including net income (losses) of $14,625,000 and $(11,985,000) for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, our accumulated deficit was $(74,211,000). Our current projections indicate that we will have operating income and/or net income during 2019, however, these projections may not be correct and our plans could change. Also, we could incur increasing operating losses in the foreseeable future for our commercialization activities, research and development and our pharmaceutical compounding business which would impact net income. Recent changes to the accounting for equity investments require those investments to be measured at fair market value, which may cause our earnings (losses) to become volatile as the stock prices of those equity investments fluctuate. Although we have been generating revenue from our pharmaceutical compounding operations, our ability to generate the revenues necessary to achieve profitability will depend on many factors, including those discussed in this “Risk Factors” section. Our business plan and strategies involve costly activities that are susceptible to failure, and, therefore, we may not be able to generate sufficient revenue to support and sustain our business or reach the level of sales and revenues necessary to achieve and sustain profitability.

We may not receive sufficient revenue to fund our operations and recover our development costs.

Our business plan involves the preparation and sale of our proprietary formulations through our compounding pharmacies and outsourcing facilities. We have limited experience operating pharmacies and commercializing compounded formulations, and we may be unable to successfully manage this business or generate sufficient revenue to recover our development costs and operational expenses. We may have only limited success in marketing and selling our proprietary formulations. Although we have established and plan to grow our internal sales teams to market and sell our proprietary formulations and other non-proprietary products, we have limited experience with such activities and may not be able to generate sufficient physician and patient interest in our formulations to generate

significant revenue from sales of these products. In addition, we are substantially dependent on our ImprimisRx compounding pharmacies and outsourcing facilities, along with any pharmacy partners with which we may contract to compound and sell our formulations using our quality standards and specifications, in a timely manner and sufficient volumes to accommodate the number of prescriptions they receive. Our pharmacies may be unable to compound our formulations successfully and we may be unable to acquire, build or enter into arrangements with pharmacies or outsourcing facilities of sufficient size, reputation and quality to implement our business plan, which would cause our business to suffer.

We sell certain of our proprietary formulations primarily through pharmaceutical compounding facilities we own, but we may not be successful in our efforts to integrate these businesses into our operations.

Our business strategy includes establishing a small compounding pharmacy group, whether through acquisitions, establishing new pharmacies or entering into licensing arrangements with third-party pharmacies and outsourcing facilities, to market and sell our proprietary formulations and other non-proprietary products in all 50 states and in certain geographies outside of the U.S.

We currently have compounding facilities in New Jersey and California. We may plan to expand our pharmacy operations and personnel and developing our facilities into a unified group compounding pharmacy facilities. We have been developing “ImprimisRx” as a uniform brand for certain compounding facilities and ophthalmology focused pharmaceutical compounding business. We have limited experience acquiring, building or operating compounding pharmacies or other prescription dispensing facilities or commercializing our formulations through ownership of or licensing arrangements with pharmacies.. In addition, as we have in the past, we have purchased and operated certain pharmaceutical compounding businesses and pharmacies, and subsequently divested or sold those associated assets, we may pursue similar strategies in the future. Those things considered, we may experience difficulties implementing and/or executing on our compounding pharmacy strategy, including difficulties that arise as a result of our lack of experience, and we may be unsuccessful and our plans may change materially. For instance:

- we have experienced delays and increased costs in our outsourcing facility construction efforts;
- we may not be successful in completing future construction plans on a timely basis or within budget;
- we may not be successful in our efforts to integrate, manage or otherwise realize the benefits we expect from acquisitions of our ImprimisRx compounding pharmacies or any additional pharmacy businesses or outsourcing facilities we to acquire, sell or build in the future;
- we may not be able to satisfy applicable federal and state licensing and other requirements for any of our pharmacy businesses in a timely manner or at all;
- changes to federal and state pharmacy regulations may restrict compounding operations or make them more costly;
- we may be unable to achieve a sufficient physician and patient customer base to sustain our pharmacy operations;
- market acceptance of compounding pharmacies generally may be curtailed or delayed; and
- we may not be able to enter into licensing or other arrangements with third-party pharmacies or outsourcing facilities when desired, on acceptable terms or at all.

Moreover, all our efforts to expand pharmacy operations will involve significant costs and other resources, which we may not be able to afford and may disrupt our other operations and distract management and employees from the other aspects of our business. As a result, our business could materially suffer if we are unable to further develop a group of unified compounding facilities and, even if we are successful, we may be unable to generate sufficient revenue to recover our costs.

We are dependent on market acceptance of compounding pharmacies and compounded formulations, and physicians may be unwilling to prescribe, and patients may be unwilling to use, our proprietary customizable compounded formulations.

We currently distribute our proprietary formulations through compounding pharmacies and an outsourcing facility. Formulations prepared and dispensed by compounding pharmacies contain FDA-approved ingredients, but are not themselves approved by the FDA. Thus, our compounded formulations have not undergone the FDA approval process and only limited data, if any, may be available about the safety and efficacy of our formulations for any particular indication. Certain compounding pharmacies have been subject to widespread negative media coverage in recent years, and the actions of these pharmacies have resulted in increased scrutiny of compounding pharmacy activities from the FDA and state governmental agencies. For example, the FDA has issued formal requests to compounding pharmacies and outsourcing facilities to conduct a recall of all non-expired, purportedly sterile drug products and to cease sterile compounding operations due to lack of sterility assurance. As a result, some health care providers may be reluctant to purchase and use compounded drugs. Our growth and future sales depend not only on our ability to demonstrate in the face of increased scrutiny the quality and safety of our pharmacies and outsourcing facilities and our compliance with more stringent regulatory standards at the federal and state levels, but also on the continued acceptance of compounded drugs and formulations, particularly outsourced compounded drugs and formulations, in the marketplace.

An incident similar to the fungal meningitis outbreak in 2012, which was caused by a compounding pharmacy employing a non-sterile-to-sterile business model, could cause our customers to reduce their use of compounded formulations significantly or even stop using compounded drugs altogether. States have in the past, and could in the future, enact regulation prohibiting or restricting the use of compounding pharmacies and outsourcing facilities in response to such incidents. Such prohibitions or restrictions by states or reduced customer demand as a result of an incident with compounded drugs and formulations could have a material adverse effect on our business, results of operations and financial condition.

In August 2017, FDA issued a MedWatch notification regarding our curcumin emulsion and two adverse events that had been associated with the use of these emulsions by prescribing physicians. We issued a press release on August 7, 2017, clarifying certain facts regarding the notice which outlined our belief that the adverse events associated with the two patients occurred due to an allergic reaction caused by the products being inappropriately administered and obtained by the prescribing physician, and our use of curcumin and excipients in our curcumin emulsion formulation met regulatory standards required for dispensing of the curcumin emulsion. In September 2017, the FDA released a letter confirming that the alleged misuse of certain ingredients in our curcumin emulsions were due to mislabeling by the underlying supplier, and not of our own misdoing. Separately, in December 2017, we were issued a warning letter from the FDA alleging that, in their interpretation of our public communications, we had made false or misleading claims and omitted risk and side effect information regarding certain of our ophthalmology focused compounded medications. We immediately performed a full review of our public communications referenced in the warning letter and responded to the FDA in January 2018. Notwithstanding our continued belief that our public communications were not in fact false and misleading, we have been in communication with the FDA and are taking steps to address the items outlined in the FDA letter. We will continue to work with the FDA to assure that all allegations in the warning letter have been addressed. We believe, to date, we have addressed all of the material items of concern in the FDA's warning letter and those related to the MedWatch notification (and any other requirements observed by FDA and noted to us), and we do not believe there will be any further action taken by FDA in this matter. Nonetheless, these two items increased further scrutiny and negative publicity on us as a company. At times, we have become aware of negative views of regulators related to certain formulations, and as a result discontinued compounding certain drug formulations in an attempt help mitigate potential regulatory risk. As a result of the MedWatch notice and other regulatory notifications, some physicians may be hesitant to prescribe and some patients may be hesitant to purchase and use non-FDA approved compounded formulations, particularly when an FDA-approved potential alternative is available. For other reasons physicians may be unwilling to prescribe or patients may be unwilling to use our proprietary compounded formulations, including the following: legal proscriptions on our ability to discuss the efficacy or safety of our formulations with potential users to the extent applicable data is available; our pharmacy operations are primarily operating on a cash-pay basis and reimbursement may or may not be available from third-party payors, including the government Medicare and Medicaid programs; and certain formulations are not required to be prepared and are not presently being prepared in a manufacturing facility governed by cGMP requirements. Any failure by physicians, patients and/or third-party payors to accept and embrace compounded formulations could substantially limit our market and cause our operations to suffer.

Our business is significantly impacted by state and federal statutes and regulations.

Our proprietary formulations are comprised of active pharmaceutical ingredients that are components of drugs that have received marketing approval from the FDA, although our proprietary compounded formulations have not themselves received FDA approval. FDA approval is not required in order to market and sell our compounded formulations. In the future we may choose to pursue FDA approval to market and sell certain potential drug candidates. The marketing and sale of compounded formulations is subject to and must comply with extensive state and federal statutes and regulations governing compounding pharmacies. These statutes and regulations include, among other things, restrictions on compounding for office use or in advance of receiving a patient-specific prescription or, for outsourcing facilities, requirements regarding preparation, such as regular FDA inspections and cGMP requirements, prohibitions on compounding drugs that are essentially copies of FDA-approved drugs, limitations on the volume of compounded formulations that may be sold across state lines, and prohibitions on wholesaling or reselling. These and other restrictions on the activities of compounding pharmacies and outsourcing facilities may significantly limit the market available for compounded formulations, as compared to the market available for FDA-approved drugs.

Our pharmacy business is impacted by federal and state laws and regulations governing the following: the purchase, distribution, management, compounding, dispensing, reimbursement, marketing and labeling of prescription drugs and related services; FDA and/or state regulation affecting the pharmacy and pharmaceutical industries, including state pharmacy licensure and registration or permit standards; rules and regulations issued pursuant to HIPAA and other state and federal laws related to the use, disclosure and transmission of health information; and state and federal controlled substance laws. Our failure to comply with any of these laws and regulations could severely limit or curtail our pharmacy operations, which would materially harm our business and prospects. Further, our business could be adversely affected by changes in these or any newly enacted laws and regulations, and federal and state agency interpretations of the statutes and regulations. Statutory or regulatory changes could require us to make changes to our business model and operations and/or could require us to incur significantly increased costs to comply with such regulations.

If one of our pharmacies fails to comply with state statutes and regulations, the pharmacy could be required to cease operations or become subject to restrictions that could adversely affect our business.

State pharmacy laws require pharmacy locations in those states be licensed as an in-state pharmacy to dispense pharmaceuticals. In addition, state controlled substance laws require registration and compliance with state pharmacy licensure, registration or permit standards promulgated by the state's pharmacy licensing authority. Pharmacy and controlled substance laws often address the qualification of an applicant's personnel, the adequacy of its prescription fulfillment and inventory control practices and the adequacy of its facilities. If one of our pharmacies, or with which we may partner is found not to comply with state pharmacy and controlled substance laws and regulations, the pharmacy could be required to cease operations or become subject to burdensome restrictions and limitations on its business. For example, in March 2018, the California Board of Pharmacy filed an accusation against our subsidiary, Park Compounding, Inc. related to a compounded formulation we believe was legally dispensed and was, without our knowledge, inappropriately administered to a patient unknown to us, by the prescribing healthcare professionals. While we dispute all claims against us and intend to vigorously defend against the accusations, if Park Compounding is found to be in non-compliance pursuant to this accusation, it may be required to permanently or temporarily cease or limit its operations including its sterile compounding operations. If Park Compounding is required to permanently or temporarily cease or limit its sterile compounding operations, we would be unable to realize the expected benefits of this pharmacy's operations, including its sales of our proprietary formulations. Although we distribute our proprietary formulations through other compounding pharmacies, and not solely through Park Compounding, the loss of Park Compounding's ability to compound sterile formulations would have an immediate adverse impact on our ability to implement our business plan in a timely manner.

If we or our partner facilities fail to comply with the Controlled Substances Act, FDCA, or similar state statutes and regulations, the pharmacy facilities could be required to cease operations or become subject to restrictions that could adversely affect our business.

State pharmacy laws require pharmacy locations in those states to be licensed as an in-state pharmacy to dispense pharmaceuticals. In addition, state controlled substance laws require registration and compliance with state pharmacy licensure, registration or permit standards promulgated by the state's pharmacy licensing authority. Pharmacy and controlled substance laws often address the qualification of an applicant's personnel, the adequacy of its prescription fulfillment and inventory control practices and the adequacy of its facilities. These laws also subject pharmacies to oversight by state boards of pharmacy and other regulators that could impose burdensome requirements or restrictions on operations if a pharmacy is found not in compliance with these laws. We believe that our compounding pharmacies are in material compliance with applicable regulatory requirements. Further, if any of our compounding pharmacies (including Park) fail to comply with regulatory requirements, they could be forced to permanently or temporarily cease or limit their compounding operations, which would severely limit our ability to market and sell our proprietary formulations and would materially harm our operations and prospects. Any noncompliance could also result in complaints or adverse actions by other state boards of pharmacy. FDA inspection of a facility to determine compliance with the FDCA, if not successful, may result in the loss of FDCA exemptions provided under Sections 503A and 503B, warning letters, injunctions, prosecution, fines and loss of required government licenses, certifications and approvals, any of which could involve significant costs and could cause us to be unable to realize

the expected benefits of these pharmacies' operations.

Further, under federal law, Section 503A of the FDCA seeks to limit the amount of compounded products that a pharmacy can dispense interstate. The interpretation and enforcement of this provision is dependent on the FDA entering into a standard Memorandum of Understanding ("MOU") with each state setting forth limits on shipments of interstate compounding. Previously, the draft MOU presented by the FDA in February 2015 intended to limit interstate shipments of compounded drug units to 30% of all compounded and non-compounded units dispensed or distributed by the pharmacy per month, the excess of which the FDA considered an "inordinate amount." The FDA stated in the guidance issued in February 2015 that it would not enforce interstate restrictions until after it published a final MOU and made it available to states for signature for some designated period of time. If the final MOU was drafted and released by the FDA and was not signed by a particular state, then interstate shipments of compounded preparations from a pharmacy located in that state would be limited to quantities not greater than 5% of total prescription orders dispensed or distributed by the pharmacy; however, we are not aware that the FDA currently enforces or has in the past enforced the 5% rule and, under current draft guidance, the FDA had historically stated that it would not enforce the 5% rule until a final MOU was made available to states for signature. The FDA originally proposed a 180-day period for states to agree to the final MOU after the final version was presented, which to date has not occurred, before it would begin to enforce the 5% rule. In January of 2018, the FDA released a "2018 Compounding Policy Priorities Plan" (the "2018 Compounding Plan") which provided an overview of the key priorities the FDA plans to focus on in 2018 in connection with compounding regulations. One of the priorities outlined in the 2018 Compounding Plan addressed the current status of the MOU and the FDA's plan to release a revised MOU (the "Revised MOU"). Pursuant to the statements in the Compounding Plan, the Revised MOU would consider amounts shipped interstate by a compounder to be inordinate amounts if the "number of prescriptions of compounded drugs distributed interstate during any calendar month is greater than 50 percent." Importantly, instead of that number serving as a "hard limit, for state action," the 50% target would trigger certain additional reporting requirements. The Revised MOU will also provide states more time to report to the FDA, and flexibility on identifying when amounts are inordinate, considering the size and scope of compounding operations. Until a the Revised MOU is issued and presented to states to consider, the extent of interstate dispensing restrictions imposed by Section 503A is unknown. However, if the final Revised MOU contains a 50% limit on interstate distribution, dependent on the additional reporting requirements to be outlined in the Revised MOU, our pharmacy operations could be materially limited.

There are many competitive risks related to marketing and selling our proprietary formulations and operating our compounding pharmacy business.

The pharmaceutical and pharmacy industries are highly competitive. We compete against branded drug companies, generic drug companies, outsourcing facilities and other compounding pharmacies. We are significantly smaller than some of our competitors. Currently we lack some of the financial and other resources needed to develop, produce, distribute and market our proprietary formulations at a level to capture a significant market share in these sectors. The drug products available through branded and generic drug companies with which our formulations compete have been approved for marketing and sale by the FDA and are required to be manufactured in facilities compliant with cGMP standards. Although we prepare our compounded formulations in accordance with the standards provided by the United States Pharmacopeia ("USP") <795> and USP <797> and applicable state and federal law, our proprietary compounded formulations are not required to be, and have not been, approved for marketing and sale by the FDA. As a result, some physicians may be unwilling to prescribe, and some patients may be unwilling to use, our formulations. Additionally, under federal and state laws applicable to our current compounding pharmacy operations, we are not permitted to prepare significant amounts of a specific formulation in advance of a prescription, compound quantities for office use or utilize a wholesaler for distribution of our formulations; instead, our compounded formulations must be prepared and dispensed in connection with a physician prescription for an individually identified patient. Pharmaceutical companies, on the other hand, are able to sell their FDA-approved products to large pharmaceutical wholesalers, which can in turn sell to and supply hospitals and retail pharmacies. Even if we are successful in registering certain of our facilities as outsourcing facilities, our business may not be scalable on the scope available to our competitors that produce FDA-approved drugs, which may limit our potential for profitable operations. These facets of our operations may subject our business to limitations our competitors with FDA-approved drugs may not face.

Our future success depends in large part on our ability to maintain a competitive position with respect to biotechnology and related pharmaceutical technologies.

Biotechnology and related pharmaceutical technologies have undergone and continue to be subject to rapid and significant change. Our future success will depend in large part on our ability to maintain a competitive position with respect to these technologies. Products developed by our competitors, including FDA-approved drugs and compounded formulations created by other pharmacies, could render our products and technologies obsolete or unable to compete. Any products that we develop may become obsolete before we recover expenses incurred in their development, which may require us to raise additional funds that may or may not be available. The competitive environment requires an ongoing, extensive search for medical and technological innovations and the ability to develop and market these innovations effectively, and we may not be competitive with respect to these factors. Other competitive factors include the safety and efficacy of a product, the size of the market for a product, the timing of market entry relative to competitive products, the availability of alternative compounded formulations or approved drugs, the price of a product relative to alternative products, the availability of third-party reimbursement, the success of sales and marketing efforts, brand recognition and the availability of scientific and technical information about a product. Although we believe we are positioned to compete favorably with respect to many of these factors, if our proprietary formulations are unable to compete with the products of our competitors, we may never gain market share

or achieve sustained profitability.

If a compounded drug formulation provided through our compounding services leads to patient injury or death or results in a product recall, we may be exposed to significant liabilities and reputational harm.

The success of our business, including our proprietary formulations and pharmacy operations, is highly dependent upon medical and patient perceptions of us and the actual safety and quality of our products. We could be adversely affected if we, any other compounding pharmacies or our formulations and technologies are subject to negative publicity. We could also be adversely affected if any of our formulations or other products we sell, any similar products sold by other companies, or any products sold by other compounding pharmacies prove to be, or are asserted to be, harmful to patients. For instance, if any of the components of approved drugs or other ingredients used to produce our compounded formulations have quality or other problems that adversely affect the finished compounded preparations, our sales could be adversely affected. Because of our dependence upon medical and patient perceptions, adverse publicity associated with illness or other adverse effects resulting from the use or misuse of our products, any similar products sold by other companies, or any other compounded formulations could have a material adverse impact on our business.

To assure compliance with USP guidelines, we have a policy whereby 100% of all sterile compound batches produced by our ImprimisRx compounding pharmacies are tested prior to their delivery to patients and physicians both in-house and externally by an independent, FDA-registered laboratory that has represented to us that it operates in compliance with current good laboratory practices. However, we could still become subject to product recalls and termination or suspension of our state pharmacy licenses if we fail to fully implement this policy, if the laboratory testing does not identify all contaminated products, or if our products otherwise cause or appear to have caused injury or harm to patients. In addition, laboratory testing may produce false positives, which could harm our business and impact our pharmacy operations and licensure even if the impacted formulations are ultimately found to be sterile and no patients are harmed by them. If adverse events or deaths or a product recall, either voluntarily or as required by the FDA or a state board of pharmacy, were associated with one of our proprietary formulations or any compounds prepared by our ImprimisRx compounding pharmacies or any pharmacy partner, our reputation could suffer, physicians may be unwilling to prescribe our proprietary formulations or order any prescriptions from such pharmacies, we could become subject to product and professional liability lawsuits, and our state pharmacy licenses could be terminated or restricted. If any of these events were to occur, we may be subject to significant litigation or other costs and loss of revenue, and we may be unable to continue our pharmacy operations and further develop and commercialize our proprietary formulations.

We carry product and professional liability insurance which may be inadequate.

Although we have secured product and professional liability insurance for our pharmacy operations and the marketing and sale of our formulations, our current or future insurance coverage may prove insufficient to cover any liability claims brought against us. Because of the increasing costs of insurance coverage, we may not be able to maintain insurance coverage at a reasonable cost or at a level adequate to satisfy liabilities that may arise.

Our ability to generate revenues will be diminished if we fail to obtain acceptable prices or an adequate level of reimbursement from third-party payors.

Currently, our ImprimisRx compounding pharmacies operate on mostly a cash-pay basis and do not submit large amounts of claims for reimbursement through Medicare, Medicaid or other third-party payors. As part of our Imprimis Cares initiative, we work with third-party insurers, pharmacy benefit managers and buying groups to offer patient-specific customizable compounded formulations at accessible prices. We plan to continue to devote time and other resources to seek reimbursement and patient pay opportunities for these and other compounded formulations. We have hired pharmacy billers to process certain existing reimbursement opportunities for certain formulations. However, we may be unsuccessful in achieving these goals, as many third-party payors have imposed significant restrictions on reimbursement for compounded formulations in recent years. Moreover, third-party payors, including Medicare, are attempting to contain health care costs by limiting coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. Further, the Health Reform Law may have a considerable impact on the existing U.S. system for the delivery and financing of health care and could conceivable have a material effect on our business. As a result, reimbursement from Medicare, Medicaid and other third-party payors may never be available for any of our products or, if available, may not be sufficient to allow us to sell the products on a competitive basis and at desirable price points. If government and other third-party payors do not provide adequate coverage and reimbursement levels for our formulations, the market acceptance for our formulations may be limited.

Additionally, we are making efforts to normalize the pricing for our currently available proprietary compounded formulations. Any efforts to attain optimized pricing for our Dropless Therapy or any of our other proprietary formulations could fail, which could make our products less attractive or unavailable to some patients or could reduce our margins.

We may not be able to correctly estimate our future operating expenses, which could lead to cash shortfalls.

The estimates of our future operating and capital expenditures are based upon our current business plan, our current operations and our current expectations regarding the commercialization of our proprietary formulations. Our projections have varied significantly in the past as a result of changes to our business model and strategy, our termination of efforts to pursue FDA approval of a drug candidate in November 2013, our acquisitions of compounding facilities and various product and corporate development opportunities since 2014, and the expenses in developing our pharmacy facilities into outsourcing facilities and registering them as such with the FDA. We may not accurately estimate the potential revenues and expenses of our operations. If we are unable to correctly estimate the amount of cash necessary to fund our business, we could spend our available financial resources much faster than we expect. If we do not have sufficient funds to continue to operate and develop our business, we could be required to seek additional financing earlier than we expect, which may not be available when needed or at all, or be forced to delay, scale back or eliminate some or all of our proposed operations.

If we do not successfully identify and acquire rights to potential formulations and successfully integrate them into our operations, our growth opportunities may be limited.

We plan to pursue the development of new proprietary compounded formulations in the ophthalmology and/or other therapeutic areas, which may include continued activities to develop and commercialize current assets or, if and as opportunities arise, potential acquisitions of new intellectual property rights and assets. We also intend to seek opportunities to introduce new lower-cost compounded formulation alternatives to higher-priced FDA-approved drugs. However, we expect acquisitions of compounding pharmacies to provide us with only limited research and development support and access to additional novel compounded formulations. We have historically relied, and we expect to continue to rely, primarily upon third parties to provide us with additional development opportunities. We may seek to enter into acquisition agreements or licensing arrangements to obtain rights to develop new formulations in the future, but only if we are able to identify attractive formulations and negotiate acquisition or license agreements on terms acceptable to us, which we may not be able to do. Moreover, we have limited resources to acquire additional potential product development assets and integrate them into our business. Acquisition opportunities may involve competition among several potential purchasers, which could include large multi-national pharmaceutical companies and other competitors that have access to greater financial resources than we do. If we are unable to obtain rights to development opportunities from third parties and we are unable to rely upon our compounding pharmacies and current and future relationships with pharmacists, physicians and other inventors to provide us with additional development opportunities, our growth and prospects could be limited.

Our product development strategy is to focus on a select few therapeutic areas in which we believe there is broad market potential, large unmet needs and/or unique value to physicians and patients and to develop and offer formulations within these therapeutic areas that could afford us with gross margins. However, our expectations and assumptions about market potential and patient needs may prove to be wrong and we may invest capital and other resources on formulations that do not generate sufficient revenues for us to recoup our investment.

We may be unable to successfully develop and commercialize our proprietary formulations or any other assets we may acquire.

We have acquired assets related to compoundable formulations and we have entered into one license agreement for rights to commercialize a compounding formulation. We are currently pursuing development and commercialization opportunities with respect to certain of these formulations, and we are in the process of assessing certain of our other assets in order to determine whether to pursue their development or commercialization. In addition, we expect to consider the acquisition of additional intellectual property rights or other assets in the future. Once we determine to pursue a potential drug candidate, we develop a commercialization strategy for it, which may include marketing and selling the formulation in compounded form through compounding pharmacies or outsourcing facilities, or pursuing FDA approval of the drug candidate. We may incorrectly assess the risks and benefits of the commercialization options or we may not pursue a commercialization strategy that proves to be successful. If we are unable to successfully commercialize one or more of our proprietary formulations, our operating results would be adversely affected. Even if we are able to successfully sell one or more proprietary formulations, we may never recoup our investment in acquiring or developing the formulations. Our failure to identify and expend our resources on formulations and technologies with commercial potential and execute an effective commercialization strategy for each of our formulations would negatively impact the long-term profitability of our business.

We have incurred significant indebtedness, which will require substantial cash to service and which subjects us to certain financial requirements and business restrictions.

On July 19, 2017, we incurred $16,000,000 of indebtedness under a loan agreement with SWK Funding, LLC and its partners (SWK) and concurrent with the funding, we utilized a portion of the SWK Loan funds as full payment to an affiliate of Life Sciences Alternative Funding, LLC (LSAF) to terminate all amounts due to LSAF in connection with the existing term loan and security agreements, as amended, originally entered into between the Company and LSAF on May 11, 2015 (the “LSAF Loan”), which loan had a principal balance of $12,120,000 at the time of final payment.

Our ability to make scheduled payments on our indebtedness depends on our future performance and ability to raise additional capital, which is subject to economic, financial, competitive and other factors, some of which are beyond our control. If we are unable to generate sufficient cash to service our debt, we may be required to adopt one or more alternatives, such as selling assets, restructuring our debt or obtaining additional capital through equity sales or

incurrence of additional debt on terms that may be onerous or highly dilutive to our stockholders. Our ability to engage in any of these activities would depend on the capital markets and our financial condition at such time, and we may not be able to do so when needed, on desirable terms or at all, which could result in a default on our debt obligations. Additionally, our SWK debt instrument contain various restrictive covenants, including, among others, our obligation to deliver to SWK certain financial and other information, our obligation to comply with certain notice and insurance requirements, and our inability, without SWK's prior consent, to dispose of certain of our assets, incur certain additional indebtedness, enter into certain merger, acquisition or change of control transactions, pay certain dividends or distributions on or repurchase any of our capital stock or incur any lien or other encumbrance on our assets, subject to certain permitted exceptions. Any failure by us to comply with any of these covenants, subject to certain cure periods, or to make all payments under the debt instruments when due, would cause us to be in default under the applicable debt instrument. In the event of any such default, SWK may be able to foreclose on our assets that secure the debt or declare all borrowed funds, together with accrued and unpaid interest, immediately due and payable, thereby potentially causing all of our available cash to be used to pay our indebtedness or forcing us into bankruptcy or liquidation if we do not then have sufficient cash available. Any such event or occurrence could severely and negatively impact our operations and prospects.

We may need additional capital in order to continue operating our business, and such additional funds may not be available when needed, on acceptable terms, or at all.

We only recently started generating cash from operations, but we do not currently earn sufficient revenues to support our operations. We may need significant additional capital to execute our business plan and fund our proposed business operations. Additionally, our plans may change or the estimates of our operating expenses and working capital requirements could be inaccurate, we may pursue acquisitions of pharmacies or other strategic transactions that involve large expenditures, or we may experience growth more quickly or on a larger scale than we expect, any of which may 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.

We have raised over $59,000,000 in funds through equity and debt financings since January 2015. We may seek to obtain additional capital through equity or debt financings, funding from corporate partnerships or licensing arrangements, sales of assets or other financing transactions. If we issue additional equity or convertible debt securities to raise funds, our existing stockholders may experience substantial dilution, and the newly issued equity or debt securities may have more favorable terms or rights, preferences and privileges senior to those of our existing stockholders. If we raise additional funds through collaboration and licensing arrangements or sales of assets, we may have to relinquish potentially valuable rights to our drug candidates or proprietary technologies, or grant licenses on terms that are not favorable to us. If we raise funds by incurring additional debt, we may be required to pay significant interest expenses and our leverage relative to our earnings or to our equity capitalization may increase. Obtaining commercial loans, assuming those loans would be available, would increase our liabilities and future cash commitments and may impose restrictions on our activities, such as the financial and operating covenants included in our loan agreement with SWK. Further, we may incur substantial costs in pursuing future capital and/or financing transactions, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we may issue, such as options, convertible notes and warrants, which would adversely impact our financial results.

We have in the past and may in the future participate in strategic transactions that could impact our liquidity, increase our expenses and distract our management.

From time to time we consider engaging in strategic transactions, such as out-licensing or in-licensing of compounds or technologies, acquisitions of companies, and asset purchases. We may also consider a variety of different business arrangements in the future, including strategic partnerships, joint ventures, spin-offs, restructurings, divestitures, business combinations and investments. In addition, another entity may pursue us or certain of our assets or aspects of our operations as an acquisition target. Any such transactions may require us to incur expenses specific to the transaction and not incident to our operations, may increase our near- and long-term expenditures, may pose significant integration challenges, may require us to hire or otherwise engage personnel with additional expertise, or may result in our selling or licensing of our assets or technologies under terms that may not prove profitable, any of which could harm our operations and financial results. Such transactions may also entail numerous other operational and financial risks, including, among others, exposure to unknown liabilities, disruption of our business and diversion of our management’s time and attention in order to develop acquired products, drug candidates, technologies or businesses.

As part of our efforts to complete any significant transaction, we would need to expend significant resources to conduct business, legal and financial due diligence, with the goal of identifying and evaluating material risks involved in the transaction. We may be unsuccessful in ascertaining or evaluating all the risks and, as a result, we may not realize the expected benefits of the transaction, whether due to unidentified risks, integration difficulties, regulatory setbacks or other events. We may incur material liabilities for the past activities of any businesses we partner with or acquire. If any of these events occur, we could be subject to significant costs and damage to our reputation, business, results of operations and financial condition.

If we are unable to establish, train and maintain an effective sales and marketing infrastructure, we will not be able to commercialize our drug candidates successfully.

We have started to build an internal sales and marketing infrastructure to implement our business plan by developing internal sales teams and education campaigns to market our proprietary formulations. We will need to expend significant resources to further establish and grow this internal infrastructure and properly train sales personnel with respect to regulatory compliance matters. We may also choose to engage or enter into other arrangements with third parties to provide sales and marketing services for us in place of or to supplement our internal commercialization infrastructure. We may not be able to secure sales personnel or relationships with third-party sales organizations that are adequate in number or expertise to successfully market and sell our proprietary formulations and pharmacy services. Further, any third-party organizations we may seek to partner with or engage may not be able to provide sales and marketing services in accordance with our expectations and standards, may be more expensive than we can afford or may not be available on otherwise acceptable terms or at all. If we are unable to establish and maintain compliant and adequate sales and marketing capabilities, through our own internal infrastructure or third-party services or other arrangements, we may be unable to sell our formulations or services or generate meaningful revenue.

Our business and operations would suffer in the event of cybersecurity or other system failures.

Despite the implementation of security measures, our internal computer systems and those of any third parties with which we partner are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any cybersecurity or system failure, accident or breach to date, if an event were to occur, it could result in a material disruption of our operations, substantial costs to rectify or correct the failure, if possible, and potentially violation of HIPAA and other privacy laws applicable to our operations. If any disruption or security breach resulted in a loss of or damage to our data or applications or inappropriate disclosure of confidential or protected information, we could incur liability, further development of our proprietary formulations could be delayed, and our pharmacy operations could be disrupted, subject to restriction or forced to terminate their operations, any of which could severely harm our business and prospects.

We depend upon consultants, outside contractors and other third-party service providers for key aspects of our business.

We are substantially dependent on consultants and other outside contractors and service providers for key aspects of our business. For instance, we rely upon pharmacist, physician and research consultants and advisors to provide us with significant assistance in the evaluation of product development opportunities, and we have engaged or supported, and expect to continue to engage or support, consultants, advisors, clinical research organizations (CROs) and others to design, conduct, analyze and interpret the results of any clinical or non-clinical trials or other studies in connection with the research and development of our products. If any of our consultants or other service providers terminates its engagement with us, or if we are unable to engage highly qualified replacements as needed on commercially reasonable terms, we may be unable to successfully execute our business plan. We must effectively manage these third-party service providers to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, these third parties often engage in other business activities and may not devote sufficient time and attention to our activities and we may have only limited contractual rights in connection with the conduct of the activities we have engaged the service providers to perform. If we are unable to effectively manage our outsourced activities or if the quality, timeliness or accuracy of the services provided by third-party service providers is compromised for any reason, our development activities may be extended, delayed or terminated, and we may not be able to commercialize our formulations or advance our business.

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

If we seek FDA approval to market and sell any of our proprietary formulations, such as with drug candidates being developed by Surface and Eton, we may be unable to demonstrate the necessary safety and efficacy to obtain such FDA approval.

Historically, our business strategy was focused on developing and commercializing product opportunities as compounded formulations. In 2017 and in the future we, alone or with project partners, may seek FDA regulatory approval to market and sell one or more of our assets as a FDA-approved drug. Obtaining FDA approval to market and sell pharmaceutical products is costly, time consuming, uncertain and subject to unanticipated delays. The FDA or other regulatory agencies may not approve a drug candidate on a timely basis or at all. Before we obtain FDA approval for the sale of any potential drug candidates, we will be required to demonstrate through preclinical studies and clinical trials that it is safe and effective for each intended use, which we may not be able to do. A failure to demonstrate safety and efficacy of a drug candidate to the FDA’s satisfaction would result in our failure to obtain FDA approval. Moreover, even if the FDA were to grant regulatory approval of a drug candidate, the approval may be limited to specific therapeutic areas or limited as to its distribution, which could reduce revenue potential, and we will be subject to extensive and costly post-approval requirements and oversight with respect to commercialization of the drug candidate.

Delays in the completion of, or the termination of, any clinical or non-clinical trials for any drug candidates for which we may seek FDA approval could adversely affect our business.

Clinical trials are very expensive, time consuming, unpredictable and difficult to design and implement. The results of clinical trials may be unfavorable, they may continue for several years, and they may take significantly longer to complete and involve significantly more costs than expected. Delays in the commencement or completion of clinical testing could significantly affect product development costs and plans with respect to any drug candidate for which we seek FDA approval. The commencement and completion of clinical trials can be delayed and experience difficulties for a number of reasons, including delays and difficulties caused by circumstances over which we may have no control. For instance, approvals of the scope, design or trial site may not be obtained from the FDA and other required bodies in a timely manner or at all, agreements with acceptable terms may not be reached in a timely manner or at all with CROs to conduct the trials, a sufficient number of subjects may not be recruited and enrolled in the trials, and third-party manufacturers of the materials for use in the trials may encounter delays and problems in the manufacturing process, including failure to produce materials in sufficient quantities or of an acceptable quality to complete the trials. If we were to experience delays in the commencement or completion of, or if we were to terminate, any clinical or non-clinical trials we pursue in the future, the commercial prospects for the applicable drug candidates may be limited or eliminated, which may prevent us from recouping our investment in research and development efforts for the drug candidate and would have a material adverse effect on our business, results of operations, financial condition and prospects.

We depend on the success of our drug candidates, and those we have royalty rights to, which have not yet demonstrated efficacy for their target or any other indications. If we are unable to generate revenues from our drug candidates, our ability to create stockholder value will be limited.

Our drug candidates are in the early stages of clinical development. We do not generate revenues from any FDA approved drug products. We expect to submit an Investigational New Drug Application (“IND”) or foreign equivalent to the FDA or international regulatory authorities seeking approval to initiate our clinical trials in humans in the United States or other countries yet to be determined. We plan on submitting our clinical trial protocols and receive approvals from the FDA and international regulatory authorities before we can 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 drug candidate will be extended and such extension will increase our expenses and increase our need for additional capital. Moreover, there is no guarantee that our clinical trials will be successful or that we will continue clinical development in support of an approval from the FDA or comparable foreign regulatory authorities for any indication. We note that most drug candidates never reach the clinical development stage and even those that do commence clinical development have only a small chance of successfully completing clinical development and gaining regulatory approval. Therefore, our business currently depends entirely on the successful development, regulatory approval and commercialization of our drug candidates, which may never occur.

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

We must successfully complete clinical trials for our drug candidates before we can apply for marketing approval. Even if we complete our clinical trials, it does not assure marketing approval. Our clinical trials may be unsuccessful, which would materially harm our business. Even if our initial clinical trials are successful, we are required to conduct additional clinical trials to establish our drug candidates' safety and efficacy, before an NDA or Biologics License Application ("BLA"), or their foreign equivalents can be filed with the FDA or comparable foreign regulatory authorities for marketing approval of our drug candidates.

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in early phases of pre-clinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates. The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We are not permitted to market our drug candidates as prescription pharmaceutical products in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. In the United States, the FDA generally requires the completion of clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before an NDA is approved. Regulatory authorities in other jurisdictions impose similar requirements. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are eventually approved for commercialization. We have not submitted an NDA to the FDA or comparable applications to other regulatory authorities. If our development efforts for our drug candidates, including regulatory approval, are not successful for their planned indications, or if adequate demand for our drug candidates is not generated, our business will be materially adversely affected.

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

- the results of toxicology studies may not support the filing of an IND for our drug candidates;
- the FDA or comparable foreign regulatory authorities or Institutional Review Boards, or "IRB", may disagree with the design or implementation of our clinical trials;
- we may not be able to provide acceptable evidence of our drug 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, European Medicines Agency (the "EMA"), or other regulatory agencies for marketing approval;

the dosing of our drug candidates in a particular 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 drug candidates;

the data collected from clinical trials may not be sufficient to support the submission of an NDA, BLA 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 or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Failure to obtain regulatory approval for our drug candidates for the foregoing, or any other reasons, will prevent us from commercializing our drug candidates, and our ability to generate revenue will be materially impaired. We cannot guarantee that regulators will agree with our assessment of the results of the clinical trials we intend to conduct in the future or that such trials will be successful. The FDA, EMA 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 drug candidates.

Excluding any activities through our ownership interest in Eton, we have not submitted an NDA or received regulatory approval to market our drug candidates in any jurisdiction. We have only limited experience in filing the applications necessary to gain regulatory approvals and expect to rely on consultants and third party contract research organizations, or "CROs", with expertise in this area to assist us in this process. Securing regulatory approvals to market a product requires the submission of pre-clinical, clinical, and/or pharmacokinetic data, information about product manufacturing processes and inspection of facilities and supporting information to the appropriate regulatory authorities for each therapeutic indication to establish a drug candidate's safety and efficacy for each indication. Our drug candidates may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the drug 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 drug 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 drug candidates in any indication will prevent us from commercializing the drug candidate, and our ability to generate revenue will be materially impaired.

If we fail to successfully commercialize any of our drug candidates, we may need to acquire additional drug candidates and our business will be adversely affected.

We have never commercialized any drug candidates and do not have any other compounds in pre-clinical testing, lead optimization or lead identification stages beyond our drug candidates. We cannot be certain that any of our drug candidates will prove to be sufficiently effective and safe to meet applicable regulatory standards for any indication. If we fail to successfully commercialize any of our drug candidates for their targeted indications, whether as stand-alone therapies or in combination with other therapeutic agents, our business would be adversely affected.

Even if we receive regulatory approval for any of our drug 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 drug 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 drug 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 drug candidates, and the target patient population to try new therapies;
- efficacy of our drug candidates compared to competing products;
- the introduction of any new products that may in the future become available targeting indications for which our drug candidates may be approved;
- new procedures or therapies that may reduce the incidences of any of the indications in which our drug candidates may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of our drug 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 or 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 reimbursement or government pricing approvals.

If any of our drug 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 drug candidates may require significant resources and may never be successful.

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our drug 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 drug candidates not commercially viable. For example, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for any of our drug candidates, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve any of our drug 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 sponsor of the NDA must submit a proposed REMS; 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 drug 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 drug candidates.

Even if we obtain marketing approval for any of our drug candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our drug 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 drug candidates.

Even if we obtain regulatory approval for any of our drug candidates for an indication, the FDA or foreign equivalent may still impose significant restrictions on their indicated uses or marketing or the conditions of approval, or impose ongoing requirements for potentially costly and time-consuming post-approval studies, including Phase 4 clinical trials, and post-market surveillance to monitor safety and efficacy. Our drug 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, or "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 current 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 drug 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. If we receive marketing approval for our drug 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 drug candidates and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure.

Obtaining and maintaining regulatory approval of our drug candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our drug candidates in other jurisdictions.

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

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

Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug 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 healthcare system that could prevent or delay marketing approval for our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our drug 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 drug 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, or "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 drug 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.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 or, collectively, the Health Care Reform Law, is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The Health Care Reform Law revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the law imposed a significant annual fee on companies that manufacture or import branded prescription drug products.

The Health Care Reform Law remains subject to legislative efforts to repeal, modify or delay the implementation of the law. Efforts to date have generally been unsuccessful. If the Health Care Reform Law is repealed or modified, or if implementation of certain aspects of the Health Care Reform Law are delayed, such repeal, modification or delay may materially adversely impact our business, strategies, prospects, operating results or financial condition. We are unable to predict the full impact of any repeal or modification in the implementation of the Health Care Reform Law on us at

this time.

In addition, other legislative changes have been proposed and adopted in the United States since the Health Care Reform Law was enacted. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce or eliminate our profitability.

Our drug candidates may face competition sooner than expected.

Our success will depend in part on our ability to obtain and maintain patent protection for our certain of our drug candidates and technologies and to prevent third parties from infringing upon our proprietary rights. We must also operate without infringing upon patents and proprietary rights of others, including by obtaining appropriate licenses to patents or other proprietary rights held by third parties, if necessary. However, the applications we have filed or may file in the future may never yield patents that protect our inventions and intellectual property assets. Failure to obtain patents that sufficiently cover our formulations and technologies would limit our protection against compounding pharmacies, outsourcing facilities, generic drug manufacturers, pharmaceutical companies and other parties who may seek to copy our products, produce products substantially similar to ours or use technologies substantially similar to those we own.

We also intend to seek data exclusivity or market exclusivity for our drug candidates provided under the FDCA, and similar laws in other countries. The FDCA provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing 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, for example, for new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Even if our drug candidates are considered to be reference products eligible for 3 years of exclusivity under the FDCA, another company could market competing products if the FDA approves a full NDA for such product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the products. Moreover, an amendment or repeal of the FDCA could result in a shorter exclusivity period for our drug candidates, which would have a material adverse effect on our business.

If we market any of our drug candidates in a manner that violates healthcare 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 subject that company 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 healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include 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 the 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 healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions 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 exemption 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, amends the intent requirement of the U.S. Anti-Kickback Statute and criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. 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 healthcare 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 substantial civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, substantial criminal fines and imprisonment.

We will be completely dependent on third parties to manufacture our drug candidates, and our commercialization of our drug 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 drug 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 drug 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 drug 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 drug candidates are approved for commercialization. We have not entered into an agreement with any contract manufacturers for commercial supply and may not be able to engage a contract manufacturer for commercial supply of any of our drug candidates on favorable terms to us, or at all.

The facilities used by our contract manufacturers to manufacture our drug candidates must be approved by the FDA or comparable foreign regulatory authorities pursuant to inspections that will be conducted after we submit an NDA or BLA 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 drug 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 and/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 drug 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 drug 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 drug 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 drug 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 drug candidates or may not be able to create a supply of our drug candidates at all. Were we to encounter manufacturing issues, our ability to produce a sufficient supply of any of our drug 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 drug 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 drug candidates if we decided to transfer the manufacture of any of our drug candidates to one or more alternative manufacturers in an effort to deal with the difficulties.

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to a future contract manufacturer caused by problems at suppliers could delay shipment of any of our drug 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 drug candidates over time. If the commercial-scale manufacturing costs of any of our drug 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 expect to rely on third parties to conduct clinical trials for our drug 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 drug candidates and our business would be substantially harmed.

We expect to enter 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 drug 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, the Competent Authorities of the Member States of the European Economic Area 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 drug 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 drug 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 drug 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 drug candidates. As a result, our financial results and the commercial prospects for any of our drug candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Any termination or suspension of, or delays in the commencement or completion of, any necessary studies of any of our drug 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 drug 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 drug 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 drug 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 drug 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 drug candidates, its commercial prospects may be materially harmed and our ability to generate product revenues will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical studies may also ultimately lead to the denial of regulatory approval of our drug 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 drug 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 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 drug candidates will achieve positive results. Drug 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 drug 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 drug 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.

Even though we may apply for orphan drug designation for a drug candidate, we may not be able to obtain orphan drug marketing exclusivity.

There is no guarantee that the FDA, EMA or their foreign equivalents will grant any future application for orphan drug designation for any of our drug candidates, which would make us ineligible for the additional exclusivity and other benefits of orphan drug designation.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the Unites States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of regulatory review and approval process. In addition to the potential period of exclusivity, orphan designation makes a company eligible for grant funding of up to $400,000 per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. There can be no assurance that we will receive orphan drug designation for any of our drug candidates in the indications for which we think they might qualify, if we elect to seek such applications.

Although we may pursue expedited regulatory approval pathways for a drug candidate, it may not qualify for expedited development or, if it does qualify for expedited development, it may not actually lead to a faster development or regulatory review or approval process.

Although we believe there may be an opportunity to accelerate the development of certain of our drug candidates through one or more of the FDA's expedited programs, such as fast track, breakthrough therapy, accelerated approval or priority review, we cannot be assured that any of our drug candidates will qualify for such programs.

For example, a drug may be eligible for designation as a breakthrough therapy if the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Although breakthrough designation or access to any other expedited program may expedite the development or approval process, it does not change the standards for approval. If we apply for breakthrough therapy designation or any other expedited program for our drug candidates, the FDA may determine that our proposed target indication or other aspects of our clinical development plans do not qualify for such expedited program. Even if we are successful in obtaining a breakthrough therapy designation or access to any other expedited program, we may not experience faster development timelines or achieve faster review or approval compared to conventional FDA procedures. Access to an expedited program may also be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory approval for such drug candidate.

If we are unable to protect our proprietary rights, we may not be able to prevent others from using our intellectual property, which may reduce the competitiveness and value of the related assets.

Our success will depend in part on our ability to obtain and maintain patent protection for our formulations and technologies and to prevent third parties from infringing upon our proprietary rights. We must also operate without infringing upon patents and proprietary rights of others, including by obtaining appropriate licenses to patents or other proprietary rights held by third parties, if necessary. The primary means by which we will be able to protect our formulations and technologies from unauthorized use by third parties is to obtain valid and enforceable patents that cover them. As of February 28, 2019, we owned and/or licensed nine U.S. issued patents, two international issued patents, and 32 U.S. patent applications, including 29 utility (including continuation, continuation-in-part and divisional) and three provisional patent applications, and we owned seven international patent applications filed under the Patent Cooperation Treaty and 42 foreign patent applications. However, the applications we have filed or may file in the future may never yield patents that protect our inventions and intellectual property assets. Failure to obtain patents that sufficiently cover our formulations and technologies would limit our protection against other compounding pharmacies and outsourcing facilities, generic drug manufacturers, pharmaceutical companies and other parties who may seek to copy our products, produce products substantially similar to ours or use technologies substantially similar to those we own. We have made, and expect to continue to make, significant investments in certain of our proprietary formulations prior to the grant of any patents covering these formulations, and we may not receive a sufficient return on these investments if patent coverage or other appropriate intellectual property protection is not obtained and their competitiveness and value decreases.

The patent and intellectual property positions of pharmacies and pharmaceutical companies, including ours, are uncertain and involve complex legal and factual questions. There is no guarantee that we have developed or obtained or will in the future develop or obtain the rights to products or processes that are patentable, that patents will issue from any pending applications or that claims allowed will be sufficient to protect the technology we have developed or may in the future develop or to which we have acquired or may in the future acquire development rights. In addition, we cannot be certain that patents issued to us will not be challenged, invalidated, infringed or circumvented, including by our competitors, or that the rights granted thereunder will provide competitive advantages to us.

We also rely on unpatented trade secrets and know-how and continuing technological innovation in order to develop our formulations, which we seek to protect, in part, by confidentiality agreements with our employees, consultants, collaborators and others, including certain service providers. We also have invention or patent assignment agreements with our current employees and certain consultants. Nonetheless, our employees and consultants may breach these agreements, and we may not have adequate remedies for the breach. Our trade secrets may otherwise become known or be independently discovered by competitors or could be developed by a person not bound by an invention assignment agreement with us, in which case we may have no rights to use the applicable invention.

We may face additional competition outside of the U.S. as a result of a lack of patent coverage in some territories and differences in patent prosecution and enforcement laws in foreign counties.

Filing, prosecuting, defending and enforcing patents on our proprietary formulations throughout the world is extremely expensive. We do not currently have patent protection outside of the U.S. that covers any of our proprietary formulations or other assets that we are currently pursuing. Competitors may use our technologies to develop their own products in jurisdictions where we have not obtained patent protection.

Even if the international patent applications we have filed or may in the future file are issued or approved, it is likely that the scope of protection provided by such patents would be different from, and possibly less than, the scope provided by corresponding U.S. patents. As a result, patent rights we are able to obtain may not be sufficient to prevent generic competition. Further, the extent of our international market opportunity may be dependent upon the enforcement of patent rights in various other countries. A number of countries in which we could file patent applications have a history of weak enforcement and/or compulsory licensing of intellectual property rights. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patents and other intellectual property protection, particularly those relating to biotechnology and/or pharmaceuticals, which would make it difficult for us to stop a third party from infringing any of our intellectual property rights. Moreover, attempting to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business.

Our proprietary formulations and technologies could potentially conflict with the rights of others.

The preparation or sale of our proprietary formulations and use of our technologies may infringe on the patent or other intellectual property rights of others. If our products infringe or conflict with the patent or other intellectual property rights of others, third parties could bring legal actions against us claiming damages and seeking to enjoin our manufacturing and marketing of our affected products. Patent litigation is costly and time consuming and may divert management’s attention and our resources. We may not have sufficient resources to bring any actions to a successful conclusion. If we are not successful in defending against these legal actions should they arise, we may be subject to monetary liability or be forced to alter our products, cease some or all of our operations relating to the affected products, or seek to obtain a license in order to continue manufacturing and marketing the affected products, which may not available on acceptable terms or at all.

We are dependent on our Chief Executive Officer, Mark L. Baum, and other key persons for the continued growth and development of our Company.

Our Chief Executive Officer, Mark L. Baum, has played a primary role in creating and developing our current business model. Further, Mr. Baum has played a primary role in securing much of our material intellectual property rights and related assets, as well as the means to make and distribute our current products. We are highly dependent on Mr. Baum for the implementation of our business plan and the future development of our assets and our business, and the loss of Mr. Baum's services and leadership would likely materially adversely impact our Company. We presently maintain key man insurance for Mr. Baum. In addition, our loan agreement, identifies other key persons including, but not limited to, our Chief Financial Officer, Andrew R. Boll and our President of ImprimisRx, John P. Saharek.

If we are unable to attract and retain key personnel and consultants, we may be unable to maintain or expand our business.

We have been focusing on building our management, pharmacy, research and development, sales and marketing and other personnel to pursue our current business model. To achieve our planned growth, we may have significant difficulty attracting and retaining necessary employees. Because of the specialized nature of our business, the ability to develop products and to compete will remain highly dependent upon our ability to attract and retain qualified pharmacy, scientific, technical and commercial employees and consultants. There is intense competition to hire qualified personnel in our industry, and we may be unable to continue to attract and retain the qualified personnel necessary for the development of our business. The loss of key employees or consultants or the failure to recruit or engage new employees and consultants could have a material adverse effect on our business.

Risks Related to Our Common Stock

Because of their significant stock ownership, some of our existing stockholders are able to exert control over us and our significant corporate decisions.

Our executive officers and directors collectively own, or have the right to acquire within 60 days after February 28, 2019, approximately 13% of our common stock that would be outstanding following such issuances. These persons, acting together, have the ability to exercise significant influence over or control the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and any significant transaction involving us, and to control our management and affairs. Additionally, since our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws permit our stockholders to act by written consent, a limited number of stockholders may approve stockholder actions without holding a meeting of stockholders. This concentration of ownership may harm the market price of our common stock by, among other things: delaying, deferring, or preventing a change in control of our Company or changes to our board of directors; impeding a merger, consolidation, takeover or other business combination involving our Company; causing us to enter into transactions or agreements that are not in the best interests of all stockholders; or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our Company.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results, which could cause our stock price to fall.

Effective internal controls are necessary for us to provide reliable financial results. If we cannot provide reliable financial results, our consolidated financial statements could be misstated, our reputation may be harmed and the trading price of our common stock could decline. As we discussed in Item 9A of this Annual Report, our management concluded that our internal controls over financial reporting were effective as of December 31, 2018. However, our controls over financial processes and reporting may not continue to be effective or we may identify material weaknesses or significant deficiencies in our internal controls in the future. Any failure to remediate any future material weaknesses or successfully implement required new or improved controls, could harm our operating results, cause us to fail to meet our reporting obligations or result in material misstatements in our consolidated financial statements or other public disclosures. 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 stock.

A consistently active trading market for shares of our common stock may not be sustained.

Historically, trading in our common stock has been sporadic and volatile and our common stock has been "thinly-traded." There have been, and may in the future be, extended periods when trading activity in our shares is minimal, as compared to a seasoned issuer with a large and steady volume of trading activity. The market for our common stock is also characterized by significant price volatility compared to seasoned issuers, and we expect that such volatility may continue. As a result, the trading of relatively small quantities of shares may disproportionately influence the market price of our common stock. A consistently active and liquid trading market in our securities may never develop or be sustained.

Our stock price may be volatile.

The market price of our common stock is likely to be highly volatile and could fluctuate widely in response to various factors, many of which are beyond our control, including the following: our ability to execute our business plan; operating results that fall below expectations; industry or regulatory developments; investor perception of our industry or our prospects; economic and other external factors; and the other risk factors discussed in this "Risk Factors" section.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock.

We have the right to issue shares of preferred stock without obtaining stockholder approval. If we were to issue preferred stock, it may have rights, preferences and privileges superior to those of our common stock.

We are authorized to issue 5,000,000 shares of "blank check" preferred stock, with such rights, preferences and privileges as may be determined from time to time by our board of directors. Our board of directors is empowered, without stockholder approval, to issue preferred stock at any time in one or more series and to fix the dividend rights, dissolution or liquidation preferences, redemption prices, conversion rights, voting rights and other rights, preferences and privileges for any series of our preferred stock that may be issued. The issuance of shares of preferred stock, depending on the rights, preferences and privileges attributable to the preferred stock, could reduce the voting rights and powers of our common stockholders and the portion of our assets allocated for distribution to our common stockholders in a liquidation event, and could also result in dilution to the book value per share of our common stock. The preferred stock could also be utilized, under certain circumstances, as a method for raising additional capital or discouraging, delaying or preventing a change in control of our Company.

We have not paid dividends in the past and do not expect to pay dividends in the future. Any return on an investment will be limited to any appreciation in the value of our common stock.

We have never paid cash dividends on our common stock and do not anticipate doing so in the foreseeable future. Any payment of dividends on our common stock would depend on contractual restrictions, such as those contained in our SWK loan agreement and convertible note, as well as our earnings, financial condition and other business and economic factors as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if our stock price appreciates.

Offers or availability for sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

The sale of substantial amounts of our common stock in the public market, or the perception that sales could occur, may cause the market price of our common stock to fall. Sales could occur upon the expiration of any statutory holding period, such as under Rule 144 under the Securities Act of 1933, as amended, applicable to outstanding shares, upon expiration of any lock-up periods applicable to outstanding shares, upon our issuance of shares upon the exercise of outstanding options or warrants, or upon our issuance of shares pursuant offerings of our equity securities. The availability for sale of a substantial number of shares of our common stock, whether or not sales have occurred or are occurring, also could make it more difficult for us to raise additional financing through the sale of equity or equity-related securities in the future when needed, on acceptable terms or at all.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We lease approximately 10,200 square feet of office space in San Diego, California, the current lease term for which expires on December 31, 2021 and includes an option to extend the lease through December 31, 2027. This office serves as our corporate headquarters.

We lease approximately 25,000 square feet of lab, warehouse and office space in Ledgewood, New Jersey, in two separate suites. The current lease term expires on July 31, 2024 and includes options to extend the lease term through 2032. This space serves as an outsourcing facility and pharmacy.

We lease approximately 4,500 square feet of lab and office space in Irvine, California. The current lease term expires on December 31, 2020 and includes the options to extend the lease term through 2030. Park Compounding, our California-based pharmacy, occupies this space.

We do not believe additional space will be required in the near-term.

ITEM 3. LEGAL PROCEEDINGS

Dr. Sobol

In December 2016, Louis L. Sobol, M.D. (“Sobol”) filed a lawsuit in the U.S. District Court for the Eastern District of Michigan, Southern Division against us, asserting claims on behalf of himself and an as-yet-uncertified class of consumers. The claims allege violations under the Telephone Consumer Protection Act, 47 U.S.C. § 227 via our alleged transmittal of advertisements to our clients via facsimile. In June 2018, Sobol filed a motion for class certification and in July 2018 we filed a response in opposition to the motion for class certification. A hearing on class

certification was heard on October 24, 2018, however, prior to a decision regarding class certification was made, in February 2019, we entered into a proposed settlement agreement to award the class up to $1.4 million in damages. However, due to the nature of the lawsuit and claims, we expect total damages related to this lawsuit will total approximately $640,000. We expect the Court will rule to accept our settlement agreement in the spring of 2019. We accrued an expense of $640,000, our estimated damages related to the settlement agreement, during the year ended December 31, 2018.

Allergan USA

In September 2017, Allergan USA, Inc. (“Allergan”) filed a lawsuit in the U.S. District Court for the Central District of California against Imprimis Pharmaceuticals, Inc., primarily claiming violations under the federal Lanham Act and California’s Sherman Act. The parties have each filed a motion for summary judgment and Imprimis also filed a motion to stay. The parties’ motions is scheduled to be heard on March 26, 2019. The trial date is currently set for April 2019. We believe the claims are frivolous, and we have previously and will continue to dispute all claims asserted against us and intend to vigorously defend these allegations. Nonetheless, we cannot predict the eventual outcome of this litigation, it could result in substantial costs, losses and a diversion of management’s resources and attention, which could harm our business and the value of our common stock.

Spectrum

In February 2018, we filed a complaint against Spectrum Laboratory Products, Inc., Spectrum Chemical Manufacturing Corp. and Spectrum Pharmacy Products, Inc. (collectively “Spectrum”) in the Los Angeles County Superior Court asserting claims for breach of contract, breach of implied covenant of good faith and fair dealing, violation of California Commercial Code Section 2101 and fraud. The claims stem from prior business dealings between us and Spectrum and allege false representation by Spectrum regarding their products, fraudulent labeling and misrepresentations of approved product usages. The complaint has been filed with the Court and in May 2018, Spectrum filed an answer with the Court. In November 2018, we dismissed, without prejudice, our lawsuit against Spectrum.

Novel Drug Solutions et al.

In April 2018, Novel Drug Solutions, LLC and Eyecare Northwest, PA, (collectively “NDS”) filed a lawsuit against us in the U.S. District Court of Delaware asserting claims for breach of contract. The claims stem from an asset purchase agreement between us and NDS entered into in 2013. In July 2018, NDS filed a first amended complaint which added a claim for fraudulent inducement. In July 2018, we filed a motion to dismiss certain causes of action found in the complaint, and our motion to dismiss was denied. In October 2018, we filed counterclaims alleging breach of contract and breach of covenant of good faith and fair dealing and named certain individual defendants. We are currently in the discovery phase of this lawsuit. We believe the claims are frivolous and have previously and will continue to dispute all claims asserted against us and intend to vigorously defend these allegations. Nonetheless, we cannot predict the

eventual outcome of this litigation, it could result in substantial costs, losses and a diversion of management's resources and attention, which could harm the Company's business and the value of its common stock.

California Board of Pharmacy

In March 2018, the California Board of Pharmacy filed an accusation against Park related to a compounded formulation we believe was legally dispensed and was, without our knowledge, inappropriately administered to a patient unknown to us, by the prescribing healthcare professional. We filed our response to the accusation and have requested a formal hearing. We dispute all claims against us and intend to vigorously defend against the allegations. Nonetheless, we cannot predict the outcome of this matter, it could result in substantial costs, losses, suspension or revocation of Park's pharmacy license and a diversion of management's resources and attention, which could harm our business and the value of our common stock.

Product and Professional Liability

Product and professional liability litigation represents an inherent risk to all firms in the pharmaceutical and pharmacy industry. We utilize traditional third-party insurance policies with regard to our product and professional liability claims. Such insurance coverage at any given time reflects current market conditions, including cost and availability, when the policy is written.

John Erick et al.

In January 2018, John Erick and Deborah Ferrell, successors-in-interest and heirs of Jade Erick, (collectively "Erick") filed a lawsuit in the San Diego County Superior against Kim Kelly, ND, MPH asserting claims related to death of Jade Erick. In April 2018, Erick filed an amendment to the lawsuit, naming us as a co-defendant. In September 2018, co-defendant Dr. Kelly filed a cross-complaint against us and various Spectrum entities. The cross-complaint seeks indemnity and contribution from us and Spectrum. We answered the claims filed by Dr. Kelly in October 2018. The case is currently in the discovery phase. We believe the claims are frivolous and have previously and will continue to dispute all claims asserted against us and intend to vigorously defend these allegations. Nonetheless, we cannot predict the eventual outcome of this litigation, it could result in substantial costs, losses and a diversion of management's resources and attention, which could harm the Company's business and the value of its common stock.

General and Other

In the ordinary course of business, we may face various claims brought by third parties and we may, from time to time, make claims or take legal actions to assert our rights, including intellectual property disputes, contractual

disputes and other commercial disputes. Any of these claims could subject us to litigation.

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 began trading on The NASDAQ Capital Market in February 2013. The following table sets forth the high and low sale prices for our common stock as reported by The NASDAQ Capital Market for the periods indicated.

Fiscal Year 2017	High	Low
First Quarter	$4.69	$2.02
Second Quarter	$4.65	$2.97
Third Quarter	$3.30	$1.47
Fourth Quarter	$2.79	$1.35

Fiscal Year 2018	High	Low
First Quarter	$2.10	$1.56
Second Quarter	$2.48	$1.72
Third Quarter	$3.24	$2.19
Fourth Quarter	$6.11	$2.25

Holders

As of March 4, 2019, there were approximately 121 stockholders of record (excluding an indeterminable number of stockholders whose shares are held in street or "nominee" name) of our common stock.

Dividends

We have not paid any dividends on our common stock since our inception and do not expect to pay dividends on our common stock in the foreseeable future. Further, our SWK loan agreement, described in Notes 13 to our consolidated financial statements included in this Annual Report, restricts our ability to pay cash dividends on our common stock.

Recent Sales of Unregistered Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and the related notes contained in this annual report on Form 10-K (Annual Report). Our consolidated financial statements have been prepared and, unless otherwise stated, the information derived therefrom as presented in this discussion and analysis is presented, in accordance with accounting principles generally accepted in the United States of America (GAAP). In addition to historical information, the following discussion contains forward-looking statements based upon our current views, expectations and assumptions that are subject to risks and uncertainties. Actual results may differ substantially from those expressed or implied by any forward-looking statements due to a number of factors, including, among others, the risks described in the "Risk Factors" section and elsewhere in this Annual Report.

As used in this discussion and analysis, unless the context indicates otherwise, the terms the "Company", "Harrow" "we", "us" and "our" refer to Harrow Health, Inc. and its consolidated subsidiaries, consisting of Park Compounding, Inc., Imprimis Rx NJ, LLC, Imprimis NJOF, LLC, Radley Pharmaceuticals, Inc. and Mayfield Pharmaceuticals, Inc.

Overview

Our business specializes in the development, production and sale of innovative medications that offer unique competitive advantages and serve unmet needs in the marketplace. Prior to 2017, the Company's business was primarily focused on its ImprimisRx business, the nation's leading ophthalmology pharmaceutical compounding business, and Park Compounding, Inc. ("Park"), a leading health and wellness compounding business. Since 2017, in addition to wholly-owning ImprimisRx and Park, we also have founded and have continuing equity positions in Eton Pharmaceuticals, Inc. ("Eton"), Surface Pharmaceuticals, Inc. ("Surface"), and Melt Pharmaceuticals, Inc. ("Melt"). In 2018, the Company also founded the subsidiaries Mayfield Pharmaceuticals, Inc. ("Mayfield") and Radley Pharmaceuticals, Inc. ("Radley"). The Company owns royalty rights in certain 505(b)(2) drug candidates being developed by Eton, Surface, Melt, Radley and Mayfield. Harrow intends to continue to pursue its operations through subsidiaries for, and found, and hold equity and royalty rights, in, new businesses that commercialize drug candidates that are internally developed or otherwise acquired or licensed from third parties

Pharmaceutical Compounding Businesses

Pharmaceutical Compounding

Pharmaceutical compounding is the science of combining different active pharmaceutical ingredients (APIs), all of which are approved by the U.S. Food and Drug Administration ("FDA") (either as a finished form product or as a bulk drug ingredient) and excipients, to create specialized pharmaceutical preparations. Physicians and healthcare institutions use compounded drugs when commercially available drugs do not optimally treat a patient's needs. In many cases, compounded drugs, such as ours, have wide market utility and may be clinically appropriate for large patient populations. Examples of compounded formulations include medications with alternative dosage strengths or unique dosage forms, such as topical creams or gels, suspensions, or solutions with more tolerable drug delivery vehicles.

Almost all of our sales revenue is derived from making, selling and dispensing our compounded prescription drug formulations as cash pay transactions between us and our end-user customer. As such, the majority of our commercial transactions do not involve distributors, wholesalers, insurance companies, pharmacy benefit managers or other middle parties. By not being reliant on insurance company formulary inclusion and pharmacy benefit manager payment clawbacks, we are able to simplify the prescription transaction process. We believe the outcome of our business model is a simple transaction, involving a patient-in-need, a physician's diagnosis and a fair price and great service for a quality pharmaceutical product. We sell our products through a network of employees and independent contractors and we dispense our formulations in all 50 states, Puerto Rico and in selected markets outside the United States.

ImprimisRx

ImprimisRx is our ophthalmology focused pharmaceutical compounding business. We offer our over 3,000 physician customers and their patients critical medicines to meet needs that are unmet by commercially available drugs. We make our formulations available at prices that are, in most cases, lower than non-customized commercial drugs. Our current ophthalmology formulary includes over twenty compounded formulations, many of which are patented or patent-pending, and are customizable for the specific needs of a patient. Some examples of our compounded medications are various combinations of drugs formulated into one bottle and numerous preservative free formulations. Depending on the formulation, the regulations of a specific state and ultimately the needs of the patient, ImprimisRx products may be dispensed as patient-specific medications from our 503A pharmacies, or for in-office use, made according to current good manufacturing practices (or cGMPs) or other FDA guidance documents, in our FDA-registered NJOF outsourcing facility.

Park Compounding

Park, our wholly owned subsidiary pharmacy based in Irvine, California, is focused on primarily on health and wellness related, customizable pharmaceutical compounding. Park dispenses sterile and non-sterile compounded medications prescribed by licensed practitioners when commercially available choices do not meet a patient's needs. Park also produces and dispenses certain of our ophthalmology-based formulations.

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Pharmaceutical Development Businesses

We have ownership interests in Eton, Surface, Melt, and Mayfield and hold royalty interests in certain of their drug candidates. These companies are pursuing market approval for their drug candidates under the FDCA, including under the abbreviated pathway described in Section 505(b)(2) which permits the submission of a new drug application (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. In 2018, we formed and created subsidiaries named Radley and Mayfield, which we intend to operate similar to Eton, Surface and Melt. In addition, we intend to create additional subsidiaries that will be focused on the development and FDA approval of certain proprietary drug formulations that we currently own, will in-license/acquire and/or otherwise develop.

Eton Pharmaceuticals, Inc.

Eton is a pharmaceutical company focused on developing and commercializing innovative products utilizing the FDA's 505(b)(2) regulatory pathway. Its pipeline includes seven products in various stages of development across a variety of dosage forms. Eton's pipeline is focused on innovative 505(b)(2) products and obtaining FDA marketing approval for currently marketed but unapproved drugs.

In May 2017, we entered into two asset purchase and license agreements (the "Eton License Agreements") with our then wholly owned subsidiary, Eton. Pursuant to the Eton License Agreements, we assigned and licensed to Eton certain intellectual property and related rights to develop, formulate, make, sell, and sub-license our proprietary formulations including synthetic corticotropin (Eton drug candidate CT-100) (collectively, the "Harrow Products"). Eton, by itself or through a development partner, intends to seek FDA approval for the commercialization of CT-100 through the Section 505(b)(2) regulatory pathway. If approved by the FDA, Eton is required to make royalty payments to us on CT-100. In addition to CT-100, Eton has acquired several additional drug candidates and ones that qualify under the Drug Efficacy Study Implementation (DESI) program which it plans to develop and commercialize. Harrow is only eligible to receive royalties on CT-100 (corticotropin) and will not receive royalties on any other drug candidates currently being developed by Eton.

In June 2017, Eton closed an offering of its Series A Preferred Stock. At the time of closing we lost our controlling interest, and deconsolidated Eton from our consolidated financial statements. As of the date of this Annual Report, we own approximately 19.98% of the equity and voting interests issued and outstanding of Eton.

Surface Pharmaceuticals, Inc.

Surface is a development-stage pharmaceutical company focused on development and commercialization of innovative therapeutics for ocular surface diseases and is seeking FDA approval for the commercialization of its drug candidates through the Section 505(b)(2) regulatory pathway under the FDCA. In 2017 and amended in April 2018, Harrow entered into asset purchase and license agreements (the "Surface License Agreements") and transferred to Surface its current drug pipeline, which consists of three proprietary drug candidates. Surface's patent-pending topical eye drop drug candidates, SURF-100 and SURF-200, utilize a patented delivery vehicle known as Klarity Drops ("Klarity"), that was invented by Harrow board member and Surface's chairman of the board and renowned ophthalmologist Dr. Richard Lindstrom. Klarity is designed to protect and rehabilitate the ocular surface pathology for patients with DED. Surface's drug candidate SURF-300 is a patent-pending oral capsule that will target patients also suffering from DED signs and symptoms.

In May and July 2018, Surface closed on an offering of its Series A Preferred Stock. At that time, we lost our controlling interest and deconsolidated Surface from our consolidated financial statements.

Melt Pharmaceuticals, Inc.

Melt is a development-stage pharmaceutical company focused on the development and commercialization of proprietary non-intravenous, or non-intravenous (or IV), sedation and anesthesia therapeutics for human medical procedures in hospital, outpatient, and in-office settings. Melt intends to seek regulatory approval through the FDA's 505(b)(2) regulatory pathway for its proprietary technologies, where possible. In December 2018, we entered into an Asset Purchase Agreement with Melt (the "Melt Asset Purchase Agreement"), and Harrow assigned to Melt the underlying intellectual property for Melt's current pipeline, including its lead drug candidate MELT-100. The core intellectual property Melt owns is a patented series of combination non-opioid sedation drug formulations that we estimate to have multitudinous applications. Pursuant to the terms of the Melt Asset Purchase Agreement, Melt is required to make royalty payments to the Company up to eight percent (8%) of net sales of products described in the Melt Asset Purchase Agreement, while any patent rights remain outstanding, as well as other conditions.

During January 2019, Melt closed on the sale of its Series A Preferred Stock. At the time of the closing of the Melt Series A Round, we lost our controlling interest, and deconsolidated Melt from our consolidated financial statements. We own approximately 44% of the equity and voting interests issued and outstanding of Melt. In addition to our Melt equity position and pursuant to the Melt Asset Purchase Agreement, Harrow is eligible to receive mid-single digit percent royalties on sales of contributed drug candidates.

Mayfield Pharmaceuticals, Inc.

Mayfield, a consolidated subsidiary of Harrow, is a development-stage women's and men's health focused pharmaceutical company. Mayfield intends to seek regulatory approval through the FDA's 505(b)(2) regulatory pathway for its proprietary drug candidates and technologies, including its lead drug candidates MAY-44 and MAY-66. MAY-44 is non-estrogen topical analgesic gel containing a patented pH-balanced formulation of 3.75% lidocaine and other essential excipients designed for use on mucosal surfaces. If FDA-approved, MAY-44 could become the first topical product indicated for dyspareunia. Other more recent estimates suggest dyspareunia affects greater than one in ten women (BJOG An International Journal of Obstetrics and Gynecology 2017). Mayfield's MAY-66 drug candidate a patented, injectable form of pentoxifylline designed for use in the treatment of symptoms associated with Peyronie's disease.

Mayfield and Harrow acquired the intellectual property associated with MAY-44 in January 2019 from Elle Pharmaceutical LLC (the "Mayfield Asset Purchase Agreement") in exchange for $25,000, with an additional $175,000 due upon third party financing of Mayfield, 1 million shares of Mayfield common stock and a 7.5% royalty rate on sales of the product. Once we have finalized the drug candidate assets Mayfield will seek to build out the Mayfield management, board and clinical advisory team.

Radley Pharmaceuticals, Inc.

Radley, a consolidated subsidiary of Harrow, is a development-stage pharmaceutical company focused on the development of proprietary 505(b)(2) drug candidates focused on rare diseases. Radley currently has three proprietary drug candidates in its pipeline. During 2019, and prior to initiating significant development activities and costs related to these drug candidates, we intend to meet with FDA to establish and understand the expected clinical and regulatory path to approval for these drug candidates. We are also pursuing investigator-initiated studies for some of Radley's drug candidates with well-known healthcare institutions. We believe this approach will allow us to better understand and weigh the economic costs, clinical feasibility and potential benefits associated with pursuing development activities associated with these drug candidates.

Factors Affecting Our Performance

We believe the primary factors affecting our performance are our ability to increase revenues of our proprietary compounded formulations and certain non-proprietary products, grow and gain operating efficiencies in our pharmacy operations, optimize pricing and obtain reimbursement options for our proprietary compounded formulations, and continue to pursue development and commercialization opportunities for certain of our ophthalmology and other

assets that we have not yet made commercially available as compounded formulations. We believe we have built a tangible and intangible infrastructure that will allow us to scale revenues efficiently in the long-term. All of these activities will require significant costs and other resources, which we may not have or be able to obtain from operations or other sources. See "—Liquidity and Capital Resources" below.

Reimbursement Options and Pricing Optimization

Our proprietary ophthalmic compounded formulations are currently primarily available on a cash-pay basis. However, we work with third-party insurers, pharmacy benefit managers and buying groups to offer patient-specific customizable compounded formulations at accessible prices. We may devote time and other resources to seek reimbursement and patient pay opportunities for these and other compounded formulations and we have hired pharmacy billers to process certain existing reimbursement opportunities for certain formulations. However, we may be unsuccessful in achieving these goals, as many third-party payors have imposed significant restrictions on reimbursement for compounded formulations in recent years. Moreover, third-party payors, including Medicare, are increasingly attempting to contain health care costs by limiting coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. Further, the Health Reform Law may have a considerable impact on the existing U.S. system for the delivery and financing of health care and could conceivable have a material effect on our business. As a result, reimbursement from Medicare, Medicaid and other third-party payors may never be available for any of our products or, if available, may not be sufficient to allow us to sell the products on a competitive basis and at desirable price points. If government and other third-party payors do not provide adequate coverage and reimbursement levels for our formulations, the market acceptance for our formulations may be limited.

Additionally, we are making efforts to normalize the pricing for our currently available proprietary compounded ophthalmic formulations. An economic study conducted in 2015 by researchers at Andrew Chang & Co, LLC and co-sponsored by us demonstrated that, assuming the cost of Dropless Therapy is $100 per dose, our Dropless Therapy formulations may provide collective savings to Medicare, Medicaid and patients of up to $13 billion, with a most likely savings estimate of $8.7 billion, over a 10-year period. Based on this research, we believe optimized pricing for our Dropless Therapy formulations could be nearly $100 per dose. Any efforts to attain optimized pricing for our Dropless Therapy or any of our other proprietary formulations could fail, which could make our products less attractive or unavailable to some patients or could reduce our margins.

Recent Developments

The following describes certain developments in 2018 to date that are important to understand our financial condition and results of operations. See the notes to our consolidated financial statements included in this report for additional information about each of these developments.

Results of Operations

The following period-to-period comparisons of our financial results are not necessarily indicative of results for the current period or any future period.

Comparison of Years Ended December 31, 2018 and 2017

Revenues

Our revenues include amounts recorded from sales of proprietary and non-proprietary pharmaceutical compounded drug formulations and revenues received from royalty and milestone payments owed to us pursuant to out-license arrangements.

The following presents our revenues for the years ended December 31, 2018 and 2017:

	For the year ended December 31,		$
	2018	2017	Variance
Product sales, net	$41,334,000	$26,684,000	$14,650,000
License revenues	38,000	90,000	(52,000)
Total revenues	$41,372,000	$26,774,000	$14,598,000

The increase in revenue between periods was largely attributable to increased sales of our proprietary formulations and furtherance of our ophthalmology related compounded formulations. Our gross ophthalmology related sales were approximately $34,135,000 for the year ended December 31, 2018, compared to $19,137,000 during last year. Net revenues generated from our New Jersey based outsourcing facility (“NJOF”) (which include certain ophthalmology related sales) totaled $22,490,000 the year ended December 31, 2018, compared to $9,374,000 during last year.

Cost of Sales

Our cost of sales includes direct and indirect costs to manufacture formulations and sell products, including active pharmaceutical ingredients, personnel costs, packaging, storage, royalties, shipping and handling costs, manufacturing equipment and tenant improvements depreciation, the write-off of obsolete inventory and other related expenses.

The following presents our cost of sales for the years ended December 31, 2018 and 2017:

	For the year ended December 31,		$
	2018	2017	Variance
Cost of sales	$16,521,000	$13,505,000	$3,016,000

The increase in our cost of sales between periods was largely attributable to an increase in the volume of unit sales of our formulations and products and our associated costs of such sales.

Gross Profit and Margin

	For the year ended December 31,		$
	2018	2017	Variance
Gross Profit	$24,851,000	$13,269,000	$11,582,000
Gross Margin	60.1 %	49.6 %	10.5 %

The increase in gross profit and gross margin between periods is largely attributable to increased efficiencies in our production process and utilization of capacities as a result of increased output, in particular, at NJOF. We estimate gross margins at NJOF were greater than 60% during 2018.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses include personnel costs, including wages and stock-based compensation, corporate facility expenses, and investor relations, consulting, insurance, filing, legal and accounting fees and expenses as well as costs associated with our marketing activities and sales of our proprietary compounded formulations and other non-proprietary pharmacy products and formulations.

The following presents our selling, general and administrative expenses for the year ended December 31, 2018 and 2017:

	For the year ended December 31,		$
	2018	2017	Variance
Selling, general and administrative	$29,243,000	$25,019,000	$4,224,000

The increase in general and administrative expenses between periods was largely attributable to increased sales commission amounts, legal expenses and settlements incurred associated with ongoing litigation and costs related to the operations of Melt.

Research and Development Expenses

Our research and development expenses primarily include expenses related to the development of acquired intellectual property, investigator-initiated research and evaluations and other costs related to the clinical development of our assets.

The following presents our research and development expenses for the years ended December 31, 2018 and 2017:

	For the year ended December 31,		$
	2018	2017	Variance
Research and development	$825,000	$413,000	$412,000

The increase in research and development expenses between periods was primarily attributable to the increase in formulation development studies and the clinical development program for our subsidiaries Radley and Melt (prior to its deconsolidation) that occurred during the year ended December 31, 2018.

Interest Expense, net

Interest expense, net was $2,728,000 and $3,026,000 for the years ended December 31, 2018 and 2017, respectively. The decrease was primarily due to interest expense recognition related to the capital leases and deferred acquisition obligations related to our acquisition of Park.

Investment Gain from Eton Pharmaceuticals, net

During the year ended December 31, 2018 and December 31, 2017, we recorded a loss of $3,507,000 and $2,218,000, respectively, for our share of losses based on our ownership of Eton. We began using equity method accounting for our investment in Eton beginning on June 16, 2017, the date we no longer had a controlling interest, prior to that date, Eton's losses were consolidated within our consolidated statements of operations. During the year ended December 31, 2017, we recorded a gain of $5,725,000 on the deconsolidation of Eton.

During the year ended December 31, 2018, our ownership of Eton fell below 20% and we ceased accounting for our investment in Eton under equity method accounting, and we recorded investment income of $21,420,000 related to the fair market value of the 3,500,000 shares of Eton common stock we hold, based on the closing price Eton common stock of $6.12 per share as of December 31, 2018.

See Note 2 and Note 4 in the notes to the consolidated financial statements for a more detailed explanation of these transactions.

Investment Gain from Surface Pharmaceuticals, net

During the year ended December 31, 2018, we recorded a loss of $373,000, for our share of losses based on our ownership of Surface. We began using equity method accounting for our investment in Surface beginning on June 11, 2018, the date we no longer had a controlling interest, prior to that date, Surface's losses were consolidated within our consolidated statements of operations. During the year ended December 31, 2018, we recorded a gain of $5,320,000 on the deconsolidation of Surface

See Note 2 and Note 5 in the notes to the consolidated financial statements for a more detailed explanation of these transactions.

Loss on Sale of Assets

During the year ended December 31, 2017, we recorded a loss of $354,000, mostly related to assets associated with the sale of Imprimis TX and our sinus assets.

During the year ended December 31, 2018 we recorded an expense of $393,000 related to the impairment and write-off of all amounts owed under a note receivable.

Other Income (Expense), net

During the year ended December 31, 2017 we recorded a loss on early extinguishment of debt of $884,000. In 2017, this loss was related to the early extinguishment of the LSAF Loan.

During the year ended December 31, 2018 we recorded other income of $103,000 related primarily to expenses that were paid by us and reimbursed by Surface following its deconsolidation.

Income Tax Benefit

Income tax benefit was $935,000 for the year ended December 31, 2017, which was related to the net change in our deferred tax liabilities and assets, specifically those related to the Park acquisition and its identifiable intangible assets.

Net Income (Loss)

The following table presents our net income (loss) for the years ended December 31, 2018 and 2017:

	For the Year Ended December 31, 2018	For the Year Ended December 30, 2017
Net income (loss)	$14,625,000	$(11,985,000)
Net income (loss) per share, basic	$0.67	$(0.60)
Net income (loss) per share, diluted	$0.61	$(0.60)

Liquidity and Capital Resources

Liquidity

Our cash on hand (including restricted cash) at December 31, 2018 was $6,838,000, compared to $4,219,000 at December 31, 2017. Since inception through December 31, 2018, we have incurred aggregate losses of $74,211,000. These losses are primarily due to selling, general and administrative and research and development expenses incurred in connection with developing and seeking regulatory approval for a former drug candidate, which activities we have now discontinued, the development and commercialization of novel compounded formulations and the development of our pharmacy operations.

As of the date of this Annual Report, we believe that cash and cash equivalents of $6,638,000 and restricted investments of $200,000 totaling approximately $6,838,000 at December 31, 2018, will be sufficient to sustain our planned level of operations and capital expenditures for at least the next 12 months. We also may consider the sale of certain assets including, but not limited to, part of, or all of, our ownership interest in Eton and/or any of our subsidiaries. However, our plans for this period may change, our estimates of our operating expenses, capital expenditures and working capital requirements could be inaccurate, we may pursue acquisitions of pharmacies or other strategic transactions that involve large expenditures 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.

We expect to use our current cash position and funds generated from our operations and any financing to pursue our business plan, which includes developing and commercializing compounded formulations and technologies, integrating and developing our compounding operations, pursuing potential future strategic transactions as opportunities arise, including potential acquisitions of additional pharmacy, outsourcing facilities, drug company and manufacturers, and/or assets or technologies, and otherwise fund our operations. We may also use our resources to conduct clinical trials or other studies in support of our formulations or any drug candidate for which we pursue FDA approval, to pursue additional development programs or to explore other development opportunities.

Net Cash Flow

The following provides detailed information about our net cash flows for the years ended December 31, 2018 and 2017:

	For the Year Ended December 31, 2018	For the Year Ended **December 31, 2017**
Net cash provided by (used in) operating activities	$ 687,000	$ (8,803,000)
Net cash used in investing activities	(2,199,000)	(961,000)
Net cash provided by financing activities	4,131,000	4,930,000
Net change in cash and cash equivalents	2,619,000	(4,834,000)
Cash, cash equivalents and restricted cash at beginning of the period	4,219,000	9,053,000
Cash, cash equivalents and restricted cash at end of the year	$ 6,838,000	$ 4,219,000

Operating Activities

Net cash provided by operating activities was $687,000 in 2018, as compared to $(8,803,000) used in operating activities in the prior year. The improvement in operating cash flows during the year ended December 31, 2018 as compared to 2017 is attributed to increased unit volumes and sales, production efficiencies and management of operating expenses.

Investing Activities

Net cash used in investing activities in 2018 and 2017 was $(2,199,000) and $(961,000), respectively. Cash used in investing activities in 2018 as compared to 2017 were primarily associated with additional equipment purchases, facility expansions and upgrades, and investments in our intellectual property portfolio.

Financing Activities

Net cash provided by financing activities in 2018 and 2017 was $4,131,000 and $4,930,000, respectively. The cash provided by financing activities during 2018 is primarily attributable to proceeds from the exercise of warrants. Cash provided by financing activities during 2017 is primarily attributable to proceeds from the registered direct offering and sale of shares of common stock in March 2017 and through the Sales Agreement, and net proceeds from the SWK Loan (less the concurrent retirement of our then existing term loan).

Sources of Capital

Our principal sources of cash consist of cash provided by operating activities from our pharmaceutical compounding business. We may also sell some or all of our ownership interests in Eton, Surface, Melt or our other subsidiaries. We just recently began producing cash from our operations during 2018, however historically, we haven't received sufficient revenues to support our operations and may not be able to continue to do so.

We may need significant additional capital to support our business plan and fund our proposed business operations. We may receive additional proceeds from the exercise of stock purchase warrants that are currently outstanding. We may also seek additional financing from a variety of sources, including other equity or debt financings, funding from corporate partnerships or licensing arrangements, sales of assets or any other financing transaction. If we issue equity or convertible debt securities to raise additional funds, our existing stockholders may experience substantial dilution, and the newly issued equity or debt securities may have more favorable terms or rights, preferences and privileges senior to those of our existing stockholders. If we raise additional funds through collaboration or licensing arrangements or sales of assets, we may be required to relinquish potentially valuable rights to our product candidates or proprietary technologies or formulations, or grant licenses on terms that are not favorable to us. If we raise funds by incurring additional debt, we may be required to pay significant interest expenses and our leverage relative to our earnings or to our equity capitalization may increase. Obtaining commercial loans, assuming they would be available, would increase our liabilities and future cash commitments and may impose restrictions on our activities, such as the financial and operating covenants included in the agreements governing the SWK Loan. Further, we may incur substantial costs in pursuing future capital and/or financing transactions, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we may issue, such as convertible notes and warrants, which would adversely impact our financial results.

We may be unable to obtain financing when necessary as a result of, among other things, our performance, general economic conditions, conditions in the pharmaceuticals and pharmacy industries, or our operating history, including our past bankruptcy proceedings. In addition, the fact that we have a limited history of profitability could further impact the availability or cost to us of future financings. As a result, sufficient funds may not be available when

needed from any source or, if available, such funds may not be available on terms that are acceptable to us. If we are unable to raise funds to satisfy our capital needs when needed, then we may need to forego pursuit of potentially valuable development or acquisition opportunities, we may not be able to continue to operate our business pursuant to our business plan, which would require us to modify our operations to reduce spending to a sustainable level by, among other things, delaying, scaling back or eliminating some or all of our ongoing or planned investments in corporate infrastructure, business development, sales and marketing and other activities, or we may be forced to discontinue our operations entirely.

Critical Accounting Policies

We rely on the use of estimates and make assumptions that impact our financial condition and results. These estimates and assumptions are based on historical results and trends as well as our forecasts of how results and trends might change in the future. Although we believe that the estimates we use are reasonable, actual results could differ materially from these estimates.

We believe that the accounting policies described below are critical to understanding our business, results of operations and financial condition because they involve the use of more significant judgments and estimates in the preparation of our consolidated financial statements. An accounting policy is deemed to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and any changes in the assumptions used in making the accounting estimates that are reasonably likely to occur could materially impact our consolidated financial statements.

Revenue Recognition and Deferred Revenue

On January 1, 2018, we adopted ASU 2014-09, using the modified retrospective transition method. There was no effect for any adjustments to retained earnings upon adoption of the standard on January 1, 2018. We have two primary streams of revenue: (1) revenue recognized from our sale of products within our pharmacy services and (2) revenue recognized from intellectual property license and asset purchase agreements.

Product Revenues from Pharmacy Services

We sell prescription drugs directly through our pharmacy and outsourcing facility network. Revenue from our pharmacy services divisions includes: (i) the portion of the price the client pays directly to us, net of any volume-related or other discounts paid back to the client, (ii) the price paid to us by individuals, and (iii) customer copayments made directly to the pharmacy network. Sales taxes are not included in revenue. Following the core principle of ASU 2014-09, we have identified the following:

1. Identify the contract(s) with a customer: A contract exists with a customer at the time the prescription or order is received by the Company.

2. Identify the performance obligations in the contract: The order received contains the performance obligations to be met, in almost all cases the product the customer is wishing to receive. If we are unable to be meet the performance obligation the customer is notified.

3. Determine the transaction price: the transaction price is based on the product being sold to the customer, and any related customer discounts. These amounts are pre-determined and built into our order management software.

4. Allocate the transaction price to the performance obligations in the contract: The transaction price associated with the product(s) being ordered is allocated according to the pre-determined amounts.

5. Recognize revenue when (or as) the entity satisfies a performance obligation: At the time of shipment from the pharmacy or outsourcing facility the performance obligation has been met.

The following revenue recognition policy has been established for the pharmacy services division:

Revenues generated from prescription or office use drugs sold by our pharmacies and outsourcing facility are recognized when the prescription is shipped. At the time of shipment, the pharmacy services division has performed substantially all of its obligations under its client contracts and does not experience a significant level of returns or reshipments. Determination of criteria (3) and (4) is based on management's judgments regarding the fixed nature of the selling prices of the products delivered and the collectability of those amounts. We record reductions to revenue for discounts at the time of the initial sale. Estimated returns and allowances and other adjustments are provided for in the same period during which the related sales are recorded and are based on actual returns history. The rate of returns is analyzed annually to determine historical returns experience. If the historical data we use to calculate these estimates do not properly reflect future returns, then a change in the allowance would be made in the period in which such a determination is made and revenues in that period could be materially affected. We will defer any revenues received for a product that has not been delivered or is subject to refund until such time that we and the customer jointly determine that the product has been delivered and no refund will be required.

Intellectual Property License Revenues

We currently hold five intellectual property license and related agreements in which we have promised to grant a license or sale which provides a customer with right to access our intellectual property. License arrangements may consist of non-refundable upfront license fees, data transfer fees, research reimbursement payments, exclusive license rights to patented or patent pending compounds, technology access fees, and various performance or sales milestones. These arrangements can be multiple element arrangements, each of which revenue is recognized at the point of time the performance obligation is met.

Non-refundable fees that are not contingent on any future performance by us and require no consequential continuing involvement on our part are recognized as revenue when the license term commences and the licensed data, technology, compounded drug preparation and/or other deliverable is delivered. Such deliverables may include physical quantities of compounded drug preparations, design of the compounded drug preparations and structure-activity relationships, the conceptual framework and mechanism of action, and rights to the patents or patent applications for such compounded drug preparations. We defer recognition of non-refundable fees if it has continuing performance obligations without which the technology, right, product or service conveyed in conjunction with the non-refundable fee has no utility to the licensee and that are separate and independent of our performance under the other elements of the arrangement. In addition, if our continued involvement is required, through research and development services that are related to its proprietary know-how and expertise of the delivered technology or can only be performed by us, then such non-refundable fees are deferred and recognized over the period of continuing involvement. Guaranteed minimum annual royalties are recognized on a straight-line basis over the applicable term.

Investment in Eton Pharmaceuticals, Inc.

In April 2017, we formed Eton as a wholly owned subsidiary. In June 2017 we lost voting and ownership control of Eton and ceased consolidating Eton’s financial statements. At the time of deconsolidation, we recorded a gain of $5,725 and adjusted the carrying value in Eton to reflect the increased valuation of Eton and our new ownership percent in accordance with ASC 810-10-40-4(c), *Consolidation*. At the time of deconsolidation, we used the equity method of accounting as management determined that we had the ability to exercise significant influence over the operating and financial decisions of Eton. Under this method, we recognized earnings and losses of Eton in its consolidated financial statements and adjusted the carrying amount of its investment in Eton accordingly. During the years ended December 31, 2018 and 2017, the Company recorded equity in net loss of Eton of $3,507,000 and $2,218,000 respectively.

Following the close of the Eton IPO we estimate our common stock position in Eton equaled approximately 19.98% of the equity and voting interests issued and outstanding of Eton, and we ceased using the equity method of accounting for our investment in Eton. We recognize earnings and losses of Eton in our financial statements based on the fair market value of the shares owned and adjust the carrying amount of our investment in Eton accordingly. Eton's common stock currently trades on the NASDAQ Global Market exchange. At December 31, 2018, the fair market value of Eton's common stock was $6.12 per share, the closing share price of Eton common stock on that day.

Investment in Surface Pharmaceuticals, Inc.

In April 2017, we formed Surface as a wholly owned subsidiary. In May and July 2018, Surface entered into and closed on a definitive stock purchase agreement with an institutional investor for the purchase of Surface's Series A Preferred Stock (the "Surface Series A Stock") that resulted in total proceeds to Surface of approximately $21 million. At the time of the first closing in May 2018, we lost voting and ownership control of Surface and ceased consolidating Surface's financial statements. The Surface Series A Stock (i) was issued at a purchase price of $3.30 per share; (ii) will vote together with the common stock and all other shares of stock of Surface having general voting power; (iii) will be entitled to the number of votes equal to the number of shares of preferred stock held; (iv) will hold liquidation preference over all other equity interests in Surface; and (v) will have mandatory conversion requirements into Surface common stock upon events including an underwritten initial public offering ("IPO") of Surface common stock or similar transaction.

At the time of deconsolidation, we recorded a gain of $5.3 million and adjusted the carrying value in Surface to reflect the increased valuation of Surface and our new ownership percent in accordance with Accounting Standard Codification ("ASC") 810-10-40-4(c), Consolidation.

We own 3,500,000 common shares (which is approximately 30% of the equity interest as of December 31, 2018, and calculated after the second closing of the sale Series A Preferred Stock in July 2018) of Surface and use the equity method of accounting for this investment, as management has determined that we have the ability to exercise significant influence over the operating and financial decisions of Surface. Under this method, we recognize earnings and losses of Surface in our consolidated financial statements and adjust the carrying amount of our investment in Surface accordingly. Our share of earnings and losses are based on the shares of common stock and in-substance common stock of Surface held by us. Any intra-entity profits and losses are eliminated.

Stock-Based Compensation

All stock-based payments to employees, directors and consultants, including grants of stock options, warrants, restricted stock units and restricted stock, are recognized in the consolidated financial statements based upon their estimated fair values. We use the Black-Scholes-Merton option pricing model and Monte Carlo Simulation to estimate the fair value of stock-based awards. Fair value is determined at the date of grant. The financial statement effect of forfeitures is estimated at the time of grant and revised, if necessary, if the actual effect differs from those estimates.

Our accounting policy for equity instruments issued to consultants and vendors in exchange for goods and services follows the Financial Accounting Standards Board (FASB) guidance. The measurement date for the fair value of the equity instruments issued is the earlier of (i) the date at which a commitment for performance by the consultant or vendor is reached or (ii) the date at which the consultant or vendor's performance is complete. In the case of equity instruments issued to consultants, the fair value of the equity instrument is primarily recognized over the term of the consulting agreement. According to FASB guidance, an asset acquired in exchange for the issuance of fully vested, nonforfeitable equity instruments should not be presented or classified as an offset to equity on the grantor's balance sheet once the equity instrument is granted for accounting purposes. Accordingly, we record the fair value of nonforfeitable equity instruments issued for future consulting services as prepaid stock-based consulting expenses in our consolidated balance sheets.

Income Taxes

As part of the process of preparing our consolidated financial statements, we must estimate our actual current tax liabilities and assess permanent and temporary differences that result from differing treatment of items for tax and accounting purposes. The temporary differences result in deferred tax assets and liabilities, which are included within the balance sheet. We must assess the likelihood that the deferred tax assets will be recovered from future taxable income and, to the extent we believe that recovery is not more likely than not, a valuation allowance must be established which reduces the amount of deferred tax assets recorded on the consolidated balance sheets. To the extent we establish a valuation allowance or increase or decrease this allowance in a period, the impact will be included in income tax expense in the statement of operations.

Research and Development

We expense all costs related to research and development as they are incurred. Research and development expenses consist of expenses incurred in performing research and development activities, including salaries and benefits, other overhead expenses, and costs related to clinical trials, contract services and outsourced contracts.

Intellectual Property

The costs of acquiring intellectual property rights to be used in the research and development process, including licensing fees and milestone payments, are charged to research and development expense as incurred in situations where we have not identified an alternative future use for the acquired rights, and are capitalized in situations where we have identified an alternative future use for the acquired rights. Patents and trademarks are recorded at cost and capitalized at a time when the future economic benefits of such patents and trademarks become more certain (see Goodwill and Intangible Assets). We began capitalizing certain costs associated with acquiring intellectual property rights during 2015, if costs are not capitalized they are expensed as incurred.

Impairment of Long-Lived Assets

Long-lived assets, such as furniture and equipment, purchased intangibles subject to amortization and patents and trademarks, 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 amount by which the carrying amount of the asset exceeds the fair value of the asset. Assets to be disposed would be separately presented in the consolidated balance sheet and reported at the lower of the carrying amount or fair value less costs to sell, and are no longer depreciated. The assets and liabilities of a disposal group classified as held-for-sale would be presented separately in the appropriate asset and liability sections of the consolidated balance sheet, if material.

Goodwill and Intangible Assets

Patents and trademarks are recorded at cost and capitalized at a time when the future economic benefits of such patents and trademarks become more certain. At that time, we capitalize third party legal costs and filing fees

associated with obtaining and prosecuting claims related to its patents and trademarks. Once the patents have been issued, we amortize these costs over the shorter of the legal life of the patent or its estimated economic life, generally 20 years, using the straight-line method. Trademarks are an indefinite life intangible asset and are assessed for impairment based on future projected cash flows as further described below.

We review our goodwill and indefinite-lived intangible assets for impairment as of January 1 of each year and when an event or a change in circumstances indicates the fair value of a reporting unit may be below its carrying amount. Events or changes in circumstances considered as impairment indicators include but are not limited to the following:

- significant underperformance of the our business relative to expected operating results;
- significant adverse economic and industry trends;
- significant decline in the our market capitalization for an extended period of time relative to net book value; and
- expectations that a reporting unit will be sold or otherwise disposed.

The goodwill impairment test consists of a two-step process as follows:

Step 1. We compare the fair value of each reporting unit to its carrying amount, including the existing goodwill. The fair value of each reporting unit is determined using a discounted cash flow valuation analysis. The carrying amount of each reporting unit is determined by specifically identifying and allocating the assets and liabilities to each reporting unit based on headcount, relative revenues or other methods as deemed appropriate by management. If the carrying amount of a reporting unit exceeds its fair value, an indication exists that the reporting unit's goodwill may be impaired and we then perform the second step of the impairment test. If the fair value of a reporting unit exceeds its carrying amount, no further analysis is required.

Step 2. If further analysis is required, we compare the implied fair value of the reporting unit's goodwill, determined by allocating the reporting unit's fair value to all of its assets and its liabilities in a manner similar to a purchase price allocation, to its carrying amount. If the carrying amount of the reporting unit's goodwill exceeds its fair value, an impairment loss will be recognized in an amount equal to the excess.

Debt Issuance Costs and Debt Discount

Debt issuance costs and the debt discount are recorded net of note payable in the consolidated balance sheet. Amortization expense of debt issuance costs and the debt discount is calculated using the effective interest method over the term of the debt and is recorded in interest expense in the accompanying consolidated statement of operations.

Off-Balance Sheet Arrangements

Since our inception, except for standard operating leases, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities. We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to stockholders.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements and supplementary data required by this item are included in this Annual Report beginning on page F-1 immediately following the signature page hereto and are incorporated herein by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer (CEO), our principal executive officer, and our Chief Financial Officer (CFO), our principal financial and accounting officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2018, the end of the period covered by this Annual Report, pursuant to Rules 13a-15(b) and 15d-15(b) under the Securities Exchange Act of 1934, as amended (Exchange Act).

In connection with that evaluation, our CEO and CFO concluded that, as of December 31, 2018, our disclosure controls and procedures were effective. For the purpose of this review, disclosure controls and procedures means controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms. These disclosure controls and procedures include, without

limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our principal executive officer, principal financial officer and principal accounting officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, our CEO and CFO and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our management, under the supervision and with the participation of our CEO and CFO, conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations (COSO). Based on such evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2018.

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation requirements by our independent registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit us to provide only management's report in this Annual Report.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during our quarter ended December 31, 2018, 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 CEO and CFO, 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

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to information contained in the Proxy Statement or an amendment to this Annual Report, in either case to be filed with the Securities and Exchange Commission on or before the 120th day after the end of the fiscal year covered by this Annual Report.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to information contained in the Proxy Statement or an amendment to this Annual Report, in either case to be filed with the Securities and Exchange Commission on or before the 120th day after the end of the fiscal year covered by this Annual Report.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference to information contained in the Proxy Statement or an amendment to this Annual Report, in either case to be filed with the Securities and Exchange Commission on or before the 120th day after the end of the fiscal year covered by this Annual Report.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to information contained in the Proxy Statement or an amendment to this Annual Report, in either case to be filed with the Securities and Exchange Commission on or before the 120th day after the end of the fiscal year covered by this Annual Report.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to information contained in the Proxy Statement or an amendment to this Annual Report, in either case to be filed with the Securities and Exchange Commission on or before the 120th day after the end of the fiscal year covered by this Annual Report.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) List of the following documents filed as part of the report:

(1) See the index to our consolidated financial statements on page F-1 for a list of the financial statements being filed in this Annual Report.

(2) All financial statement schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or the notes thereto.

(3) See Item 15(b) below for all exhibits being filed or incorporated by reference herein.

Exhibits:

(b)

The Exhibit Index attached to this Annual Report is incorporated by reference herein.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

HARROW HEALTH, INC.

By: */s/ Mark L. Baum*
Name: Mark L. Baum
Title: Chief Executive Officer (Principal Executive Officer)

Date: March 12, 2019

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Mark L. Baum and Andrew R. Boll, and each of them individually, as his true and lawful attorneys-in-fact and agents with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities to any or all amendments to this Annual Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents or any of them the full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the foregoing, as full to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	**Title**	**Date**
/s/ Mark L. Baum Mark L. Baum	Chief Executive Officer and Director *(Principal Executive Officer)*	March 12, 2019
/s/ Andrew R. Boll Andrew R. Boll	Chief Financial Officer *(Principal Accounting and Financial Officer)*	March 12, 2019

/s/ Robert J. Kammer Robert J. Kammer	Chairman of the Board of Directors	March 12, 2019
/s/ Stephen G. Austin Stephen G. Austin	Director	March 12, 2019
/s/ Richard L. Lindstrom Richard L. Lindstrom	Director	March 12, 2019
/s/ Anthony J. Principi Anthony J. Principi	Director	March 12, 2019

FINANCIAL STATEMENTS

Harrow Health, Inc.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Harrow Health, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Harrow Health, Inc. and subsidiaries (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 consolidated 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 consolidated 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 consolidated 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 consolidated 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 2007.

Costa Mesa, California
March 12, 2019

HARROW HEALTH, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share data)

	December 31, 2018	December 31, 2017
ASSETS		
Current assets		
Cash and cash equivalents, including restricted cash of $200	$6,838	$4,219
Investment in Eton Pharmaceuticals	21,420	-
Accounts receivable, net	1,914	1,529
Inventories	1,834	2,249
Prepaid expenses and other current assets	837	714
Note receivable, current portion	-	95
Total current assets	32,843	8,806
Property, plant and equipment, net	6,375	6,215
Intangible assets, net	3,059	2,860
Investment in Surface Pharmaceuticals	4,947	-
Investment in Eton Pharmaceuticals	-	3,507
Note receivable, less current portion	-	302
Goodwill	2,227	2,227
TOTAL ASSETS	$49,451	$23,917
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$6,250	$3,885
Accrued payroll and related liabilities	2,283	1,209
Deferred revenue and customer deposits	119	29
Current portion of deferred acquisition obligation and accrued interest	-	53
Current portion of note payable, net of unamortized debt discount	2,529	-
Current portion of capital lease obligations, net of unamortized discount	720	598
Total current liabilities	11,901	5,774
Capital lease obligations, net of current portion and unamortized discount	-	720
Accrued expenses, net of current portion	800	800
Note payable, net of current portion and unamortized debt discount	11,999	14,008
TOTAL LIABILITIES	24,700	21,302
STOCKHOLDERS' EQUITY		
Preferred stock, $0.001 par value, 5,000,000 shares authorized, and no shares issued and outstanding at December 31, 2018 and 2017	-	-
Common stock, $0.001 par value, 50,000,000 and 90,000,000 shares authorized, 24,339,610 and 20,623,129 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	24	21
Additional paid-in capital	98,938	91,430

Accumulated deficit	(74,211)	(88,836)
TOTAL STOCKHOLDERS' EQUITY	24,751	2,615
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$49,451	$23,917

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

HARROW HEALTH, INC.

CONSOLIDATED STATEMENTS OF OPERTATIONS

(In thousands, except for share and per share data)

	For the Year Ended December 31, 2018	For the Year Ended December 31, 2017
Revenues:		
Sales, net	$41,334	$26,684
License revenues	38	90
Total revenues	41,372	26,774
Cost of sales	(16,521)	(13,505)
Gross profit	24,851	13,269
Operating expenses:		
Selling, general and administrative	29,243	25,019
Research and development	825	413
Total operating expenses	30,068	25,432
Loss from operations	(5,217)	(12,163)
Other income (expense):		
Interest expense, net	(2,728)	(3,026)
Investment gain from Surface Pharmaceuticals, net	4,947	-
Investment gain from Eton Pharmaceuticals, net	17,913	3,507
Loss on sale of assets	(393)	(354)
Other income (expense), net	103	(884)
Total other income (expense), net	19,842	(757)
Income (loss) before income taxes	14,625	(12,920)
Income tax benefit, net	-	935
Net income (loss)	$14,625	$(11,985)
Basic net income (loss) per share of common stock	$0.67	$(0.60)
Diluted net income (loss) per share of common stock	$0.61	$(0.60)
Weighted average number of shares of common stock outstanding, basic	21,917,570	20,027,712
Weighted average number of shares of common stock diluted	23,812,045	20,027,712

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

HARROW HEALTH, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

For the years ended December 31, 2018 and 2017

(In thousands, except for share data)

	Common Stock		Additional		Total
	Shares	Par Value	Paid-in Capital	Accumulated Deficit	Stockholders' Equity
Balance at January 1, 2017	18,627,915	$ 19	$ 83,264	$ (76,851)	$ 6,432
Issuance of common stock in connection with:					
Exercise of warrants	100,000	-	179	-	179
Registered direct offering sale of stock, net of offering costs	1,312,500	1	2,939	-	2,940
Sale of stock, net of costs (ATM)	557,714	1	1,123	-	1,124
Stock-based payment for services provided	25,000	-	60		60
Relative fair value of warrants to purchase common stock issued in connection with note payable	-	-	982	-	982
Stock-based compensation expense	-	-	2,883	-	2,883
Net loss	-	-	-	(11,985)	(11,985)
Balance at December 31, 2017	20,623,129	21	91,430	(88,836)	2,615
Issuance of common stock in connection with:					
Exercise of warrants	3,275,162	3	4,230	-	4,233
Vesting of RSUs, net of tax withholding	60,000	-	-	-	-
Sale of stock, net of costs (ATM)	305,619	-	642	-	642
Stock-based payment for services provided	75,700	-	150	-	150
Stock-based compensation expense	-	-	2,486	-	2,486
Net income	-	-	-	14,625	14,625
Balance at December 31, 2018	24,339,610	$ 24	$ 98,938	$ (74,211)	$ 24,751

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

HARROW HEALTH, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	For the Year Ended December 31, 2018	For the Year Ended December 31, 2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income (loss)	$ 14,625	$ (11,985)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization of property, plant and equipment	1,608	1,401
Amortization of intangible assets	235	364
Deferred income taxes	-	(935)
Amortization of debt issuance costs and discount	613	978
Debt extinguishment	-	884
Investment gain from Eton, net	(17,913)	(3,507)
Investment gain from Surface, net	(4,947)	-
Loss on sale and disposal of assets and write down of assets and note receivable	393	354
Stock-based payment for services provided	150	-
Stock-based compensation	2,486	2,943
Changes in assets and liabilities:		
Accounts receivable	(384)	1,392
Inventories	415	(821)
Prepaid expenses and other current assets	(123)	274
Accounts payable and accrued expenses	2,365	346
Accrued payroll and related liabilities	1,074	(429)
Deferred revenue and customer deposits	90	(62)
NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES	687	(8,803)
CASH FLOWS FROM INVESTING ACTIVITIES		
Repayment of note receivable	4	-
Proceeds on sale of assets	-	113
Investment in patent and trademark assets	(435)	(252)
Purchase of Klarity license	-	(50)
Purchases of property, plant and equipment	(1,768)	(772)
NET CASH USED IN INVESTING ACTIVITIES	(2,199)	(961)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payments on capital lease obligations	(691)	(626)
Net proceeds from public equity offering	-	2,940
Payments on Park deferred acquisition obligation	(53)	(206)

Proceeds from SWK debt, net of costs	-	15,518
Principal payments on LSAF note payable	-	(13,999)
Net proceeds from ATM sales of common stock	642	1,124
Net proceeds from exercises of warrants and stock options, net of taxes remitted for RSU's	4,233	179
NET CASH PROVIDED BY FINANCING ACTIVITIES	4,131	4,930
NET CHANGE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	2,619	(4,834)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, beginning of period	4,219	9,053
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, end of period	$6,838	$4,219
RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH		
Cash and cash equivalents	$6,638	$4,019
Restricted cash	200	200
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD	$6,838	$4,219
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for income taxes	$4	$9
Cash paid for interest	$2,097	$1,543
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Final fee on note payable recorded as debt discount and included in accrued expenses	$-	$800
Estimated relative fair value of warrants issued in connection with note payable	$-	$982
Note receivable in connection with sale of assets	$-	$410

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

HARROW HEALTH, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

For the years ended December 31, 2018 and 2017

(all dollar amounts are expressed in thousands, except share and per share data)

NOTE 1. ORGANIZATION

Harrow Health, Inc. (together with its subsidiaries, partially owned companies and royalty arrangements unless the context indicates or otherwise requires, the "Company" or "Harrow") specializes in the development, production and sale of innovative medications that offer unique competitive advantages and serve unmet needs in the marketplace. Prior to 2017, the Company's business was primarily focused on its ImprimisRx business, the nation's leading ophthalmology pharmaceutical compounding business, and Park Compounding, Inc. ("Park"), a leading health and wellness compounding business. Since 2017, in addition to wholly-owning ImprimisRx and Park, the Company also has equity positions in Eton Pharmaceuticals, Inc. ("Eton"), Surface Pharmaceuticals, Inc. ("Surface"), and Melt Pharmaceuticals, Inc. ("Melt"). In 2018, the Company also founded its subsidiaries Mayfield Pharmaceuticals, Inc. ("Mayfield") and Radley Pharmaceuticals, Inc. ("Radley"). The Company owns royalty rights in certain 505(b)(2) drug candidates being developed by Eton, Surface, Melt, Radley and Mayfield.

In December 2018, the Company amended its restated certificate of incorporation to change its corporate name from "Imprimis Pharmaceuticals, Inc." to "Harrow Health, Inc.".

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

Harrow has prepared the accompanying consolidated financial statements in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The accompanying consolidated financial statements include the accounts of the Company and its wholly and majority owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting periods. Significant estimates made by management are, among others, allowance for doubtful accounts and contractual adjustments, realizability of inventories, valuation of investments in equity securities, deferred taxes, goodwill and intangible assets, recoverability of long-lived assets and goodwill, valuation of contingent acquisition obligations and deferred acquisition obligations, valuation of notes payable, and valuation of stock-based transactions with employees and non-employees. Actual results could differ from those estimates.

Liquidity

The Company has incurred significant operating losses and negative cash flows from operations since its inception. The Company incurred operating losses of $5,217 and $12,163 for the years ended December 31, 2018 and 2017, respectively, and had an accumulated deficit of $74,211 and $88,836 as of December 31, 2018 and 2017, respectively. In addition, cash provided by (used in) operating activities were $687 and $(8,803) for the years ended December 31, 2018 and 2017, respectively.

While there is no assurance, the Company believes its existing cash resources, restricted cash and marketable securities of approximately $28,258 at December 31, 2018 will be sufficient to sustain the Company’s planned level of operations for at least the next twelve months. However, estimates of operating expenses and working capital requirements could be incorrect, and the Company could use its cash resources faster than anticipated. Further, some or all of the ongoing or planned activities may not be successful and could result in further losses.

The Company may seek to increase liquidity and capital resources by one or more of the following which may include, but are not limited to: the sale of assets and/or businesses, obtaining financing through the issuance of equity, debt, or convertible securities; and working to increase revenue growth through sales. There is no guarantee that the Company will be able to obtain capital when needed on terms it deems as acceptable, or at all.

Revenue Recognition and Deferred Revenue

The Company recognizes revenue at the time of transfer of promised goods to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. (see Note 3).

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Cost of Sales

Cost of sales includes direct and indirect costs to manufacture formulations and other products sold, including active pharmaceutical ingredients, personnel costs, packaging, storage, royalties (see Note 18), shipping and handling costs and the write-off of obsolete inventory.

Research and Development

The Company expenses all costs related to research and development as they are incurred. Research and development expenses consist of expenses incurred in performing research and development activities, including salaries and benefits, other overhead expenses, and costs related to clinical trials, contract services and outsourced contracts.

Debt Issuance Costs and Debt Discount

Debt issuance costs and the debt discount are recorded net of notes payable and capital lease obligations in the consolidated balance sheets. Amortization expense of debt issuance costs and the debt discount is calculated using the effective interest method over the term of the debt and is recorded in interest expense in the accompanying consolidated statements of operations.

Intellectual Property

The costs of acquiring intellectual property rights to be used in the research and development process, including licensing fees and milestone payments, are charged to research and development expense as incurred in situations where the Company has not identified an alternative future use for the acquired rights, and are capitalized in situations where we have identified an alternative future use for the acquired rights. Patents and trademarks are recorded at cost and capitalized at a time when the future economic benefits of such patents and trademarks become more certain (see Goodwill and Intangible Assets). The Company began capitalizing certain costs associated with acquiring intellectual property rights during 2015, if costs are not capitalized they are expensed as incurred.

Income Taxes

As part of the process of preparing the Company's consolidated financial statements, the Company must estimate the actual current tax liabilities and assess permanent and temporary differences that result from differing treatment of items for tax and accounting purposes. The temporary differences result in deferred tax assets and liabilities, which are included within the consolidated 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 more likely than not, a valuation allowance must be established which reduces the amount of deferred tax assets recorded on the consolidated balance sheets. To the extent the Company establishes a valuation allowance or increase or decrease this allowance in a period, the impact will be included in income tax expense in the consolidated statement of operations.

The Company accounts for income taxes under the provisions of Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("ASC") 740, "Income Taxes", or ASC 740. As of December 31, 2018, and 2017, there were no unrecognized tax benefits included in the consolidated balance sheets that would, if recognized, affect the effective tax rate. The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties in its consolidated balance sheets at December 31, 2018 and 2017, and has not recognized interest and/or penalties in the consolidated statements of operations for the years ended December 31, 2018 and 2017. The Company is subject to taxation in the United States, California, Florida, Georgia, Illinois, New Jersey, New York, and Wisconsin. The Company's tax years since 2000 may be subject to examination by the federal and state tax authorities due to the carryforward of unutilized net operating losses.

Cash and Cash Equivalents

Cash equivalents include short-term, highly liquid investments with maturities of three months or less at the time of acquisition.

Concentrations of Credit Risk

The Company places its cash with financial institutions deemed by management to be of high credit quality. The Federal Deposit Insurance Corporation ("FDIC") provides basic deposit coverage with limits up to $250 per owner. From time to time the Company has cash deposits in excess of FDIC limits.

Investment in Eton Pharmaceuticals, Inc.

In April 2017, the Company formed Eton as a wholly owned subsidiary. In June 2017 the Company lost voting and ownership control of Eton and it ceased consolidating Eton's financial statements. At the time of deconsolidation, the Company recorded a gain of $5,725 and adjusted the carrying value in Eton to reflect the increased valuation of Eton and the Company's new ownership percent in accordance with ASC 810-10-40-4(c), *Consolidation*. At the time of deconsolidation, the Company used the equity method of accounting as management determined that the Company had the ability to exercise significant influence over the operating and financial decisions of Eton. Under this method, the Company recognized earnings and losses of Eton in its consolidated financial statements and adjusted the carrying amount of its investment in Eton accordingly. During the years ended December 31, 2018 and 2017, the Company recorded equity in net loss of Eton of $3,507 and $2,218, respectively.

In November 2018, Eton closed on an initial public offering of 4,140,000 shares of its common stock at $6.00 per share for gross proceeds of approximately $24,800 (the "Eton IPO"). Following the close of the Eton IPO, the Company's common stock position in Eton equaled 19.98% of the equity and voting interests issued and outstanding of Eton, and it ceased using the equity method of accounting for its investment in Eton. The Company recognizes earnings and losses of Eton in its consolidated financial statements based on the fair market value of the shares owned and adjust the carrying amount of the Company's investment in Eton accordingly. Eton's common stock currently trades on the NASDAQ Global Market exchange. At December 31, 2018, the fair market value of Eton's common stock was $6.12 per share, the closing share price of Eton common stock on that day. In accordance with ASU 2016-01, *Financial Instruments-Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*, for the year ended December 31, 2018, the Company recorded a net investment gain from Eton of $17,913, which consisted of a gain of $21,420 related to the change in fair market value of the Company's investment in Eton less an equity in net loss of Eton of $3,507. As of December 31, 2018, the fair market value of the Company's investment in Eton was $21,420.

Accounts Receivable

Accounts receivable are stated net of allowances for doubtful accounts and contractual adjustments. The accounts receivable balance primarily includes amounts due from customers the Company has invoiced or from third-party providers (e.g., insurance companies and governmental agencies), but for which payment has not been received. Charges to bad debt are based on both historical write-offs and specifically identified receivables. Accounts receivable are presented net of allowances for doubtful accounts and contractual adjustments in the amount of $270 and $275 as of December 31, 2018 and 2017, respectively.

Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined on a first-in, first-out basis. The Company evaluates the carrying value of inventories on a regular basis, based on the price expected to be obtained for products in their respective markets compared with historical cost. Write-downs of inventories are considered to be permanent reductions in the cost basis of inventories.

The Company also regularly evaluates its inventories for excess quantities and obsolescence (expiration), taking into account such factors as historical and anticipated future sales or use in production compared to quantities on hand and the remaining shelf life of products and active pharmaceutical ingredients on hand. The Company establishes reserves for excess and obsolete inventories as required based on its analyses.

Investment in Surface Pharmaceuticals, Inc.

In April 2017, the Company formed Surface as a wholly owned subsidiary. In May and July 2018, Surface entered into and closed on definitive stock purchase agreements with an institutional investor for the purchase of Surface's Series A Preferred Stock (the "Surface Series A Stock") that resulted in total proceeds to Surface of approximately $21,000. At the time of the first closing in May 2018, the Company lost voting and ownership control of Surface and it ceased consolidating Surface's financial statements. The Surface Series A Stock (i) was issued at a purchase price of $3.30 per share; (ii) will vote together with the common stock and all other shares of stock of Surface having general voting power; (iii) will be entitled to the number of votes equal to the number of shares of preferred stock held; (iv) will hold liquidation preference over all other equity interests in Surface; and (v) will have mandatory conversion requirements into Surface common stock upon events including an underwritten initial public offering of Surface common stock or similar transaction.

At the time of deconsolidation, the Company recorded a gain of $5,320 and adjusted the carrying value in Surface to reflect the increased valuation of Surface and the Company's new ownership percent in accordance with ASC 810-10-40-4(c).

The Company owns 3,500,000 common shares (which is approximately 30% of the equity interest as of December 31, 2018, and calculated after the second closing of the sale Series A Preferred Stock in July 2018) of Surface and uses the equity method of accounting for this investment, as management has determined that the Company has the ability to exercise significant influence over the operating and financial decisions of Surface. Under this method, the Company recognizes earnings and losses of Surface in its consolidated financial statements and adjusts the carrying amount of its investment in Surface accordingly. The Company's share of earnings and losses are based on the shares of common stock and in-substance common stock of Surface held by the Company. Any intra-entity profits and losses are eliminated. During the year ended December 31, 2018, the Company recorded equity in net loss of Surface of $373 (which, net of the equity in net loss of Surface totaled an investment gain from Surface of $4,947 during the year ended December 31, 2018). As of December 31, 2018, the carrying value of the Company's investment in Surface was $4,947.

Property, Plant and Equipment

Property, plant and equipment is stated at cost less accumulated depreciation and amortization. Depreciation and amortization is calculated using the straight-line method over the estimated useful life of the asset. Leasehold improvements and capital lease equipment are amortized over the estimated useful life or remaining lease term, whichever is shorter. Computer software and hardware and furniture and equipment are depreciated over three to five years.

Business Combinations

The Company accounts for business combinations by recognizing the assets acquired, liabilities assumed, contractual contingencies, and contingent consideration at their fair values on the acquisition date. The purchase price allocation process requires management to make significant estimates and assumptions, especially with respect to intangible assets, estimated contingent consideration payments and pre-acquisition contingencies. Examples of critical estimates in valuing certain of the intangible assets the Company has acquired or may acquire in the future include but are not limited to:

- future expected cash flows from product sales, support agreements, consulting contracts, other customer contracts, and acquired developed technologies and patents; and
- discount rates utilized in valuation estimates.

Unanticipated events and circumstances may occur that may affect the accuracy or validity of such assumptions, estimates or actual results. Additionally, any change in the fair value of the acquisition-related contingent consideration subsequent to the acquisition date, including changes from events after the acquisition date, such as changes in our estimates of relevant revenue or other targets, will be recognized in earnings in the period of the estimated fair value change. A change in fair value of the acquisition-related contingent consideration or the occurrence of events that cause results to differ from our estimates or assumptions could have a material effect on the consolidated financial position, statements of operations or cash flows in the period of the change in the estimate.

Goodwill and Intangible Assets

Patents and trademarks are recorded at cost and capitalized at a time when the future economic benefits of such patents and trademarks become more certain. At that time, the Company capitalizes third-party legal costs and filing

fees associated with obtaining and prosecuting claims related to its patents and trademarks. Once the patents have been issued, the Company amortizes these costs over the shorter of the legal life of the patent or its estimated economic life, generally 20 years, using the straight-line method. Trademarks are an indefinite life intangible asset and are assessed for impairment based on future projected cash flows as further described below.

The Company reviews its goodwill and indefinite-lived intangible assets for impairment as of January 1 of each year and when an event or a change in circumstances indicates the fair value of a reporting unit may be below its carrying amount. Events or changes in circumstances considered as impairment indicators include but are not limited to the following:

- significant underperformance of the Company’s business relative to expected operating results;
- significant adverse economic and industry trends;
- significant decline in the Company’s market capitalization for an extended period of time relative to net book value; and
- expectations that a reporting unit will be sold or otherwise disposed.

The goodwill impairment test consists of a two-step process as follows:

Step 1. The Company compares the fair value of each reporting unit to its carrying amount, including the existing goodwill. The fair value of each reporting unit is determined using a discounted cash flow valuation analysis. The carrying amount of each reporting unit is determined by specifically identifying and allocating the assets and liabilities to each reporting unit based on headcount, relative revenues or other methods as deemed appropriate by management. If the carrying amount of a reporting unit exceeds its fair value, an indication exists that the reporting unit’s goodwill may be impaired and the Company then performs the second step of the impairment test. If the fair value of a reporting unit exceeds its carrying amount, no further analysis is required.

Step 2. If further analysis is required, the Company compares the implied fair value of the reporting unit’s goodwill, determined by allocating the reporting unit’s fair value to all of its assets and its liabilities in a manner similar to a purchase price allocation, to its carrying amount. If the carrying amount of the reporting unit’s goodwill exceeds its fair value, an impairment loss will be recognized in an amount equal to the excess.

Impairment of Long-Lived Assets

Long-lived assets, such as property, plant and equipment, purchased intangibles subject to amortization and patents and trademarks, 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 amount by which the carrying amount of the asset exceeds the fair value of the asset. Assets to be disposed of would be separately presented in the consolidated balance sheet and reported at the lower of the carrying amount or fair value less costs to sell, and are no longer depreciated. The assets and liabilities of a disposal group classified as held-for-sale would be presented separately in the appropriate asset and liability sections of the consolidated balance sheet, if material (See Note 9).

Third Party Billing and Collection Agreements

In connection with its acquisition of Park, the Company entered into a billing and collection agreement with a third party to assist in the billing and collection of workers' compensation claims. Under the terms of the agreement, the Company is obligated to pay a fixed fee to the third party equal to 55% of the amounts billed and collected under the workers' compensation claims. The Company accrues for such fees in accounts payable and accrued expenses in the accompanying consolidated balance sheets. Total billing and collection management expense under this agreement for the years ended December 31, 2018 and 2017 was $1 and $0, respectively, and is included in selling and marketing expenses in the accompanying consolidated statements of operations. The amount due under the agreement as of December 31, 2018 and 2017 was $25 and $41, respectively.

Deferred Rent

The Company accounts for rent expense related to its operating leases by determining total minimum rent payments on the leases over their respective periods and recognizing the rent expense on a straight-line basis. The difference between the actual amount paid and the amount recorded as rent expense in each fiscal year and interim periods within each fiscal year is recorded as an adjustment to deferred rent (see Note 18).

Fair Value Measurements

Fair value measurements are determined based on the assumptions that market participants would use in pricing an asset or liability. GAAP establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. The established fair value hierarchy prioritizes the use of inputs used in valuation methodologies into the following three levels:

Level 1: Applies to assets or liabilities for which there are quoted prices (unadjusted) for identical assets or liabilities in active markets. A quoted price in an active market provides the most reliable evidence of fair value and must be used to measure fair value whenever available.
Level 2: Applies to assets or liabilities for which there are significant other observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.
Level 3: Applies to assets or liabilities for which there are significant unobservable inputs that reflect a reporting entity's own assumptions about the assumptions that market participants would use in pricing an asset or liability. For example, Level 3 inputs would relate to forecasts of future earnings and cash flows used in a discounted future cash flows method.

At December 31, 2017, the Company did not have any financial assets or liabilities that are measured on a recurring basis. At December 31, 2018, the Company measured its investment in Eton on a recurring basis. The Company's investment in Eton is classified as Level 1 as the fair value is determined using quoted market prices in active markets for the same securities. As of December 31, 2018, the fair market value of the Company's investment in Eton was $21,420.

The Company's financial instruments included cash and cash equivalents, restricted short-term investments, investment in Eton, accounts receivable, accounts payable and accrued expenses, accrued payroll and related liabilities, deferred revenue and customer deposits, deferred acquisition obligations, notes payable and capital leases. The carrying amount of these financial instruments, except for deferred acquisition obligations, notes payable and capital leases, approximates fair value due to the short-term maturities of these instruments. The Company's restricted short-term investments are carried at amortized cost, which approximates fair value. Based on borrowing rates currently available to the Company, the carrying values of the deferred acquisition obligations, notes payable and capital leases, approximate their respective fair values.

Stock-Based Compensation

All stock-based payments to employees, directors and consultants, including grants of stock options, warrants, restricted stock units ("RSUs") and restricted stock, are recognized in the consolidated financial statements based upon their estimated fair values. The Company uses the Black-Scholes-Merton option pricing model and Monte Carlo Simulation to estimate the fair value of stock-based awards. The estimated fair value is determined at the date of grant. The financial statement effect of forfeitures is estimated at the time of grant and revised, if necessary, if the actual effect differs from those estimates.

The Company's accounting policy for equity instruments issued to consultants and vendors in exchange for goods and services follows FASB guidance. The measurement date for the estimated fair value of the equity instruments issued is the earlier of (i) the date at which a commitment for performance by the consultant or vendor is reached or (ii) the date at which the consultant or vendor's performance is complete. In the case of equity instruments issued to consultants, the estimated fair value of the equity instrument is primarily recognized over the term of the consulting agreement. According to FASB guidance, an asset acquired in exchange for the issuance of fully vested, nonforfeitable equity instruments should not be presented or classified as an offset to equity on the grantor's balance sheet once the equity instrument is granted for accounting purposes. Accordingly, the Company records the estimated fair value of nonforfeitable equity instruments issued for future consulting services as prepaid stock-based consulting expenses in its consolidated balance sheets.

Basic and Diluted Net Income (Loss) per Common Share

Basic net income (loss) per common share is computed by dividing income (loss) attributable to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted income (loss) per share is computed by dividing the income (loss) attributable to common stockholders for the period by the weighted average number of common and common equivalent shares, such as stock options and warrants, outstanding during the period.

Basic and diluted net income (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 or "if converted" method) from deferred acquisition obligations, convertible note payable, stock options, unvested restricted stock units ("RSUs") and warrants were 6,201,355 and 9,980,454 at December 31, 2018 and 2017, respectively, and, for the year ended December 31, 2017 are excluded from the calculation of diluted net (loss) per share for the period presented, because the effect is anti-dilutive for that time period. Included in the basic and diluted net income (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 resigns. The number of shares underlying vested RSUs at December 31, 2018 and 2017 was 236,693 and 137,067, respectively.

The following table shows the computation of basic net income (loss) per share of common stock for the years ended December 31, 2018 and 2017:

	For the Year Ended December 31, 2018	For the Year Ended December 30, 2017
Numerator – net income (loss)	$14,625	$(11,985)
Denominator – weighted average number of shares outstanding, basic	21,917,570	20,027,712
Net income (loss) per share, basic	$0.67	$(0.60)

For the year end December 31, 2018, the Company computed diluted net income per share using the weighted-average number of common shares and dilutive common equivalent shares outstanding during that period. Diluted common equivalent shares for the year ended December 31, 2018, consisted of the following:

	For the Year Ended December 31, 2018 Shares
Diluted shares related to:	21,917,570
Warrants	1,844,272
Restricted stock units	-
Stock options	50,203
Dilutive common equivalent shares	23,812,045

The following table shows the computation of diluted net income (loss) per share using the weighted-average number of common shares and dilutive common equivalent shares outstanding for the years ended December 31, 2018 and 2017:

	For the Year Ended December 31, 2018	For the Year Ended December 30, 2017
Numerator – net income (loss)	$14,625	$(11,985)
Weighted average number of shares outstanding, basic	21,917,570	20,027,712
Dilutive common equivalents	1,894,475	-
Denominator – number of shares used for diluted earnings per share computation	23,812,045	20,027,712
Net income (loss) per share, diluted	$0.61	$(0.60)

Reclassification

Certain amounts in the 2017 consolidated financial statements have been reclassified to conform to the classifications used to prepare the 2018 consolidated financial statements. These reclassifications had no material impact on the Company's financial position, results of operations, or cash flow as previously reported.

Recently Adopted Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers* and has subsequently issued several amendments to ASU 2014-09. This updated guidance supersedes the current revenue recognition guidance, including industry-specific guidance. The updated guidance introduces a five-step model to achieve its core principal of the entity recognizing revenue to depict the transfer of goods or services to customers at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard's stated core principle is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this core principle, ASU 2014-09 includes provisions within its five-step model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations, and recognizing revenue when, or as, an entity satisfies a performance obligation. In addition, the standard requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers.

The new standard became effective for the Company beginning January 1, 2018 and permits two methods of adoption: the full retrospective method, which requires the standard to be applied to each prior period presented, or the modified retrospective method, which requires the cumulative effect of adoption to be recognized as an adjustment to opening retained earnings in the period of adoption. The Company adopted the standard using the modified retrospective method. There was no effect for any adjustments to retained earnings upon adoption of the standard on January 1, 2018. Adoption of the new standard resulted in additional revenue-related disclosures in the footnotes to the Company's consolidated financial statements (see Note 3).

In January 2016, the FASB issued ASU 2016-01 , which requires that investments in equity securities (excluding equity method investments) be measured at fair value with changes in fair value recognized in net earnings. Under previous guidelines, changes in fair value of available-for-sale equity securities are recorded in other comprehensive income. The Company adopted ASU 2016-01 as of January 1, 2018. As of that date, adoption of the standard did not have an effect on the Company's financial position, results of operations and cash flows because the Company did not have any investments in equity securities (at January 1, 2018) that were not equity method investments.

In January 2017, the FASB issued ASU 2017-01, *Business Combinations, Clarifying the Definition of a Business*, which revises the definition of a business and provides new guidance in evaluating when a set of transferred assets and activities is a business. The Company adopted the standard on January 1, 2018. Adoption of the standard did not have an impact on the Company's financial position, results of operations and cash flows.

In August 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows: Classification Restricted Cash*, which requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The Company adopted the standard on January 1, 2018 by using the retrospective transition method. Adoption of the standard effected the presentation of cash equivalents in Company's consolidated statements of cash flows and related disclosures, restricted cash of $200 has been reclassified within that financial statement for the periods presented as a cash equivalent.

In May 2017, the FASB issued ASU 2017-09, *Compensation - Stock Compensation: Scope of Modification Accounting*. The amendments in this update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting under Topic 718. An entity should account for effects of a modification unless all of the following are met: (1) the fair value of the modified award is the same as the fair value of the original award immediately before the original award is modified; (2) the vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified; (3) the classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. The Company adopted this standard on January 1, 2018. Adoption of the standard did not have an effect on the Company's financial position, results of operations and cash flows.

In June 2018, the FASB issued ASU 2018-07, *Compensation – Stock Compensation: Improvements to Nonemployee Share-Based Payment Accounting* which simplifies several aspects of the accounting for nonemployee share-based payment transactions resulting from expanding the scope of Topic 718, Compensation-Stock Compensation, to include share-based payment transactions for acquiring goods and services from nonemployees. Some of the areas for simplification apply only to nonpublic entities. The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The amendments also clarify that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606, Revenue from Contracts with Customers. The amendments in this Update are effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted. The Company adopted this standard on July 1, 2018. Adoption of the standard did not have an effect on the Company's financial position, results of operations and cash flows.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued new lease accounting guidance in ASU No. 2016-02, *Leases* (Topic 842). This new guidance was initiated as a joint project with the International Accounting Standards Board to simplify lease accounting and improve the quality of and comparability of financial information for users. This new guidance would eliminate the concept of off-balance sheet treatment for "operating leases" for lessees for the vast majority of lease contracts. Under ASU No. 2016-02, at inception, a lessee must classify all leases with a term of over one year as either finance or operating, with both classifications resulting in the recognition of a defined "right-of-use" asset and a lease liability on the balance sheet. However, recognition in the income statement will differ depending on the lease classification, with finance leases recognizing the amortization of the right-of-use asset separate from the interest on the lease liability and operating leases recognizing a single total lease expense. Lessor accounting under ASU No. 2016-02 would be substantially unchanged from the previous lease requirements under GAAP. ASU No. 2016-02 will take effect for public companies in fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted and for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, lessees and lessors must apply a modified retrospective transition approach. During the year ended December 31, 2017, the Company evaluated this new

accounting standard and engaged professionals in the new lease accounting implementation to assist in determining the effect of the new standard as of January 1, 2018 with respect to the Company's real estate leases. The Company currently has three real estate leases and evaluated each of these leases in accordance with the new lease accounting standard under ASC Topic 842. As of December 31, 2018, the Company estimates that the right of use asset to be recorded on its consolidated balance sheet would be approximately $2,106 and that the related lease liability would be approximately $2,624 related to operating leases. The difference between the right of use asset and related lease liability is predominantly deferred rent and other related lease expenses under the new lease accounting standard. The Company will continue this effort with respect to equipment leases and any other leases contemplated under Topic 842 in a manner to be appropriately prepared for its implementation on January 1, 2019.

In January 2017, the FASB issued ASU 2017-04, *Intangibles-Goodwill and Other*. This guidance simplifies the accounting for goodwill impairment for all entities by requiring impairment charges to be based on the first step in the current two-step impairment test under ASC 350. The updated standard eliminates the requirement to calculate a goodwill impairment charge using Step 2. If a reporting unit's carrying amount exceeds its fair value, an entity will record an impairment charge based on that difference. The impairment charge will be limited to the amount of goodwill allocated to that reporting unit. ASU 2017-04 is effective for reporting periods beginning after December 31, 2019 on a prospective basis, and early adoption is permitted. The Company does not expect ASU 2017-04 to have a material effect on the Company's financial position, results of operations and cash flows.

NOTE 3. REVENUES

On January 1, 2018, the Company adopted ASU 2014-09, using the modified retrospective transition method. There was no effect for any adjustments to retained earnings upon adoption of the standard on January 1, 2018. The Company has two primary streams of revenue: (1) revenue recognized from our sale of products within our pharmacy services and (2) revenue recognized from intellectual property license and asset purchase agreements.

Product Revenues from Pharmacy Services

The Company sells prescription drugs directly through our pharmacy and outsourcing facility network. Revenue from our pharmacy services divisions includes: (i) the portion of the price the client pays directly to us, net of any volume-related or other discounts paid back to the client, (ii) the price paid to us by individuals, and (iii) customer copayments made directly to the pharmacy network. Sales taxes are not included in revenue. Following the core principle of ASU 2014-09, we have identified the following:

1. Identify the contract(s) with a customer: A contract exists with a customer at the time the prescription or order is received by the Company.

2. Identify the performance obligations in the contract: The order received contains the performance obligations to be met, in almost all cases the product the customer is wishing to receive. If we are unable to be meet the performance obligation the customer is notified.

3. Determine the transaction price: the transaction price is based on the product being sold to the customer, and any related customer discounts. These amounts are pre-determined and built into our order management software.

4. Allocate the transaction price to the performance obligations in the contract: The transaction price associated with the product(s) being ordered is allocated according to the pre-determined amounts.

5. Recognize revenue when (or as) the entity satisfies a performance obligation: At the time of shipment from the pharmacy or outsourcing facility the performance obligation has been met.

The following revenue recognition policy has been established for the pharmacy services division:

Revenues generated from prescription or office use drugs sold by our pharmacies and outsourcing facility are recognized when the prescription is shipped. At the time of shipment, the pharmacy services division has performed substantially all of its obligations under its client contracts and does not experience a significant level of returns or reshipments. Determination of criteria (3) and (4) is based on management's judgments regarding the fixed nature of the selling prices of the products delivered and the collectability of those amounts. The Company records reductions to revenue for discounts at the time of the initial sale. Estimated returns and allowances and other adjustments are provided for in the same period during which the related sales are recorded and are based on actual returns history. The rate of returns is analyzed annually to determine historical returns experience. If the historical data we use to calculate these estimates do not properly reflect future returns, then a change in the allowance would be made in the period in which such a determination is made and revenues in that period could be materially affected. The Company will defer any revenues received for a product that has not been delivered or is subject to refund until such time that the Company and the customer jointly determine that the product has been delivered and no refund will be required.

Intellectual Property License Revenues

The Company currently holds five intellectual property license and related agreements in which the Company has promised to grant a license or sale which provides a customer with right to access the Company's intellectual property. License arrangements may consist of non-refundable upfront license fees, data transfer fees, research reimbursement payments, exclusive license rights to patented or patent pending compounds, technology access fees, and various performance or sales milestones. These arrangements can be multiple element arrangements, each of which revenue is recognized at the point of time the performance obligation is met.

Non-refundable fees that are not contingent on any future performance by the Company and require no consequential continuing involvement on the part of the Company are recognized as revenue when the license term commences and the licensed data, technology, compounded drug preparation and/or other deliverable is delivered. Such deliverables may include physical quantities of compounded drug preparations, design of the compounded drug preparations and structure-activity relationships, the conceptual framework and mechanism of action, and rights to the patents or patent applications for such compounded drug preparations. The Company defers recognition of non-refundable fees if it has continuing performance obligations without which the technology, right, product or service conveyed in conjunction with the non-refundable fee has no utility to the licensee and that are separate and independent of the Company's performance under the other elements of the arrangement. In addition, if the Company's continued involvement is required, through research and development services that are related to its proprietary know-how and expertise of the delivered technology or can only be performed by the Company, then such non-refundable fees are deferred and recognized over the period of continuing involvement. Guaranteed minimum annual royalties are recognized on a straight-line basis over the applicable term.

Revenue disaggregated by revenue source for the year ended December 31, 2018 and 2017, consists of the following:

	For the year ended December 31,	
	2018	2017
Product sales, net	$41,334	$26,684
License revenues	38	90
Total revenues	$41,372	$26,774

Deferred revenue and customer deposits at December 31, 2018 and 2017, was $119 and $29, retrospectively. All deferred revenue and customer deposit amounts at December 31, 2017 were recognized as revenue during the year ended December 31, 2018.

NOTE 4. INVESTMENT IN ETON PHARMACEUTICALS, INC. AND AGREEMENTS - RELATED PARTY TRANSACTIONS

In May 2017, the Company entered into two asset purchase and license agreements (the “Eton License Agreements”) with its previously wholly owned subsidiary, Eton. Pursuant to the terms of the Eton License Agreements, the Company assigned and licensed to Eton certain intellectual property and related rights to develop, formulate, make, sell, and sub-license formulations of synthetic corticotropin and injectable pentoxifylline (collectively, the “Eton Products”). Eton is required to make royalty payments to the Company of six percent (6%) of net sales of the Eton Products while any patent rights remain outstanding and then three percent (3%) of net sales in the event patent claims are not issued. In addition, Eton is required to make certain milestone payments to the Company including payments of $50 upon initial patent issuances for each Eton Product. The Eton License Agreements were conditioned upon Eton receiving net proceeds of the sale of its equity securities of not less than $10,000, which occurred in June 2017. See also Note 2, under the subheading *Investment in Eton Pharmaceuticals, Inc.*

On May 1, 2017, the Company and Eton entered into a Management Services Agreement (the “MSA”), whereby the Company provided to Eton certain administrative services and support, including bookkeeping, web services and human resources related activities, and Eton will pay the Company a monthly amount of $10. A 30-day notice of termination was delivered to the Company on August 29, 2017. Eton paid the Company $40 for services under the MSA.

As of December 31, 2018, the Company held 3.5 million shares in Eton at a fair market value of $6.12 per share. In November 2018, the Company entered into a lock-up agreement, that prohibits the sale of any of our Eton common stock until November 2019, without the approval of National Securities Corporation. As of December 31, 2018, the

carrying value of the Company's investment in Eton was $21,420.

The Company owns 19.98% of the voting interests in Eton (3,500,000 shares of Eton common stock). The Company's Chief Executive Officer, Mark L. Baum, is a director of Eton, and several employees of the Company (including Mr. Baum and the Company's Chief Financial Officer, Andrew R. Boll) previously entered into consulting agreements with Eton.

NOTE 5. INVESTMENT IN SURFACE PHARMACEUTICALS, INC. AND AGREEMENTS - RELATED PARTY TRANSACTIONS

In 2017 and amended in April 2018, the Company entered into two asset purchase and license agreements (the "Surface License Agreements") with its previously wholly owned subsidiary, Surface. Pursuant to the terms of the Surface License Agreements, the Company assigned and licensed to Surface certain intellectual property and related rights to develop, formulate, make, sell, and sub-license formulations of certain topical eye drop formulations that utilize a proprietary delivery vehicle and a proprietary doxycycline capsule (collectively, the "Surface Products"). Surface is required to make royalty payments to the Company of four to six percent (4%-6%) of net sales of the Surface Products while any patent rights remain outstanding. Certain of the Surface License Agreements were conditioned upon Surface receiving net proceeds of the sale of its equity securities of not less than $10,000, which occurred in May 2018. See also Note 2, under the subheading *Investment in Surface Pharmaceuticals, Inc*.

In January 2018, the Company and Surface entered into an amended Management Services Agreement (the "MSA"), whereby the Company provided to Surface certain administrative services and support, including bookkeeping, web services and human resources related activities, and Surface paid the Company a monthly amount of $10. The MSA was terminated effective July 31, 2018.

As of December 31, 2018, the Company was due $50 from Surface for reimbursable expenses and amounts due under the MSA and included in prepaid expenses and other current assets on the accompanying consolidated balance sheets.

As of December 31, 2018, the Company owned 3,500,000 shares of Surface common stock (approximately 30% issued and outstanding equity interests). One of the Company's directors, Richard L. Lindstrom, and the Company's Chief Executive Officer, Mark L. Baum, are directors of Surface. In addition, the Company's Chief Financial Officer, Andrew R. Boll, was a director of Surface and resigned as a director of Surface concurrent with the sale of the Surface Series A Stock. Several employees and a director of the Company (including Mr. Baum, Dr. Lindstrom and Mr. Boll) previously entered into consulting agreements and provided consulting services to Surface. Surface is required to make royalty payments to Dr. Lindstrom of 3% of net sales of certain Surface products while certain patent rights remain outstanding. Dr. Lindstrom is also a principal of Flying L Partners, an affiliate of the funding investor.

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The unaudited condensed results of operations information of Surface is summarized below:

	For the Year Ended December 31, 2018
Revenues, net	$ -
Loss from operations	1,370
Net loss	$ (1,370)

The unaudited condensed balance sheet information of Surface is summarized below:

	At December 31, 2018
Current assets	$ 19,699
Non current assets	50
Total assets	19,749
Total liabilities	165
Total stockholders equity	19,584
Total liabilities and stockholders' equity	$ 19,749

NOTE 6. RESTRICTED CASH

The restricted cash at December 31, 2018 and 2017 consisted of funds held in a money market account. At December 31, 2018 and 2017, the restricted cash was recorded at amortized cost, which approximates fair value.

At December 31, 2018 and 2017, the funds held in a money market account of $200 were classified as a current asset. The money market account funds are required as collateral as additional security for the Company's New Jersey facility lease.

NOTE 7. INVENTORIES

Inventories are comprised of finished compounded formulations, over-the-counter and prescription retail pharmacy products, commercial pharmaceutical products, related laboratory supplies and active pharmaceutical ingredients. The composition of inventories as of December 31, 2018 and 2017 was as follows:

	December 31, 2018	December 31, 2017
Raw materials	$ 1,119	$ 956
Work in progress	6	-
Finished goods	709	1,293
Total inventories	$ 1,834	$ 2,249

NOTE 8. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	December 31, 2018	December 31, 2017
Prepaid insurance	$ 328	$ 164
Other prepaid expenses	334	426
Receivable due from Surface	50	-
Deposits and other current assets	125	124
Total prepaid expenses and other current assets	$ 837	$ 714

NOTE 9. ASSET SALES AND NOTE RECEIVABLE

On June 27, 2017, the Company entered into an Asset Purchase Agreement (the "PA Agreement") with Creative Pharmacy Solutions Central, LLC (the "Buyers"), which closed in July 2017. Under the terms of the PA Agreement, the Company sold substantially all its assets associated with its sinus related business, including but not limited to, certain intellectual property rights, trademarks, copyrights, inventories, equipment, customer lists, databases, permits, licenses, and assignment of the Company's lease obligation for its Pennsylvania based pharmacy (the "PA Assets"), for a total purchase price of approximately $450.

Under the terms of the PA Agreement, the Buyers, upon closing, paid to the Company an aggregate cash amount of $40. In addition, the Buyers are obligated to pay the remaining $410 pursuant to a note bearing interest at 6% per annum (the "Sellers Note"). The Buyers are required to make forty-eight monthly cash payments to the Company of $10 following the closing, totaling $462; provided however, that the Buyer had the option to make a one-time payment of $365 any time prior to December 31, 2017, and the Company would waive any remaining amounts due on the Sellers Note. The principal amount of the Sellers Note was also subject to post-closing adjustment through December 31, 2017, if certain criteria were met, however, that period ended and no adjustments were made. There was $397 due under the Sellers Note as of December 31, 2017, which has not yet been paid.

The Company recorded a loss of $69 during the year ended December 31, 2017, related to the sale of the PA Assets.

The Company recorded a loss of $393, which was recorded in other expense, net, during the year ended December 31, 2018, related to the impairment and write-off of all amounts owed to it under its note receivable. The write-off is due to the Company's estimate of collectability of the asset.

In June 2017, in a separate transaction, the Company entered into an agreement to sell certain equipment to a third party for amount of $60 and closed the transaction in July 2017. The Company recorded a loss related to equipment of $52 during the year ended December 31, 2017.

Assets sold during the year ended December 31, 2017 consisted of the following:

	December 31, 2017
Inventories	$ 413

Furniture and equipment	226
	639
Loss on asset sale	(127)
Assets sold	$ 512

In February 2017, the Company entered into a stock purchase agreement (the "SPA") with Livernois & London, LLC ("Livernois"). Pursuant to the terms of the SPA, the Company sold to Livernois 100% of the issued and outstanding shares of common stock of its Texas based subsidiary, ImprimisRx TX, Inc. dba ImprimisRx ("Imprimis TX"). The SPA did not transfer to Livernois any of the Company's rights to intellectual property, products, clients, nor any of its existing business operations. As consideration for the purchase of Imprimis TX, Livernois paid the Company $10 and the Company assigned, and Livernois assumed, the remaining lease obligation totaling $113 for the Texas based facility. The Company recorded a loss of $173 from the sale of Imprimis TX for the year ended December 31, 2017, which is included in the accompanying consolidated statements of operations.

NOTE 10. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment at December 31, 2018 and 2017 consisted of the following:

	December 31, 2018	December 31, 2017
Property, plant and equipment, net:		
Computer software and hardware	$ 1,662	$ 1,239
Furniture and equipment	397	377
Lab and pharmacy equipment	3,184	2,545
Leasehold improvements	5,496	4,810
	10,739	8,971
Accumulated depreciation and amortization	(4,364)	(2,756)
	$ 6,375	$ 6,215

The Company recorded depreciation and amortization expense of $1,608 and $1,401 during the years ended December 31, 2018 and 2017, respectively.

NOTE 11. INTANGIBLE ASSETS AND GOODWILL

The Company's intangible assets at December 31, 2018 consisted of the following:

	Amortization periods (in years)	Cost	Accumulated amortization	Impairment	Net Carrying value
Patents	17-19 years	$755	$ (49)	$ -	$ 706
Licenses	20 years	50	-	-	50
Trademarks	Indefinite	320	-	-	320
Customer relationships	3-15 years	2,998	(1,014)	(15)	1,969
Trade name	5 years	16	(13)	(1)	2
Non-competition clause	3-4 years	294	(274)	(20)	-
State pharmacy licenses	25 years	45	(5)	(28)	12
		$4,478	$ (1,355)	$ (64)	$ 3,059

Amortization expense for intangible assets for the year ended December 31 was as follows:

	For the Year Ended December 31, 2018	For the Year Ended December 31, 2017
Patents	$ 28	$ 15
Licenses	-	-
Customer relationships	201	257
Trade name	4	3
Non-competition clause	1	87
State pharmacy licenses	2	2
	$ 235	$ 364

Estimated future amortization expense for the Company's intangible assets at December 31, 2018 is as follows:

Years ending December 31,	
2019	$244
2020	242
2021	242
2022	242
Thereafter	2,089
	$3,059

There have been no changes in the carrying value of the Company's goodwill during the year ended December 31, 2018.

NOTE 12. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses at December 31, 2018 and 2017 consisted of the following:

	December 31, 2018	December 31, 2017
Accounts payable	$ 5,606	$ 3,241
Deferred rent	388	388
Accrued interest (see Note 13)	256	256
Accrued exit fee for note payable (see Note 13)	800	800
Total accounts payable and accrued expenses	7,050	4,685
Less: Current portion	(6,250)	(3,885)
Non-current total accrued expenses	$ 800	$ 800

NOTE 13. DEBT

LSAF Senior Note

During 2015 and 2016, the Company entered into a loan and security agreement (the “Loan Agreement”) with IMMY Funding LLC, an affiliate of Life Sciences Alternative Funding LLC (“LSAF”), as lender and collateral agent. Pursuant to the terms of the Loan Agreement, as amended in January 2016 and December 2016, LSAF made available to the Company a term loan in the aggregate principal amount of up to $10,000, all of which was drawn on May 11, 2015. The term loan bore interest at a fixed per-annum rate of 12.5% and allowed for 2% of the interest to be paid-in-kind until December 2016. The Loan Agreement included a final fee of 5% of the aggregate principal amount of the term loan and prepayment fees of up to 1% of the principal balance were due on January 1, 2019. In connection with the Loan Agreement, the Company issued a warrant to purchase up to 125,000 shares of the Company’s common stock to LSAF. The Company then entered into subsequent amendments and related note payable agreements with LSAF related to the Loan Agreement and its warrants during 2016, including a convertible note agreement and note exchange agreement. Beginning January 1, 2017, the Company owed LSAF $13,332 under the Loan Agreement, its subsequent amendments and related agreements, including any interest that has been paid in kind of the principal balance, in aggregate.

SWK Senior Note and LSAF Payoff – 2017

In July 2017, the Company entered into a term loan and security agreement in the principal amount of $16,000 (the "SWK Loan Agreement" or "SWK Loan") with SWK Funding LLC and its partners ("SWK"), as lender and collateral agent. The SWK Loan Agreement was fully funded at closing with a five-year term, however, such term may be reduced to four years if certain revenue requirements are not achieved. Concurrently with the funding, the Company utilized a portion of the SWK Loan funds as full payment to an affiliate of LSAF to terminate all amounts due to LSAF in connection with the LSAF Agreement. In total, including previously made principal payments, the Company made payments of $13,999 to pay-off the LSAF Agreement and expenses, which also included the previously accrued exit fee, interest paid in kind and other expenses related to the payoff. The Company also recorded a loss on early extinguishment of debt during the year ended December 31, 2017 of $884 related to the pay-off.

The SWK Loan bears interest at a variable rate equal to the three-month London Inter-Bank Offered Rate (subject to a minimum of 1.50% and maximum of 3.00%), plus an applicable margin of 10.50%. The SWK Loan Agreement permits the Company to pay interest only on the principal amount loaned thereunder for the first six payments (payments are due on a quarterly basis), which interest-only period could have been reduced to four payments if the Company had not met certain minimum revenue requirements. Following the interest-only period, the Company will be required to pay interest, plus repayments of the principal amount loaned under the SWK Loan Agreement, in quarterly payments, which shall not exceed $750 per quarter. All amounts owed under the SWK Loan Agreement, including a final fee equal to 5% of the aggregate principal amount loaned thereunder, will be due and payable on July 19, 2022. The Company may elect to prepay all, but not less than all, of the amounts owed under the SWK Loan Agreement prior to the maturity date at any time after July 19, 2019. The Company is also obligated under the SWK Loan Agreement to pay for certain expenses incurred by the SWK Lender through and after the date of the SWK Loan Agreement, including certain fees and expenses relating to the preparation and administration of the SWK Loan Agreement. The Company incurred expenses and final fee of approximately $1,282 in connection with the SWK Loan Agreement. The final fee and expenses are being amortized as interest expense over the term of the SWK Loan using the effective interest rate method and the related liability of $800 for the final fee is included in accrued expenses (see Note 12) in the accompanying consolidated balance sheets as of December 31, 2018 and 2017.

In connection with the SWK Loan Agreement, the Company issued to SWK warrants to purchase up to 415,586 shares of the Company's common stock (the "Lender Warrants") with an exercise price of $3.08. In August 2017, the Company and SWK amended the warrants, to allow for the purchase up to 615,386 warrants with an exercise price of $2.08. The Lender Warrants are exercisable immediately, and have a term of 7 years. The Lender 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 Lender Warrants was approximately $982 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 $2.08 per share; seven-year contractual term; 113.5% volatility; 0% dividend rate; and a risk-free interest rate of 1.77%.

For the years ended December 31, 2018 and 2017, debt discount amortization related to notes payable were $520 and $811, respectively.

Notes payable at December 31, 2018 were as follows:

	December 31, 2018
SWK note	$ 16,000
Less: Discount on note	(1,472)
Less: Current portion	(2,529)
Long-term portion	$ 11,999

Future minimum payments under notes payable outstanding at December 31, 2018 are as follows:

	Amount
2019	$5,018
2020	4,402
2021	4,033
2022	7,410
Total minimum payments	20,863
Less: amount representing interest	(4,863)
Notes payable, gross	16,000
Less: unamortized discount	(1,472)
Less: current portion, net of unamortized discount	(2,529)
Note payable, net of current portion and unamortized debt discount	$11,999

NOTE 14. CAPITAL LEASE OBLIGATION

On August 9, 2016, the Company entered into a commercial lease agreement (the “Lease Agreement”) with Essex Capital Corporation (“Essex”). Pursuant to the terms of the Lease Agreement, the Company sold certain equipment (the “Equipment”) to Essex for a total purchase price of approximately $2,000, which was then leased back to the Company under a thirty-six month term net basis lease with monthly payments of approximately $64. The fair value of equipment sold and then leased under the Lease Agreement totaled approximately $2,000. The lease term may be extended for an additional twelve month period in the event the Company achieves certain financial milestones. The Company has the right to purchase the Equipment from Essex upon the expiration of the Lease Agreement for a purchase price equal to the Equipment’s then fair market value, with such fair market value not to exceed fifteen percent of the original Equipment value on August 9, 2016. If the Equipment is not purchased at the end of the term,

the Company may automatically extend the lease on a month-to-month basis or return the Equipment and terminate the Lease Agreement. The Company expects to purchase the Equipment at the end of the term of the lease and has accrued the final payment amount of $300. The Company also incurred expenses of approximately $67 in connection with the Lease Agreement. The issuance costs were recorded as a discount. The discount is being amortized as interest expense over the term of the lease using the effective interest method. The Company used an interest rate of 16.8% for calculation of the present value of the future minimum payments under the Lease Agreement. For the years ended December 31, 2018 and 2017, debt discount amortization related to the Lease Agreement was $93 and $167, respectively, and is included in interest expense in the accompanying consolidated statement of operations.

At December 31, 2018, future payments under the Company's capital lease were as follows:

	Amount
2019	$ 751
Total minimum lease payments	751
Less: amount representing interest payments	(15)
Present value of future minimum lease payment	736
Less: unamortized discount	(16)
	720
Less: current portion, net of unamortized discount	(720)
Capital lease obligation net of current portion and unamortized discount	$ -

The cost of the equipment under capital leases as of December 31, 2018 and 2017 was $2,070, with related accumulated depreciation of $729 and $444, respectively.

NOTE 15. STOCKHOLDERS' EQUITY AND STOCK-BASED COMPENSATION

Common Stock

At December 31, 2018 and 2017, the Company had 50,000,000 and 90,000,000 shares of common stock, $0.001 par value, authorized, respectively. On July 10, 2018, the Company amended its amended and restated certificate of incorporation to reduce the number of authorized shares of common stock from 90,000,000 to 50,000,000.

Issuances During the Year Ended December 31, 2017

In March 2017, we entered into securities purchase agreements with two accredited investors, which provided for the sale by the Company of 1,312,500 shares of its common stock, at a price of $2.40 per share (the "Registered Offering"). We received net proceeds of $2,940 after deducting the underwriter discount of 6% of the gross proceeds from the Registered Offering and other related expenses.

In March 2017, the Company issued 25,000 shares of its restricted common stock, with a fair value of $60, as payment for investor relations related services.

In April 2017, the Company issued 100,000 shares of common stock as a result of warrant exercises. The Company received cash proceeds of $179 upon the exercise of the warrants with an exercise price of $1.79.

In November 2015, the Company entered into a Controlled Equity Offering^{SM} sales agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as agent ("Cantor Fitzgerald"), pursuant to which the Company may offer and sell, from time to time through Cantor Fitzgerald, shares of our common stock having an aggregate offering price as set forth in the Sales Agreement and a related prospectus supplement filed with the Securities and Exchange Commission. The Company agreed to pay Cantor Fitzgerald a cash commission of 3.0% of the aggregate gross proceeds from each sale of shares under the Sales Agreement. The Company sold 557,714 shares of common stock and received net proceeds of $1,124, after deducting $35 for sales commission and offering expenses, under the Sales Agreement during the year ended December 31, 2017.

During the year ended December 31, 2017, 56,822 shares of the Company's common stock underlying RSUs issued to directors vested, but the issuance and delivery of these shares are deferred until the director resigns.

Issuances During the Year Ended December 31, 2018

In January 2018, the Company issued 25,273 shares of its restricted common stock, with a fair value of $44, in lieu of a cash payment for accrued royalty expenses.

RSUs granted in February 2015 to Andrew R. Boll, the Company's Chief Financial Officer, vested, and in February 2018, 30,000 shares the Company's common stock were issued to Mr. Boll.

RSUs granted in February 2015 to John P. Saharek, the President of ImprimisRx (formerly, the Company's Chief Commercial Officer), vested, and in February 2018, 30,000 shares the Company's common stock were issued to Mr. Saharek.

In March 2018, the Company issued 35,427 shares of its restricted common stock, with a fair value of $64, in lieu of a cash payment for accrued royalty expenses.

In December 2018, the Company issued 15,000 shares of its restricted common stock, with a fair value of $42, related to a milestone payment due under a sales and marketing agreement.

The Company sold 305,619 shares of common stock and received net proceeds of $642, after deducting $20 for sales commission and offering expenses, under the Sales Agreement during the nine months ended September 30, 2018. In November 2018, the Company terminated the Sales Agreement.

During the year ended December 31, 2018, the Company issued 2,364,889 shares of its common stock related to the exercise of common stock warrants with an exercise price of $1.79, and received net proceeds of $4,233.

During the year ended December 31, 2018, the Company issued 910,273 shares of its common stock related to the cashless exercise of 1,576,665 common stock warrants with an exercise price of $1.79.

During the year ended December 31, 2018, 99,626 shares of the Company’s common stock underlying RSUs issued to directors vested, but the issuance and delivery of these shares are deferred until the director resigns.

Preferred Stock

At December 31, 2018 and 2017, the Company had 5,000,000 shares of preferred stock, $0.001 par value, authorized and no shares of preferred stock issued and outstanding.

Stock Option Plan

On September 17, 2007, the Company's Board of Directors and stockholders adopted the Company's 2007 Incentive Stock and Awards Plan, which was subsequently amended on November 5, 2008, February 26, 2012, July 18, 2012, May 2, 2013 and September 27, 2013 (as amended, the "2007 Plan"). The 2007 Plan reached its term in September 2017, and we can no longer issue additional awards under this plan, however, options still outstanding and previously issued under the 2007 Plan will remain outstanding until they are exercised, reach their maturity or are otherwise cancelled/forfeited. On June 13, 2017, the Company's Board of Directors and stockholders adopted the Company's 2017 Incentive Stock and Awards Plan (the "2017 Plan" together with the 2007 Plan, the "Plan"). As of December 31, 2018, the 2017 Plan provide for the issuance of a maximum of 2,000,000 shares of the Company's common stock. The purpose of the Plan is to attract and retain directors, officers, consultants, advisors and employees whose services are considered valuable, to encourage a sense of proprietorship and to stimulate an active interest of such persons in the Company's development and financial success. Under the Plan, the Company is authorized to issue incentive stock options intended to qualify under Section 422 of the Internal Revenue Code, non-qualified stock options, restricted stock units and restricted stock. The Plan is administered by the Compensation Committee of the Company's Board of Directors. The Company had 1,572,640 shares available for future issuances under the 2017 Plan at December 31, 2018.

Stock Options

A summary of stock option activity under the Plan for the year ended December 31, 2018 is as follows:

	Number of shares	Weighted Avg. Exercise Price	Weighted Avg. Remaining Contractual Life	Aggregate Intrinsic Value
Options outstanding - January 1, 2018	2,259,979	$ 5.50		
Options granted	296,500	$ 1.80		
Options exercised	-	$ -		

Options cancelled/forfeit	(74,470)	$ 4.29		
Options outstanding - December 31, 2018	2,482,009	$ 5.10	5.51	$ 3,990
Options exercisable	1,337,780	$ 4.94	6.22	$ 3,525
Options vested and expected to vest	2,368,925	$ 5.09	5.53	$ 3,805

The aggregate intrinsic value in the table above represents the total pre-tax amount of the proceeds, net of exercise price, which would have been received by option holders if all option holders had exercised and immediately sold all options with an exercise price lower than the market price on December 31, 2018, based on the closing price of the Company’s common stock of $5.69 on that date.

During 2018 and 2017, the Company granted stock options to certain employees, directors and consultants. The stock options were granted with an exercise price equal to the current market price of the Company’s common stock, as reported by the securities exchange on which the common stock was then listed, at the grant date and have contractual terms ranging from five to 10 years. Vesting terms for options granted in 2018 and 2017 to employees and consultants typically included one of the following vesting schedules: 25% of the shares subject to the option vest and become exercisable on the first anniversary of the grant date and the remaining 75% of the shares subject to the option vest and become exercisable quarterly in equal installments thereafter over three years; quarterly vesting over three years. Certain option awards provide for accelerated vesting if there is a change in control (as defined in the Plan) and in the event of certain modifications to the option award agreement.

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton option pricing model. Beginning on April 1, 2018, the Company began calculating expected volatility based solely on the historical volatilities of the common stock of the Company. In the past, the expected volatility was based on the historical volatilities of the common stock of the Company and comparable publicly traded companies, the Company previously utilized this methodology based on its estimate that it had limited relevant historical data regarding the volatility of its stock price on which to base a meaningful estimate of expected volatility. The expected volatility is based on the historical volatilities of the common stock of the Company and comparable publicly traded companies based on the Company’s belief that it currently has limited relevant historical data regarding the volatility of its stock price on which to base a meaningful estimate of expected volatility. The expected term of options granted was determined in accordance with the “simplified approach,” as the Company has limited, relevant, historical data on employee exercises and post-vesting employment termination behavior. The expected risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The financial statement effect of forfeitures is estimated at the time of grant and revised, if necessary, if the actual effect differs from those estimates. For option grants to employees and directors, the Company assigns a forfeiture factor of 10%. These factors could change in the future, which would affect the determination of stock-based compensation expense in future periods. Utilizing these assumptions, the fair value is determined at the date of grant.

The table below illustrates the fair value per share determined using the Black-Scholes-Merton option pricing model with the following assumptions used for valuing options granted to employees:

	2018	2017
Weighted-average fair value of options granted	$1.42	$2.04
Expected terms (in years)	5.77 - 6.11	5.81 - 6.11
Expected volatility	76 - 126 %	112 - 117 %
Risk-free interest rate	2.05 - 3.00 %	1.77 - 2.01 %
Dividend yield	-	-

The following table summarizes information about stock options outstanding and exercisable at December 31, 2018:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$1.47 - $2.60	837,375	7.74	$ 2.04	420,774	$ 2.16
$3.04 - $4.50	536,622	6.97	$ 3.96	415,784	$ 3.98
$5.49 - $6.36	99,350	4.52	$ 5.97	97,784	$ 5.97
$6.64 - $8.99	1,003,632	2.98	$ 7.98	398,408	$ 8.16
$42.80	5,030	1.62	$ 42.80	5,030	$ 42.80
$1.47 - $42.80	2,482,009	5.51	$ 5.10	1,337,780	$ 4.94

As of December 31, 2018, there was approximately $1,888 of total unrecognized compensation expense related to unvested stock options granted under the Plan. That expense is expected to be recognized over the weighted-average remaining vesting period of 1.9 years. The stock-based compensation for all stock options was $1,317 and $1,672 during the years ended December 31, 2018 and 2017, respectively.

Restricted Stock Units

RSU awards are granted subject to certain vesting requirements and other restrictions, including performance and market based vesting criteria. The grant-date fair value of the RSUs, which has been determined based upon the market value of the Company’s common stock on the grant date, is expensed over the vesting period of the RSUs. Unvested portions of RSUs issued to consultants are remeasured on an interim basis until vesting criteria is met.

Grants During the Year Ended December 31, 2017

During the year ended December 31, 2017, the Company granted an aggregate of 62,892 RSUs to its non-employee directors valued at $200. These RSUs vest in equal quarterly installments over a one-year period subject to the director's continued service at the vesting date, but the issuance and delivery of these shares are deferred until the director resigns.

A summary of the Company's RSU activity and related information for the year ended December 31, 2017 is as follows:

	Number of RSUs	Weighted Average Grant Date Fair Value
RSUs unvested - January 1, 2017	1,292,876	$ 2.43
RSUs granted	62,892	3.18
RSUs vested	(56,822)	3.94
RSUs cancelled/forfeit	-	
RSUs unvested at December 31, 2017	1,298,946	$ 2.42

Grants During the Year Ended December 31, 2018

During the year ended December 31, 2018, the Company granted an aggregate of 136,360 RSUs to its non-employee directors valued at $300. These RSUs vest in equal quarterly installments over a one-year period subject to the director's continued service at the vesting date, but the issuance and delivery of these shares are deferred until the director resigns.

A summary of the Company's RSU activity and related information for the year ended December 31, 2018 is as follows:

	Number of RSUs	Weighted Average Grant Date Fair Value
RSUs unvested - January 1, 2018	1,298,946	$ 2.42
RSUs granted	136,360	2.20
RSUs vested	(159,626)	3.94
RSUs cancelled/forfeit	-	
RSUs unvested at December 31, 2018	1,275,680	$ 2.16

As of December 31, 2018, the total unrecognized compensation expense related to unvested RSUs was approximately $441 which is expected to be recognized over a weighted-average period of 0.1 years, based on estimated vesting schedules. The stock-based compensation for RSUs was $1,149 and $1,211 during the years ended December 31, 2018 and 2017, respectively.

Subsidiary Stock-Based Transactions

During the year ended December 31, 2018 the Company recognized $21 in stock-based compensation related to equity instruments granted by Surface and Melt to consultants, the Company's employees and directors, including its CEO, Mark Baum, CFO, Andrew Boll, and a director, Richard Lindstrom,.

The Company recorded stock-based compensation (including issuance of common stock for services and accrual for stock-based compensation) related to equity instruments granted to employees, directors and consultants as follows:

	For the Year Ended December 31, 2018	For the Year Ended December 31, 2017
Employees - selling and marketing	$ 82	$ 449
Employees - general and administrative	2,169	2,229
Directors - general and administrative	235	205
Consultants - selling and marketing	150	60
Total	$ 2,636	$ 2,943

Warrants

From time to time, the Company issues warrants to purchase shares of the Company's common stock to investors, lenders (see Note 13), underwriters and other non-employees for services rendered or to be rendered in the future.

A summary of warrant activity during the year ended December 31, 2018 is as follows:

	Number of Shares Subject to Warrants Outstanding	Weighted Avg. Exercise Price
Warrants outstanding - January 1, 2018	6,264,215	$ 1.91
Granted	-	
Exercised	(3,941,554)	1.79
Expired	(115,688)	6.94
Warrants outstanding and exercisable - December 31, 2018	2,206,973	$ 1.91
Weighted average remaining contractual life of the outstanding warrants in years - December 31, 2018	2.60	

The table below illustrates the fair value per share determined by the Black-Scholes-Merton option pricing model with the following assumptions used for valuing warrants granted during the year ended December 31, 2017 related to loan agreements:

	2017
Weighted-average fair value of warrants granted	$1.70
Expected terms (in years)	7.00
Expected volatility	113.5%
Risk-free interest rate	1.77 %
Dividend yield	-

All warrants outstanding as of December 31, 2018 are included in the following table:

	Warrants Outstanding			Warrants Exercisable	
Warrant Series	Issue Date	Warrants Outstanding	Exercise Price	Warrants Exercisable	Expiration Date
Lender warrants	5/11/2015	125,000	$1.79	125,000	5/11/2025
Settlement warrants	8/16/2016	40,000	$3.75	40,000	8/16/2021
PIPE Investor and Placement Agent Warrants	12/27/2016	1,426,587	$1.79	1,426,587	12/27/2019
Lender warrants (see Note 13)	7/19/2017	615,386	$2.08	615,386	7/19/2024
		2,206,973	$1.91	2,206,973	

NOTE 16. INCOME TAXES

The Company is subject to taxation in the United States, California, New Jersey, Texas and Pennsylvania. The provision for income taxes for the years ended December 31, 2018 and 2017 are summarized below:

	December 31, 2018	December 31, 2017
Current:		
Federal	$ -	$ -
State	6	5
Total current	$ 6	$ 5
Deferred:		
Federal	$ 3,294	$ 6,474
State	440	(283)

Change in valuation allowance	(3,734)	(7,126)
Total deferred	-	(935)
Income tax provision (benefit)	$ 6	$ (931)

Income tax expense for the years ended December 31, 2018 and 2017, are recorded in the general and administrative expenses line item in the accompanying consolidated statements of operations.

A reconciliation of income taxes computed by applying the statutory U.S. income tax rate to the Company's loss before income taxes to the income tax provision is as follows:

	December 31, 2018		December 31, 2017	
U.S. federal statutory tax rate	21.00	%	35.00	%
Benefit of lower tax brackets	0.00	%	(1.00	)%
State tax benefit, net	0.04	%	1.60	%
Research and development credits	(0.14	)%	0.00	%
Employee stock-based compensation	0.46	%	(0.84	)%
Loss on debt conversion	0.00	%	(2.39	)%
Change in Rate	0.00	%	(62.97	)%
Other	0.13	%	3.04	%
Valuation allowance	(21.93	)%	34.82	%
Effective income tax rate	(0.44	)%	7.27	%

Deferred tax assets and liabilities 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. Significant components of the Company's deferred tax assets are as follows:

	December 31, 2018	December 31, 2017
Deferred tax assets (liabilities):		
NOL's	$ 19,726	$ 17,405
Depreciation and amortization	30	58
Other	602	351
Research & development credits	617	596
Deferred stock compensation	3,036	2,534
Basis Difference in Surface	(1,464)	-
Basis Difference in Eton	(6,340)	(985)
Park stock purchase identifiable intangibles	(484)	(501)
Total deferred tax assets, net	15,723	19,457
Valuation allowance	(15,723)	(19,457)
Net deferred tax liabilities	$ -	$ -

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance decreased by approximately $3,700 and increased by approximately $7,100 during 2018 and 2017, respectively.

As of December 31, 2018, the Company had net operating loss carryforwards for federal income tax purposes of approximately $67,463 and federal research and development tax credits of approximately $375. Under new tax law, federal NOLs can be carried forward indefinitely. The federal research credits will expire beginning in the year 2026. As of December 31, 2018, the Company had net operating loss carryforwards for state income tax purposes of approximately $64,629 which expire beginning in the year 2017 and state research and development tax credits of approximately $305 which do not expire.

In March 2016, the FASB issued ASU 2016-09, *Improvement to Employee Share – Based Payment Accounting*. The new standard contains several amendments that will simplify the accounting for employee share-based payment transactions. The changes in the new standard eliminate the accounting for excess tax benefits to be recognized in additional paid-in capital and tax deficiencies recognized either in income tax provision or in additional paid-in capital. The Company's deferred tax asset at December 31, 2018 did not include any excess tax benefits from employee stock option exercises, which are a component of the federal and state net operating loss carryforwards and on a go forward basis the excess tax benefits will be recognized as a component of income tax expense.

Utilization of the net operating losses may be subject to substantial annual limitation due to federal and state ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such annual limitations could result in the expiration of the net operating losses ad credits before their utilization.

In June 2006, the FASB issued interpretation ASC 740-10-50, *Accounting for Uncertainty in Income Tax*. This pronouncement clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with ASC 740-10-50, *Accounting for Income Taxes*. This interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in the tax return. ASC 740 also provides guidance on derecognition of tax benefits, classification on the balance sheet, interest and penalties, accounting in interim periods, disclosure and transaction. The Company adopted ASC 740-10-50 effective January 1, 2009. In accordance with ASC 740-10-50, the Company is classifying interest and penalties as a component of tax expense.

The Company did not have any unrecognized tax benefits as of December 31, 2018 and 2017, all of which is offset by a full valuation allowance. These unrecognized tax benefits, if recognized, would not affect the effective tax rate. There was no interest or penalties accrued at the adoption date and at December 31, 2017.

A reconciliation of the change in the UTB balance from January 1, 2018 to December 31, 2017 is as follows:

	Fed & State Tax
Balance at January 1, 2018	$-
Additions for tax positions related to current year	-
Additions/(reductions) for tax positions related to prior years	-
Balance at December 31, 2018	-
Total unrecognized tax benefits as of December 31, 2018	$-

On December 27, 2017, the United States Government passed new tax legislation that, among other provisions, will lower the corporate tax rate from 35% to 21%. In addition to applying the new lower corporate tax rate in 2018 and thereafter to any taxable income the Company may have, the legislation affects the way the Company can use and carryforward net operating losses previously accumulated and results in a revaluation of deferred tax assets and liabilities recorded on our consolidated balance sheet. Given the current deferred tax assets are offset by a full valuation allowance, these changes will have no net impact on the consolidated balance sheet. However, when the Company become profitable, it will receive a reduced benefit from such deferred tax assets. The effect of the legislation was a reduction in the deferred tax assets and the corresponding valuation allowance of approximately $8,059.

NOTE 17. EMPLOYEE SAVINGS PLAN

The Company has established an employee savings plan pursuant to Section 401(k) of the Internal Revenue Code, effective January 1, 2014. 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. The Company contributed approximately $248 and $288 to the plan during the years ended December 31, 2018 and 2017, respectively.

NOTE 18. COMMITMENTS AND CONTINGENCIES

Operating Leases

In May 2014, the Company entered into a lease agreement for 7,565 square feet of office space that commenced on September 1, 2014. In May 2017, the Company entered into an amended lease agreement, to lease an additional 2,635 square feet (10,200 square feet in total). Monthly rent following the amendment is $29, with a 3% increase in the base rent amount on an annual basis. The lease agreement allows for the monthly rent amount to be abated for two months at various times during the lease agreement and expires on December 31, 2021, and includes an option to extend the lease through December 31, 2027.

In January 2015, the Company entered into a commercial lease agreement, for the lease to Park of approximately 4,500 square feet of laboratory and office space. The monthly rent amount is $10 and includes annual increases of approximately 3%. The current lease term expires on December 31, 2020 and includes 2 options that allow for the lease term to be extended 10 additional years beyond the stated expiration date.

In February 2015, the Company entered into a lease agreement for approximately 8,600 square feet of laboratory, warehouse and office space in Ledgewood, New Jersey. The Company amended the lease agreement in July 2017, to add approximately 7,000 square feet of additional space and amended the lease agreement again in September 2018, to add approximately 9,400 square feet. The lease term expires on July 31, 2024, and includes 2 options that allow for the lease term to be extended 10 additional years beyond the stated expiration date. The monthly rent amount is $25 and includes annual increases of approximately 3.75%, and the lease allowed for the first five months of rent amounts to be abated.

Rent expense for the years ended December 31, 2018 and 2017 was $725 and $649, respectively. The following represents future annual minimum lease payments, as of December 31, 2018:

2019	$797
2020	857
2021	742
2022	320
2023	330
2024	196
Total	$3,242

Legal

Dr. Sobol

In December 2016, Louis L. Sobol, M.D. (“Sobol”) filed a lawsuit in the U.S. District Court for the Eastern District of Michigan, Southern Division against the Company, asserting claims on behalf of himself and an as-yet-uncertified class of consumers. The claims allege violations under the Telephone Consumer Protection Act, 47 U.S.C. § 227 via the Company’s alleged transmittal of advertisements to its clients via facsimile. In June 2018, Sobol filed a motion for class certification and in July 2018 the Company filed a response in opposition to the motion for class certification. A hearing on class certification was heard in October 2018, however, prior to a decision regarding class certification was made, in February 2019, the Company entered into a proposed settlement agreement to award the proposed class up to $1,400 in damages. Due to the nature of the lawsuit and claims, the Company expects total damages related to this lawsuit will total approximately $640. The Company expects the Court will rule to accept the settlement agreement in the spring of 2019. The Company accrued an expense of $640, its estimated damages related to the settlement agreement, during the year ended December 31, 2018.

Allergan USA

In September 2017, Allergan USA, Inc. (“Allergan”) filed a lawsuit in the U.S. District Court for the Central District of California against Imprimis Pharmaceuticals, Inc., primarily claiming violations under the federal Lanham Act and California’s Sherman Act. The parties have each filed a motion for summary judgment and Imprimis also filed a motion to stay. The parties’ motions is scheduled to be heard on March 26, 2019. The trial date is currently set for April 2019. The Company believes the claims are frivolous, and we have previously and will continue to dispute all claims asserted against it and intends to vigorously defend these allegations. Nonetheless, the Company cannot predict the eventual outcome of this litigation, it could result in substantial costs, losses and a diversion of management’s resources and attention, which could harm the Company’s business and the value of its common stock.

Spectrum

In February 2018, the Company filed a complaint against Spectrum Laboratory Products, Inc., Spectrum Chemical Manufacturing Corp. and Spectrum Pharmacy Products, Inc. (collectively “Spectrum”) in the Los Angeles County Superior Court asserting claims for breach of contract, breach of implied covenant of good faith and fair dealing, violation of California Commercial Code Section 2101 and fraud. The claims stem from prior business dealings between the Company and Spectrum and allege false representation by Spectrum regarding their products, fraudulent labeling and misrepresentations of approved product usages. The complaint was filed with the Court and in May 2018,

Spectrum filed an answer with the Court. In November 2018, we dismissed, without prejudice, the Company lawsuit against Spectrum.

Novel Drug Solutions et al.

In April 2018, Novel Drug Solutions, LLC and Eyecare Northwest, PA, (collectively “NDS”) filed a lawsuit against the Company in the U.S. District Court of Delaware asserting claims for breach of contract. The claims stem from an asset purchase agreement between the Company and NDS entered into in 2013. In July 2018, NDS filed a first amended complaint which added a claim for fraudulent inducement. In July 2018, the Company filed a motion to dismiss certain causes of action found in the complaint, and the Company motion to dismiss was denied. In October 2018, the Company filed counterclaims alleging breach of contract and breach of covenant of good faith and fair dealing and named certain individual defendants. The lawsuit is currently in the discovery phase. The Company believe the claims are frivolous and have previously and will continue to dispute all claims asserted against it and intends to vigorously defend these allegations. Nonetheless, the Company cannot predict the eventual outcome of this litigation, it could result in substantial costs, losses and a diversion of management’s resources and attention, which could harm the Company’s business and the value of its common stock.

California Board of Pharmacy

In March 2018, the California Board of Pharmacy filed an accusation against Park related to a compounded formulation the Company believes was legally dispensed and was, without its knowledge, inappropriately administered to a patient unknown to the Company, by the prescribing healthcare professional. The Company filed its response to the accusation and has requested a formal hearing. The Company believes the claims are frivolous and have previously and will continue to dispute all claims asserted against it and intends to vigorously defend these allegations. Nonetheless, the Company cannot predict the eventual outcome of this litigation, it could result in substantial costs, losses and a diversion of management’s resources and attention, which could harm the Company’s business and the value of its common stock.

Product and Professional Liability

Product and professional liability litigation represents an inherent risk to all firms in the pharmaceutical and pharmacy industry. The Company utilizes traditional third-party insurance policies with regard to its product and professional liability claims. Such insurance coverage at any given time reflects current market conditions, including cost and availability, when the policy is written.

John Erick et al.

In January 2018, John Erick and Deborah Ferrell, successors-in-interest and heirs of Jade Erick, (collectively "Erick") filed a lawsuit in the San Diego County Superior against Kim Kelly, ND, MPH asserting claims related to death of Jade Erick. In April 2018, Erick filed an amendment to the lawsuit, naming the Company as a co-defendant. In September 2018, co-defendant Dr. Kelly filed a cross-complaint against the Company and various Spectrum entities. The cross-complaint seeks indemnity and contribution from the Company and Spectrum. The Company answered the claims filed by Dr. Kelly in October 2018. The case is currently in the discovery phase. The Company believe the claims are frivolous and have previously and will continue to dispute all claims asserted against it and intends to vigorously defend these allegations. Nonetheless, the Company cannot predict the eventual outcome of this litigation, it could result in substantial costs, losses and a diversion of management's resources and attention, which could harm the Company's business and the value of its common stock.

General and Other

In the ordinary course of business, the Company may face various claims brought by third parties and it may, from time to time, make claims or take legal actions to assert its rights, including intellectual property disputes, contractual disputes and other commercial disputes. Any of these claims could subject the Company to litigation.

Indemnities

In addition to the indemnification provisions contained in the Company's charter documents, the Company generally enters into separate indemnification agreements with each of the Company's directors and officers. These agreements require the Company, among other things, to indemnify the director or officer against specified expenses and liabilities, such as attorneys' fees, judgments, fines and settlements, paid by the individual in connection with any action, suit or proceeding arising out of the individual's status or service as the Company's director or officer, other

than liabilities arising from willful misconduct or conduct that is knowingly fraudulent or deliberately dishonest, and to advance expenses incurred by the individual in connection with any proceeding against the individual with respect to which the individual may be entitled to indemnification by the Company. The Company also indemnifies its lessors in connection with its facility leases for certain claims arising from the use of the facilities. These indemnities do not provide for any limitation of the maximum potential future payments the Company could be obligated to make. Historically, the Company has not incurred any payments for these obligations and, therefore, no liabilities have been recorded for these indemnities in the accompanying consolidated balance sheets.

Klarity License Agreement – Related Party

In April 2017, the Company entered into a license agreement (the "Klarity License Agreement") with Richard L. Lindstrom, M.D., a member of its Board of Directors. Pursuant to the terms of the Klarity License Agreement, the Company licensed certain intellectual property and related rights from Dr. Lindstrom to develop, formulate, make, sell, and sub-license the topical ophthalmic solution Klarity designed to protect and rehabilitate the ocular surface (the "Klarity Product").

Under the terms of the Klarity License Agreement, the Company is required to make royalty payments to Dr. Lindstrom ranging from 3% to 6% of net sales, dependent upon the final formulation of the Klarity Product sold. In addition, the Company is required to make certain milestone payments to Dr. Lindstrom including: (i) an initial payment of $50 upon execution of the Klarity License Agreement, (ii) a second payment of $50 following the first $50 in net sales of the Klarity Product; and (iii) a final payment of $50 following the first $100 in net sales of the Klarity Product. All of the above referenced milestone payments were payable at the Company's election in cash or shares of the Company's restricted common stock. Dr. Lindstrom was paid $122 and $50 in cash during the years ended December 31, 2018 and 2017, respectively, and was due an additional $15 and $19 at December 31, 2018 and 2017, respectively. The Company incurred $118 and $183 for royalty expenses related to the Klarity License Agreement during the years ended December 31, 2018 and 2017, respectively. Dr. Lindstrom is a member of the Company's Board of Directors.

Sales and Marketing Agreements

During 2017 and 2018, the Company entered various sales and marketing agreements with certain organizations, to provide sales and marketing representation services to ImprimisRx in select geographies in the U.S., in connection with the Company's ophthalmic compounded formulations.

Under the terms of the sales and marketing agreements, the Company is required to make commission payments to equal to 10% - 14% of net sales for products above and beyond the initial existing sales amounts. In addition, the Company is required to make periodic milestone payments to certain organizations in shares of the Company's restricted common stock if net sales in the assigned territory reach certain future levels by the end of their terms, as applicable. The Company accrued $42 related to stock-based payments for these agreements during the year ended

December 31, 2018, and $1,511 and $183 were incurred under these agreements for commission expenses during the years ended December 31, 2018 and 2017, respectively.

Asset Purchase, License and Related Agreements

The Company has acquired and sourced intellectual property rights related to certain proprietary innovations from certain inventors and related parties (the "Inventors") through multiple asset purchase agreements, license agreements, strategic agreements and commission agreements. In general, these agreements provide that the Inventors will cooperate with the Company in obtaining patent protection for the acquired intellectual property and that the Company will use commercially reasonable efforts to research, develop and commercialize a product based on the acquired intellectual property. In addition, the Company has acquired a right of first refusal on additional intellectual property and drug development opportunities presented by these Inventors.

In consideration for the acquisition of the intellectual property rights, the Company is obligated to make payments to the Inventors based on the completion of certain milestones, generally consisting of: (1) a payment payable within 30 days after the issuance of the first patent in the United States arising from the acquired intellectual property (if any); (2) a payment payable within 30 days after the Company files the first investigational new drug application ("IND") with the FDA for the first product arising from the acquired intellectual property (if any); (3) for certain of the Inventors, a payment payable within 30 days after the Company files the first new drug application with the FDA for the first product arising from the acquired intellectual property (if any); and (4) certain royalty payments based on the net receipts received by the Company in connection with the sale or licensing of any product based on the acquired intellectual property (if any), after deducting (among other things) the Company's development costs associated with such product. If, following five years after the date of the applicable asset purchase agreement, the Company either (a) for certain of the Inventors, has not filed an IND or, for the remaining Inventors, has not initiated a study where data is derived, or (b) has failed to generate royalty payments to the Inventors for any product based on the acquired intellectual property, the Inventors may terminate the applicable asset purchase agreement and request that the Company re-assign the acquired technology to the Inventors. $245 and $108 were accrued in accounts payable and accrued expenses under these agreements during the years ended December 31, 2018 and 2017, respectively, and $561 and $153 were incurred under these agreements as royalty expenses for the years ended December 31, 2018 and 2017, respectively.

NOTE 19. SEGMENT INFORMATION AND CONCENTRATIONS

The Company operates the business on the basis of a single reportable segment, which is the business of developing proprietary drug therapies and providing such therapies through sterile and non-sterile pharmaceutical compounding services and drug development. While the Company is described as having certain individual businesses, in general, those business operations often overlap, decisions and resources may be intermingled between components and discrete financial information about the businesses, on an individual basis, is not available. The Company's chief operating decision-maker is the Chief Executive Officer, who evaluates the Company as a single operating segment.

The Company categorizes revenues by geographic area based on selling location. All operations are currently located in the United States; therefore, total revenues for 2018 and 2017 are attributed to the United States. All long-lived assets at December 31, 2018 and 2017 are located in the United States.

The Company sells its compounded formulations to a large number of customers. No single customer contributed 10% or more of the Company's total pharmacy sales in the years ended December 31, 2018 and 2017.

The Company receives its active pharmaceutical ingredients from three main suppliers during the years ended December 31, 2018 and 2017. These suppliers collectively accounted for 51% and 68% of drug and chemical purchases during the years ended December 31, 2018 and 2017, respectively.

NOTE 20. SUBSEQUENT EVENTS

The Company has performed an evaluation of events occurring subsequent to December 31, 2018 through the filing date of this Annual Report on Form 10-K (the "Annual Report"). Based on its evaluation, nothing other than the events described below needs to be disclosed.

From January 1, 2019 through the date of the filing of the Annual Report, the Company issued 52,000 shares of its common stock related to the exercise of common stock warrants with an exercise price of $1.79 and received net proceeds of $93.

From January 1, 2019 through the date of the filing of the Annual Report, the Company issued 293,984 shares of its common stock related to the cashless exercise of 419,800 common stock warrants with an exercise price of $1.79.

Mayfield and Elle Pharmaceuticals

On February 1, 2019, the Company entered into an Asset Purchase Agreement (the "May Asset Purchase Agreement") with Elle Pharmaceutical, LLC ("Elle"), where the Company acquired intellectual property and related rights from Elle to develop, formulate, make, sell, and sub-license lidocaine-based gel formulations (collectively, the "May Products"). As consideration, the Company agreed to pay Elle $25 at the time of signing the May Asset Purchase Agreement and make royalty payments to Elle up to seven and a half percent (7.5%) of net sales of the Products as compounded drug formulations.

In connection with the May Asset Purchase Agreement, the Company assigned the May Products to Mayfield, and Mayfield entered into a separate Royalty Agreement with Elle (the "Elle Royalty Agreement"). Pursuant to the terms of the Elle Royalty Agreement, Mayfield, is required to make royalty payments to Elle up to seven and a half percent (7.5%) of net sales of the May Products as commercially available drugs (e.g. a market approved drug via the U.S. Food and Drug Administration 505(b)(2) pathway), while any patent rights remain outstanding, as well as other conditions. In addition, Mayfield agreed to pay Elle $175 upon Mayfield receiving third-party financing equal to or greater than $10,000 of gross proceeds. In connection with the May Asset Purchase Agreement and Elle Royalty Agreement Mayfield issued to Elle 1,000,000 of its common stock.

Segment of Business Operations

Beginning on January 1, 2019, the Company began evaluating performance of the Company based on operating segments. Segment performance for its two operating segments will be based on segment contribution. Our reportable segments consist of (i) our commercial stage pharmaceutical compounding business (Pharmaceutical Compounding), generally including the operations of our ImprimisRx and Park Compounding businesses; and (ii) our start-up operations associated with pharmaceutical drug development business (Pharmaceutical Drug Development). Segment contribution for our segments represents net revenues less cost of sales, research and development, selling and marketing expenses, and select general and administrative expenses. The Company does not evaluate the following items at the segment level:

Operating expenses within selling, general and administrative expenses that result from the impact of corporate initiatives. Corporate initiatives primarily include integration, restructuring, acquisition and other shared costs.

Selling, general and administrative expenses that result from shared infrastructure, including certain expenses associated with legal matters, our board of directors and principal executive officers, investor relations and other like shared expenses.

Other select revenues and operating expenses including R&D expenses, amortization, and asset sales and impairments, net as not all such information has been accounted for at the segment level, or such information has not been used by all segments.

Total assets including capital expenditures.

For periods beginning on and after January 1, 2019, results of operations, including segment net revenues, segment operating expenses and segment contribution, the Company expects to present segment information in a format similar to the table below:

	Pharmaceutical Compounding	Pharmaceutical Drug Development	Total
Net revenues	$	$	$
Cost of sales			
Gross profit			
Operating expenses:			
Selling, general and administrative			
Research and development			
Segment contribution			
Corporate			
Research and development			
Amortization			
Asset sales and impairments, net			
Operating loss			$

EXHIBIT INDEX

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated as of September 17, 2007, by and among Imprimis Pharmaceuticals, Inc., Transdel Pharmaceuticals Holdings, Inc. and Trans-Pharma Acquisition Corp. Incorporation (incorporated herein by reference to Exhibit 2.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
2.2	Membership Interest Purchase Agreement, dated February 10, 2014, among John Scott Karolchyk and Bernard Covalesky and Imprimis Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on February 11, 2014)
2.3	Stock Purchase Agreement, dated as of November 26, 2014, by and between Imprimis Pharmaceuticals, Inc., and Dennis Saadeh and Tina Sulic-Saadeh (incorporated herein by reference to Exhibit 2.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 2, 2014)
2.4	Stock Purchase Agreement, effective as of July 10, 2015, by and between Imprimis Pharmaceuticals, Inc. and Jonathan Nguyen and Julie Trinh, to acquire all of the outstanding capital stock of JT Pharmacy, Inc. D/B/A Central Allen Pharmacy and completed on August 4, 2015 (incorporated herein by reference to Exhibit 10.4 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on August 12, 2015)
3.1	Amended and Restated Certificate of Incorporation, as amended by the Certificate of Amendment to Amended and Restated Certificate of Incorporation effective February 28, 2012, as further amended by the Certificate of Amendment to Amended and Restated Certificate of Incorporation effective February 7, 2013, and as further amended by the Certificate of Amendment to Amended and Restated Certificate of Incorporation effective September 10, 2014 (incorporated herein by reference to Exhibit 3.1 to the Annual Report on Form 10-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on March 12, 2015)
3.2	Amended and Restated Bylaws of Imprimis Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 3.2 to the Annual Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on March 28, 2014)
3.3	Certificate of Designation of Series A Convertible Preferred Stock of Imprimis Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 20, 2011)
3.4	Amended and Restated Certificate of Incorporation, filed July 2, 2018 (incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on July 2, 2018)
3.5	Amendment to the Restated Certificate of Incorporation for the name change, filed as of December 27, 2018 (incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 31, 2018)
10.1	Form of Directors and Officers Indemnification Agreement (incorporated herein by reference to Exhibit 10.8 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
10.2#	

	Imprimis Pharmaceuticals, Inc. Amended and Restated 2007 Stock Incentive and Awards Plan (incorporated herein by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on May 8, 2013)
10.3#	Amendment No. 1 to Imprimis Pharmaceuticals, Inc. Amended and Restated 2007 Incentive Stock and Awards Plan (incorporated herein by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on November 6, 2013)
10.4#	Form of Incentive Stock Option Agreement (incorporated herein by reference to Exhibit 10.12 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
10.5#	Form of Non-Qualified Stock Option Agreement (incorporated herein by reference to Exhibit 10.13 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
10.6#	Form of Restricted Stock Unit Agreement (incorporated herein by reference to Exhibit 10.4 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on May 8, 2013)
10.7	Form of Warrant dated as of April 25, 2012 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on 8-K filed with the Securities and Exchange Commission on April 27, 2012)
10.8#	Stand-alone Restricted Stock Unit Agreement, dated July 18, 2012, granted by Imprimis Pharmaceuticals, Inc. to Mark L. Baum (incorporated herein by reference to Exhibit 10.40 to the Company's Registration Statement on Form S-1 (File No. 333-182846) filed on July 25, 2012)
10.9#	Stand-alone Restricted Stock Unit Agreement, dated July 18, 2012, granted by Imprimis Pharmaceuticals, Inc. to Robert J. Kammer (incorporated herein by reference to Exhibit 10.41 to the Company's Registration Statement on Form S-1 (File No. 333-182846) filed on July 25, 2012)
10.10	Form of Underwriter's Warrant (incorporated herein by reference to Exhibit 10.41 to the Company's Registration Statement on Form S-1 (File No. 333-182846) filed on October 26, 2012)

10.11#	Amended and Restated Employment Agreement, dated May 2, 2013, by and between Imprimis Pharmaceuticals, Inc. and Mark L. Baum (incorporated herein by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on May 8, 2013)
10.12#	Performance Stock Units Agreement, dated May 2, 2013, by and between Imprimis Pharmaceuticals, Inc. and Mark L. Baum (incorporated herein by reference to Exhibit 10.4 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on August 14, 2013)
10.13+	Asset Purchase Agreement, dated June 11, 2013, by and between Imprimis Pharmaceuticals, Inc. and Buderer Drug Company, Inc. (incorporated herein by reference to Exhibit 10.5 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on August 14, 2013)
10.14+	Asset Purchase Agreement, dated August 8, 2013, by and among Imprimis Pharmaceuticals, Inc., Novel Drug Solutions, LLC and Eye Care Northwest, PA (incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on November 6, 2013)
10.15	Amendment to Asset Purchase Agreement, dated as of October 14, 2013, by and among Imprimis Pharmaceuticals, Inc., Novel Drug Solutions, LLC and EyeCare Northwest, PA (incorporated herein by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on November 6, 2013)
10.16+	Asset Purchase Agreement, dated October 8, 2013, by and between Imprimis Pharmaceuticals, Inc. and Novel Drug Solutions, LLC (incorporated herein by reference to Exhibit 10.27 to the Annual Report on Form 10-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on March 28, 2014)
10.17	Amendment to Asset Purchase Agreement, dated as of October 21, 2013, by and between Imprimis Pharmaceuticals, Inc. and Buderer Drug Company, Inc. (incorporated herein by reference to Exhibit 10.28 to the Annual Report on Form 10-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on March 28, 2014)
10.18	Amendment to Asset Purchase Agreement, dated as of October 21, 2013, by and between Imprimis Pharmaceuticals, Inc. and Novel Drug Solutions, LLC and EyeCare Northwest, PA (incorporated herein by reference to Exhibit 10.29 to the Annual Report on Form 10-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on March 28, 2014)
10.19	License Agreement, dated as of October 24, 2014, by and between Imprimis Pharmaceuticals, Inc. and Urigen Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on October 29, 2014)
10.20#	Amended and Restated Employment Agreement, effective as of February 1, 2015, by and between Imprimis Pharmaceuticals, Inc. and Andrew R. Boll (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on February 2, 2015)
10.21#	Performance Stock Units Award Agreement, effective as of February 1, 2015, by and between Imprimis Pharmaceuticals, Inc. and Andrew R. Boll (incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on February 2, 2015)
10.22#	Employment Agreement, effective as of February 1, 2015, by and between Imprimis Pharmaceuticals, Inc. and John P. Saharek (incorporated herein by reference to Exhibit 10.3 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on February 2, 2015)
10.23	Warrant to Purchase Stock, dated May 11, 2015, issued by Imprimis Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on May 12, 2015)
10.24	

	Loan and Security Agreement, dated May 11, 2015, by and between Imprimis Pharmaceuticals and IMMY Funding LLC. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-Kof Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on May 12, 2015)
10.25	License Agreement dated as of August 11, 2015, between Imprimis Pharmaceuticals, Inc. and Advance Dosage Forms, Inc. and John DiGenova (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on August 12, 2015)
10.26	Asset Purchase Agreement originally dated September 23, 2015 and subsequently amended on October 15, 2015, between ImprimisRx PA, Inc. (“ImprimisRx PA”), a Delaware corporation and a wholly-owned subsidiary of Imprimis Pharmaceuticals, Inc. and Thousand Oaks Holding Company, a Delaware corporation, and its wholly owned subsidiaries Topical Apothecary Group, LLC, a Pennsylvania limited liability company and owner and operator of TAG Pharmacy, a licensed pharmacy in Folcroft, PA; Aerosol Science Laboratories, Inc., a California corporation and former operator of ASL Pharmacy; SinuTopic, Inc., a Delaware corporation and former operator of Sinus Dynamics Pharmacy; and Mycotoxins, LLC, a California limited liability company (incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on November 12, 2015)
10.27	Controlled Equity Offering^{SM} Sales Agreement, dated November 27, 2015, by and between Imprimis Pharmaceuticals, Inc. and Cantor Fitzgerald & Co (incorporated herein by reference to Exhibit 1.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on November 27, 2015)
10.28	PCCA Commission Agreement, dated December 21, 2015, by and between Imprimis Pharmaceuticals, Inc. and Professional Compounding Centers of America, Inc.
10.29	8.00% Convertible Senior Secured Note issued on January 22, 2016 by Imprimis Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on January 25, 2016)

10.30	Note Purchase Agreement dated January 22, 2016 between Imprimis Pharmaceuticals, Inc. and IMMY Funding LLC (incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on January 25, 2016)
10.31	Second Amendment to Loan and Security Agreement dated January 22, 2016 between Imprimis Pharmaceuticals, Inc. and IMMY Funding LLC (incorporated herein by reference to Exhibit 10.3 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on January 25, 2016)
10.32	Amendment to Warrant to Purchase Stock dated January 22, 2016 between Imprimis Pharmaceuticals, Inc. and IMMY Funding LLC (incorporated herein by reference to Exhibit 10.4 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on January 25, 2016)
10.33	Underwriting Agreement, dated as of March 11, 2016, by and between Imprimis Pharmaceuticals, Inc. and National Securities Corporation (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on March 11, 2016)
10.34	Securities Purchase Agreement, dated December 19, 2016, between the Registrant and the Investors party thereto (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 23, 2016)
10.35	Form of Registration Rights Agreement between the Registrant and the Investors party thereto (incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 23, 2016)
10.36	Form of Investor Warrant (incorporated herein by reference to Exhibit 10.3 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 23, 2016)
10.37	Third Amendment to Loan and Security Agreement, dated December 27, 2016, by and between Imprimis Pharmaceuticals and IMMY Funding LLC (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 29, 2016)
10.38	Exchange and Discharge Agreement, dated December 27, 2016, by and between Imprimis Pharmaceuticals and IMMY Funding LLC (incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 29, 2016)
10.39	Warrant Amendment to Purchase Stock, dated December 27, 2016, issued by Imprimis Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.3 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 29, 2016)
10.40	Stock Purchase Agreement dated February 13, 2017 between Imprimis Pharmaceuticals, Inc. and Livernois & London, LLC (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on February 17, 2017)
10.41	Form of Securities Purchase Agreement, dated March 21, 2017, between the Registrant and the Investors (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on March 22, 2017)
10.42	License Agreement dated April 1, 2017 between Imprimis Pharmaceuticals, Inc. and Richard L. Lindstrom, M.D. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on April 6, 2017)
10.43	Strategic Sales & Marketing Agreement dated April 13, 2017 between Imprimis Pharmaceuticals, Inc. and Cameron Ehlen Group, Inc. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on April 17, 2017)
10.44	Strategic Sales & Marketing Agreement dated April 28, 2017 between Imprimis Pharmaceuticals, Inc. and SightLife Surgical, Inc. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on May 2, 2017)

10.45	Consulting Agreement dated May 1, 2017 between Eton Pharmaceuticals, Inc. and Mark L. Baum (incorporated herein by reference to Exhibit 10.8 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on August 10, 2017)
10.46	Consulting Agreement dated May 1, 2017 between Eton Pharmaceuticals, Inc. and Andrew R. Boll (incorporated herein by reference to Exhibit 10.9 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on August 10, 2017)
10.47	Consulting Agreement dated May 1, 2017 between Eton Pharmaceuticals, Inc. and John P. Saharek (incorporated herein by reference to Exhibit 10.10 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on August 10, 2017)
10.48	Consulting Agreement dated May 1, 2017 between Eton Pharmaceuticals, Inc. and Clayton Edwards (incorporated herein by reference to Exhibit 10.11 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on August 10, 2017)
10.49	Asset Purchase and License Agreement (pentoxifylline) dated May 9, 2017 between Imprimis Pharmaceuticals, Inc. and Eton Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on June 20, 2017)
10.50	Asset Purchase and License Agreement (corticotropin) dated May 9, 2017 between Imprimis Pharmaceuticals, Inc. and Eton Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on June 20, 2017)

10.51	Management Services Agreement dated May 1, 2017 between Imprimis Pharmaceuticals, Inc. and Eton Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.4 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on June 20, 2017)
10.52	Asset Purchase Agreement dated June 27, 2017 between Imprimis Pharmaceuticals, Inc. and its wholly owned subsidiaries ImprimisRx PA, Inc. and ImprimisRx CA, Inc. and Creative Pharmacy Solutions Central, LLC
10.53	Consulting Agreement dated October 27, 2017 between Surface Pharmaceuticals, Inc. and Mark L. Baum (incorporated herein by reference to Exhibit 10.53 to the Annual Report on Form 10-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on March 8, 2017)
10.54	Consulting Agreement dated October 27, 2017 between Surface Pharmaceuticals, Inc. and Andrew R. Boll (incorporated herein by reference to Exhibit 10.54 to the Annual Report on Form 10-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on March 8, 2017)
10.55	Consulting Agreement dated October 27, 2017 between Surface Pharmaceuticals, Inc. and John P. Saharek (incorporated herein by reference to Exhibit 10.55 to the Annual Report on Form 10-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on March 8, 2017)
10.56	Asset Purchase and License Agreement dated September 28, 2017 between Imprimis Pharmaceuticals, Inc. and Surface Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on May 15, 2018)
10.57	Amend and Restated Asset Purchase and License Agreement dated April 10, 2018 between Imprimis Pharmaceuticals, Inc. and Surface Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on May 15, 2018)
10.58	Amended and Restated License Agreement dated April 10, 2018 between Imprimis Pharmaceuticals, Inc. and Richard L. Lindstrom, M.D. (incorporated herein by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on August 6, 2018)
10.59	Consulting Agreement dated March 1, 2018 between Surface Pharmaceuticals, Inc. and Richard L. Lindstrom, M.D. (incorporated herein by reference to Exhibit 10.4 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on August 6, 2018)
10.60	Consulting Agreement dated May 1, 2018 between Melt Pharmaceuticals, Inc. and Mark L. Baum (incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on November 13, 2018)
10.61	Consulting Agreement dated May 1, 2018 between Melt Pharmaceuticals, Inc. and Andrew R. Boll (incorporated herein by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on November 13, 2018)
10.62	Consulting Agreement dated May 1, 2018 between Melt Pharmaceuticals, Inc. and John P. Saharek (incorporated herein by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q of Imprimis Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on November 13, 2018)
21.1*	List of Subsidiaries
23.1*	Consent of Independent Registered Public Accounting Firm
24.1*	Power of Attorney (included on the signature page to this Annual Report)
31.1*	Certification of Mark L. Baum, Chief Executive Officer, pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Andrew R. Boll, Chief Financial Officer, pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of

	2002.
32.1**	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Mark L. Baum, Chief Executive Officer.
32.2**	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Andrew R. Boll, Chief Financial Officer.
101.INS*	XBRL Instant Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

Management contract or compensatory plan or arrangement.

* Filed herewith.

** Furnished herewith.

+ Confidential treatment has been granted with respect to portions of this exhibit pursuant to Rule 24b-2 of the Exchange Act and these confidential portions have been redacted from the filing that is incorporated herein by reference. A complete copy of this exhibit, including the redacted terms, has been separately filed with the Securities and Exchange Commission.